Diversity in Biobanking: Embracing Differences, Harnessing Commonalities
May 11-14, 2010
Rotterdam, The Netherlands
De Doelen Concert Hall and Congress Centre

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ISBER 2010 Annual Meeting & Exhibits

Diversity in Biobanking: Embracing Differences, Harnessing Commonalities

May 11-14, 2010
De Doelen Concert Hall and Congress Centre
Rotterdam, The Netherlands

ISBER VISION
ISBER’s vision is to be the leading international forum for promoting consistent, high quality standards, ethical principles and innovation in biospecimen banking by uniting the global biobanking community.

ISBER MISSION
ISBER creates opportunities for sharing ideas internationally and harmonizing approaches to evolving challenges in biobanking and repository operation. ISBER fosters collaborations, creates education and training opportunities, and provides an international showcase for state-of-the-art research findings and cutting edge technologies, discussion of legal and ethical issues, and products and services. Together, these activities promote best practices that cut across the broad range of repositories that ISBER serves.
ISBER gratefully acknowledges the generous support of our 2010 Corporate Partners

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ISBER 2010 Annual Meeting & Exhibits
Exhibit Hall

Willem Burger Hall (Ground Floor)

Registration
Exhibits
Breaks/Meals (Seating)

1st Floor

Exhibits
Breaks/Meals

3rd Floor

Posters
Working Group Breakfasts
Willem Burger Zaal (Main Session Room)
Education and Training Workshops

4th Floor

Working Group Breakfasts
Education and Training Workshops
Dear Colleagues and Friends,

Welcome to the 2010 Annual Meeting of the International Society for Biological and Environmental Repositories (ISBER). The ISBER Annual Meeting provides an international forum for discussion of a broad range of issues related to the establishment and operation of a wide variety of biobanks including human, animal, seed, museum and environmental collections.

Meeting Highlights
We are also excited about bringing the Annual Meeting to Rotterdam. This is the first time the ISBER Meeting will be held in The Netherlands. The interest in ISBER as the organization to serve all members of the biobanking community continues to grow and the ISBER Annual Meeting continues to be the “not-to-miss” meeting for biorepository operators, scientists, consultants, and vendors. This is evident by the large increase in the number of abstracts and vendor booths. Working with the Program Committee this past year makes us truly appreciative of the hard work that has gone into previous meetings. Our theme of “Diversity in Biobanking: Embracing Differences, Harnessing Commonalities” was selected based on the focuses of our many strengths.

At this meeting we have invited world leaders in biobanking who will emphasize the important work that members of ISBER are contributing on a daily basis. The first four speakers on Tuesday will report their experiences that highlight the Diversity in Biobanking. Dr. Jeffery Trent presents “Integrating Genetics, Genomics, and Biology Towards a More Personalized Medicine.” This is followed by “Differences in Sample Collections from an Environmental Specimen Bank Perspective” (Rebecca Pugh), “Fungi of Agricultural, Industrial and Medical Importance (FAIM) and Beyond” (Pedro Crous), and finally the “European Research Infrastructure for Biobanking and Biomolecular Resources (BBMRI)” by Kurt Zatloukal. This session sets the theme of our meeting. The following invited speaker sessions present topics in Connecting Biorepositories (Wednesday), Quality Assurance, Quality Control and Harmonization (Thursday), and Global Harmonization (Friday).

Tuesday will end with the Opening Reception to visit posters, exhibits and to connect with friends and colleagues. Wednesday, Thursday, and Friday are scheduled for Working Groups, RoundTable discussions, and workshops. This year, attendees have submitted the largest number of abstracts (140) ever submitted to an ISBER annual meeting. We have selected 24 oral presentations to be presented on Thursday and 16 lightning round presentations on Wednesday. On the floor there will be 116 posters to show the richness and diversity of the interests of ISBER members, providing you with a great opportunity to discuss a wide variety of biobanking topics. In addition, this year ISBER, with support from Asterand, will present monetary awards for the three top posters in Biospecimen Science and ISBER will present non-monetary awards for other top posters.

High Variety of ISBER Activities
We have maintained the successful activities of past meetings to provide opportunities for participation, education, and networking. Educational and corporate workshops, RoundTable discussions, contributed oral and poster presentations, exhibits, and a reception are available to complete your experience.

There will be an opportunity when you arrive at the Registration Desk to sign up for specific RoundTable discussions during the lunch breaks. The Wednesday workshops are “Practical Approaches to the Daily Workflow Processes of a Tissue Bank,” organized by Stella Somiari and “Digital Microscopy as a Tool in Tissue Banking,” organized by Anand Kulkarni. On Friday, workshops continue with “Potentials and Pitfalls in Establishing a Global Network to Identify Biospecimens for Research,” organized by Rivka Ravid, “Expanding the Role of the Consumer in Biobanking,” organized by Liz Horn and “New Tissue Preservation Technologies Improving Commercialization of Human Biospecimens,” organized by Olga Potapova.
ISBER Awards Presentation and Business Meeting:
The ISBER Awards Presentation and Business Meeting will identify and review accomplishments of ISBER over the past year, ISBER’s finances, and strategic planning going forward for the membership and attendees. Special Service Awards and the ISBER Distinguished Leadership and Service Award will be presented. ISBER has established a new award, the ISBER Award for Outstanding Achievement in Biobanking, which will be presented during the meeting. We will also announce the results of the recent ISBER elections. Please attend to meet your new President-Elect and ISBER Councilors. We will also hold the drawing for the exhibitor game card prizes — you must be present to win.

We will also be presenting poster awards during the Business Meeting. The Asterand–ISBER Biospecimen Science Poster Award is a new award program, which joins the ISBER Biobanking Poster Award Program, now in its third year.

The Asterand-ISBER Biospecimen Science Poster Awards recognize excellence in poster presentations on Biospecimen Science. The mission of the Biospecimen Science Poster Award Program is to encourage ISBER members and all attendees of the annual meeting to ask important original questions in biospecimen science, to design sound, controlled experiments with a clear rationale, and to present the results clearly in a poster format. Asterand has provided an unrestricted educational grant to ISBER to fund three poster awards at the ISBER 2010 Annual Meeting. Award winning posters will be selected by the Awards Subcommittee of the ISBER Program Committee; Asterand will have no influence on the selection of the awardees.

The ISBER Biobanking Poster Awards recognize excellence in poster presentations on all topics (except posters competing for the above-mentioned biospecimen science award) submitted to the annual meeting. The mission of the Biobanking Poster Award Program is to encourage ISBER members and all attendees of the annual meeting to ask important questions and to clearly report important findings in a poster format. Award winning posters will be selected by an Awards Subcommittee of the ISBER Program Committee.

Special Acknowledgements:
We gratefully acknowledge all who provided so much input and effort into the planning and execution of the meeting. Many thanks to the members of the ISBER Program Committee, the ISBER Education and Training Committee, the ISBER Marketing Committee, the ISBER Council and to the ISBER staff in the ASIP office. We, of course, also thank our invited speakers and workshop presenters for their contributions to the program. Finally, we sincerely appreciate the support from our vendors, sponsors and corporate partners, without whom the meeting would not be possible!

We look forward to your participation and we are looking forward to a successful annual meeting. Thank you for your participation and enjoy the meeting.

With kind regards,
Scott Jewell - ISBER President-Elect and Chair of the Program Committee
On behalf of the ISBER 2010 Program Committee
ISBER Council 2009 - 2010

President
Peter H.J. Riegman, PhD
Erasmus MC Tissue Bank
Dept of Pathology
Josephine Neffkens Inst Be 235b
PO Box 2040
Rotterdam, 3000CA The Netherlands
Tel: 31-0-10-7044421
Email: p.riegman@erasmusmc.nl

President-Elect
Scott Jewell, PhD
Dept of Pathology
The Ohio State University
Innovation Centre
2001 Polaris Parkway, Rm-2060
Columbus, OH 43240 USA
Tel: (614) 293-6906
Email: scott.jewell@osumc.edu

Past President
Robert Hewitt, MBBS, BSc (Hons), PhD
Hewitt Biobank Consultancy
20 Boulevard du Roi René
13100 Aix-en-Provence
France
Tel: +352 621 553 200
Email: reh@biobankconsultancy.com

Secretary-Treasurer
Phil Baird, MS
Kendle International
7361 Calhoun Place
Ste 500
Rockville, MD 20855 USA
Tel: (301) 296-1354
Email: baird.philipm@kendle.com

Councilor
Fay Betsou, DrSc, HDR
Integrated BioBank of Luxembourg
1 Rue Thomas Edison
Strassen L 1445 Luxembourg
Tel: +33 3 22 33 11 50
Email: Fay.betsou@ibbl.lu

Councilor
Marianne K. Henderson, MS
Office of Division Operations and Analysis
Division of Cancer Epidemiology and Genetics,
National Cancer Institute
6120 Executive Blvd, Rm 8060
Bethesda, MD 20892 USA
Phone: (301) 496-8672
Email: handerson@mail.nih.gov

Councilor
Cheryl Michels, BA
Dataworks Development, Inc.
PO Box 174
Mountlake Terrace, WA 98043 USA
Tel: (425) 673-1974
cheryl@dwdev.com

Councilor
Lisa Miranda
Biobusiness Consulting, Inc.
Tel: (610) 580-7506
Email: lisa.miranda.007@gmail.com

Councilor
Rebecca Pugh, MS
National Inst of Standards & Technology
Analytical Chem Div
331 Fort Johnson Road
Charleston, SC 29412-9110 USA
Tel: (843) 762-8952
Email: rebecca.pugh@nist.gov

Ex-Officio
Roger L. Aamodt, PhD (Chair, Long Range Planning Committee)
Aamodt Enterprises
17 Montgomery Ave
Gaithersburg, MD 20877 USA
Tel: (301) 963-2447
Email: aamodtr@rcn.com

Ex-Officio
Chon Boon Eng, PhD (Chair, Marketing Committee)
National University of Singapore
NUH-NUS Tissue Repository
5 Lower Kent Ridge Rd
119074 SINGAPORE
Tel: 65 67722379
Email: chon_boon_eng@nuhs.edu.sg

Ex-Officio
Mark E. Sobel, MD, PhD (Executive Officer)
American Society for Investigative Pathology
9650 Rockville Pike
Bethesda, MD 20814 USA
Tel: (301) 634-7130
Email: mesobel@asip.org

Ex-Officio
Jim Vaught, PhD (Chair, Publications Committee)
Office of Biorepositories & Biospecimen Research
National Cancer Institute
31 Center Drive
Rm-10A03, MSC 2580
Bethesda, MD 20892-2580 USA
Tel: (301) 451-7314
Email: vaughtj@mail.nih.gov
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Ole Seberg
Peter Watson
Tuesday, May 11, 2010

GENERAL INFORMATION:

10:00am – 6:30pm  Registration/Information
   Registration Desk (Ground Floor)

PROGRAM INFORMATION:

12:30pm – 1:30pm  Special Pre-Meeting Session: Has the Time Come to Form a European Chapter of ISBER?  
   (This session is not part of the official meeting agenda; see page 89 for session information)
   Willem Burger Zaal (3rd Floor)
   Robert Hewitt, MBBS, BSc (Hons), PhD, and Pasquale De Blasio, MBA

2:00pm – 4:30pm  Diversity in Biobanking: Embracing Differences, Harnessing Commonalities
   Willem Burger Zaal (3rd Floor)

This session features speakers who will present topics regarding diversity and commonalities between biobanks and how biobanks are vital to future advances in medicine, biological and environmental science.

Co-Chairs: Peter Riegman, PhD, Erasmus Medical Center, Rotterdam, The Netherlands, and Scott Jewell, PhD, The Ohio State University, Columbus, Ohio, USA

2:00  Welcome and Introductions
2:05  Welcome from the Ministry
2:10  Integrating Genetics, Genomics, and Biology Towards a More Personalized Medicine
   Jeffrey Trent, PhD, FACMG, Van Andel Research Institute, Grand Rapids, Michigan, USA
2:40  Differences in Sample Collections from an Environmental Specimen Bank Perspective
   Rebecca Pugh, MS, National Institute of Standards & Technology, Charleston, South Carolina, USA
3:10  Fungi of Agricultural, Industrial and Medical Importance (FAIM) and Beyond
   Pedro Crous, CBS Fungal Biodiversity Centre, Utrecht, The Netherlands
3:40  The European Research Infrastructure for Biobanking and Biomolecular Resources (BBMRI): Towards Implementation and Global Integration
   Kurt Zatloukal, MD, Medical University of Graz, Graz, Austria
4:10  Panel Discussion

4:30pm – 6:30pm  Opening Reception, Visit the Posters and Exhibits
   Exhibit Floor (Ground/1st Floors), Willem Burger Foyer (3rd Floor)
Wednesday, May 12, 2010

GENERAL INFORMATION:

7:30am – 6:30pm  Registration/Information
Registration Desk (Ground Floor)

PROGRAM INFORMATION:

7:30am – 8:20am  Breakfast (Concurrent Sessions)
“Get to Know ISBER” Breakfast
Van Beuningen Zaal (3rd Floor)
See description on page 89

Continental Breakfast (for all attendees)
Exhibit Floor (Ground/1st Floors)

8:30am – 10:00am  Connecting Repositories
Willem Burger Zaal (3rd Floor)
This session features speakers who present topics of diversity, interoperability, access and sharing, and informatics.

Co Chairs: Paul Bartels, PhD, Wildlife Biological Resource Centre / BioBankSA, Pretoria, South Africa, and Ole Seberg, FLS, DSc, PhD Botanical Garden and Museum, The Natural History Museum of Denmark, Copenhagen, Denmark

8:30  Introduction

8:35  Collaboration Between Competitors: The Creation of a Joint Infrastructure for Disease Oriented Biobanks in the Netherlands
Maurits Ros, MSc, String of Pearls Initiative, Rotterdam, The Netherlands

9:05  GBIF: Building the Biodiversity Informatics Commons, Making Biodiversity Information Accessible to All
Vishwas Chavan, Global Biodiversity Information Facility, Copenhagen, Denmark

9:35  Biobanking Opportunities in Europe - Next Steps for BBMRI, in FP7 and Nationally
Gert-Jan van Ommen, PhD, Leiden University Medical Center, Centre for Medical Systems Biology, Leiden, The Netherlands

10:00am – 11:00am  Break, Visit the Posters and Exhibits
Exhibit Floor (Ground/1st Floors), Willem Burger Foyer (3rd Floor)
Supported by: Nexus Biosystems

11:00am – 12:30pm  ISBER Working Group Presentations
Willem Burger Zaal (3rd Floor)
(See Working Group descriptions on page 99)
11:00 Welcome & Introduction  
  Katherine C. Sexton, MBA, Chair, Education & Training Committee

11:05 Automated Repositories  
  Leader: Andy Zaayenga

11:15 Biorepository Funding & Promotion  
  Leaders: Sara Loud & Hollie Schmidt

11:25 Biospecimen Science  
  Leader: Fay Betsou, DSc, HDR

11:35 Informatics  
  Leader: Cheryl Michels, BA

11:45 Informed Consent Procedures  
  Leader: Scott Jewell, PhD

11:55 Enviro-Bio Specimens  
  Leaders: Paul Bartels, PhD & Yeonhee Lee, PhD

12:05 Pharma-Academia  
  Leader: Joseph Kessler

12:15 Rights to & Control of Human Tissue  
  Leaders: Ty Hoover, MD, JD, FCLM & Rajiv Dhir, MD

12:25 Questions and Closing Remarks

12:30pm – 2:00pm Lunch (Concurrent Sessions)

RoundTable Lunch Discussions  
(Please see RoundTable Topics and room assignments on page 97)

Corporate-Sponsored Workshop: Ambient Temperature Technology for Sustainable Biobanking of DNA, RNA and Blood  
Supported by GenVault – see page 91 for more information  
Mees Zaal (4th Floor)

Informal Networking Lunch  
Exhibit Floor (Ground/1st Floors)

2:00pm – 3:30pm Lightning Round Poster Session (Poster Discussion)  
Willem Burger Zaal (3rd Floor)

Co-Chairs: Jan-Eric Litton, Karolinska Institutet, Stockholm, Sweden, and Daniel Simeon-Dubach, MD, MHA, Shiftung Biobank-Suisse, Bern, Switzerland

2:00 Welcome and Opening Remarks

2:05 BSS 01 Do you Have an Idea for an Innovative Technology to Advance the Biospecimen Sciences? Resources from the US National Cancer Institute’s Program for Innovative Molecular Analysis Technologies (IMAT)  
Mark David Lim, U.S. National Cancer Institute, NIH
2:10  **BSS 08 Global Methylation Surveys of Colorectal Cancer for Cancer Discovery in Archival Paraffin Tissue Samples: Split Sample Strategy to Support Experimental Evidence**
Galen Hostetter, MD, Translational Genomics Research Institute

2:15  **CCP 01 Comparison of Three Density Gradient Separation Methods for Peripheral Blood Mononuclear Cell Isolation**
Heather M. Siefers, MS, SeraCare Life Sciences

2:20  **QAC 15 Integrative Multi-level System to Monitor the Quality of Stored Biological Samples**
Daniel Rivard, PhD, Genome Quebec and Chicoutimi Hospital/Ecogene-21 Biobank

2:25  **QAC 16 High-Throughput DNA Quality Control: Allelic Discrimination Panel for Determining Sample Contamination, Gender and Ethnicity in a Biorepository Setting**
Andrew I. Brooks, PhD, Rutgers University

2:30  **LE 06 Cross-Border Exchanges of Human Biological Samples for Research Purposes: hSERN, a New Tool for Information on Regulation**
Anne Cambon-Thomsen, INSERM

2:35  **LE 03 Challenge and Triumph Utilizing Fresh Human Tissue Samples in Oncology Drug Absorption Studies**
Chris Womack, AstraZeneca

2:40  **HSR 05 Biobanking Solution Adapted to the Needs of Sites Participating in Clinical Trials Conducted in Collaboration with the Pharmaceutical Industry**
Julie Méthot, PhD, ECOGENE-21 Clinical Trial Center

2:45  **HSR 31 Building a State-of-the-Art Biobanking Infrastructure: The Genome Quebec and Chicoutimi Hospital/Ecogene-21 Experience**
Nancy Tremblay, MS, Genome Quebec and Chicoutimi Hospital/Ecogene-21 Biobank

2:50  **HT 02 Disease Advocacy Organization-initiated Biorepositories and Registries – An Exploratory Survey**
Elizabeth J. Horn, Genetic Alliance

2:55  **RAT 02 Automated Versus Manual Buffy Coat Recovery**
Kristian B.S. Spreckley, RTS Life Science

3:00  **RIF 13 BioBanking for Explorative Research – A Collaborative Approach to Enhance Research Efforts**
Inge Tarnow, DVM PhD, University of Copenhagen

3:05  **RIF 01 Health Data Integration: Linking Clinical and Research Databases**
Melissa N. Barber, PhD, BSc, Baker IDI Heart and Diabetes Institute
(Wednesday, May 12, 2010 continued…)

3:10  RIF 03 Practical Experience with Integration of IT Systems Used to Collect Biospecimen and Patient Data
Rainer Warth, PhD, Foundation Biobank-Suisse

3:15  RAT 08 An Integrated Platform for DNA Management: From Sampling to Downstream Analysis
Céline Lefebvre, MSc, Genome Quebec and Chicoutimi Hospital/Ecogene-21 Biobank

3:20  RIF 14 Integrating Patient Specimen Biorepositories with Clinical Laboratory Information Systems to Advance and Support Personalized Medicine: The Massachusetts General Hospital Model
Patrick M. Sluss, PhD, Massachusetts General Hospital

3:25  Closing Remarks

3:30pm – 4:30pm  Break, Visit the Posters and Exhibits
Exhibit Floor (Ground/1st Floors), Willem Burger Foyer (3rd Floor)

4:30pm – 6:30pm  Education & Training Workshops
(Concurrent Workshops)

Practical Approaches to the Daily Workflow Processes of a Tissue Bank
Willem Burger Zaal (3rd Floor)
Stella Somiari, PhD, Tissue Bank, Windber Research Institute

Digital Microscopy as a Tool in Tissue Banking
Fortis Bank Zaal (4th Floor)
Anand Kulkarni, MD, Tissue Services Core (Tumor Bank)

Thursday, May 13, 2010

GENERAL INFORMATION:

7:30am – 6:30pm  Registration/Information
Registration Desk (Ground Floor)

PROGRAM INFORMATION:

7:30am – 8:20am  Breakfast (Concurrent Sessions)

Working Group Breakfasts
(See Working Group descriptions on page 99)

Biospecimen Science
(Current WG members only)
Schadee Zaal (3rd Floor)
Leader: Fay Betsou, DSc, HDR

Informatics
Mees Zaal (4th Floor)
Leader: Cheryl Michels, BA
(Thursday, May 13, 2010 continued…)

**Informed Consent Procedures**  
*Ruys Zaal (4th Floor)*  
*Leader: Scott Jewell, PhD*

**Enviro-Bio Specimens**  
*Hudic Zaal (3rd Floor)*  
*Leaders: Paul Bartels, PhD & Yeonhee Lee, PhD*

**Pharma-Academia**  
*Van Beuningen Zaal (3rd Floor)*  
*Leader: Joseph Kessler*

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**Continental Breakfast (for all attendees)**  
*Exhibit Floor (Ground/1st Floors)*

**8:30am – 10:30am**  
**Quality Assurance, Quality Control & Harmonization**  
*Willem Burger Zaal (3rd Floor)*

This session features speakers who present topics of quality control between varying biobanks, evidenced-based procedures and principles of QC analysis and anticipated use.

*Co-Chairs: Fay Betsou, DSc, HDR, Integrated Biobank of Luxembourg (IBBL), Luxembourg and Scott Jewell, PhD, The Ohio State University, Columbus, Ohio, USA*

8:30  
**Introduction**

8:35  
**Quality Control in the Biobanking Process: New Solutions to Old Problems, Old Solutions to New Problems**  
*Fay Betsou, DSc, HDR, Integrated Biobank of Luxembourg (IBBL), Luxembourg*

9:05  
**EU Project SPIDIA - Standardisation and Improvement of Generic Pre-analytical Tools and Procedures for Sample Workflows**  
*Uwe Oelmueller, PhD, QIAGEN Gmbh, Hilden, Germany*

9:35  
**Developing the Underlying Science Necessary for Successful Biobanking**  
*Helen Moore, PhD, Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, Maryland, USA*

10:05  
**Safeguarding Against “Identity Theft” in a Biorepository Setting: Implementing Standard QC Measures to Identify Sample Discrepancies**  
*David Toke, PhD, Rutgers University Cell & DNA Repository, Piscataway, New Jersey, USA*

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**10:30am – 11:30am**  
**Break, Visit the Posters and Exhibits**  
*Exhibit Floor (Ground/1st Floors), Willem Burger Foyer (3rd Floor)*  
*Supported by: MVE-Chart*
11:30am – 12:30pm  
Awards Presentation & Business Meeting
Willem Burger Zaal (3rd Floor)
(Please see page 90 for the Agenda)

12:30pm – 2:00pm  
Lunch (Concurrent Sessions)
RoundTable Lunch Discussions
(Please see RoundTable topics and room assignments on page 97)
Informal Networking Lunch
Exhibit Floor (Ground/1st Floors)

2:00pm – 4:00pm  
Contributed Papers – Sessions I & II (Concurrent Sessions)

2:00pm – 4:00pm  
Session I: Legal, Social and Hot Topics
Willem Burger Zaal (3rd Floor)
Co-Chairs: Yeonhee Lee, PhD, Korea National Research Center, Nowngu, Republic of Korea and Peter Watson, MB B.Chir FRCPC, BC Cancer Agency, Victoria, BC, Canada

2:00  LE 01 A Persistent Dilemma - Legal/Ethical Issues Associated with Informed Consent and Genetic Testing in Dementia Research Biobanks
Rivka Ravid, MD, PhD, Netherlands Institute for Neurosciences / KNAW

2:20  RIF 17 Integrating Biospecimen Management with the Rest of Research and Healthcare Using caBIG® and caTissue Suite
Ian Fore, D. Phil, National Cancer Institute, Center for Biomedical Informatics and Information Technology

2:40  HT 06 Banked Mammalian Cell Cultures as a Wildlife Conservation Resource
Eric Harley, MD, PhD, University of Cape Town

3:00  PSR 01 Brassica Resource Bank (BRB)
Yong Pyo Lim, PhD, Chungnam National University

3:20  ASR 04 Securing Components of Southern Africa’s Biodiversity in a Biological Resource Bank – Contributing to Biodiversity Conservation & Biotechnology Development
Paul Bartels, PhD, National Zoological Gardens of SA, NRF

3:40  DR 01 Biobanking: Disaster Recovery in a Cold Climate
Rita Lawlor, University Hospital of Verona

2:00pm – 4:00pm  
Session II: Biospecimen Science
Fortis Bank Zaal (4th Floor)
Co-Chairs: Jodi Black, PhD, MMSc, NHLBI, NIH, Bethesda, MD, USA and Pasquale De Blasio, MBA, BioRep, Milan Italy
2:00  CCP 05 New Cryostore Solutions and Cryopreservation Strategies Used in a Mesenchymal Stem Cells (MSCs) Bank  
Maura Ferrari, Istituto Zooprofilattico Sperimentale di Brescia

2:20  CCP 07 Cryo-Banking of Cells and Tissues from Freshwater and Marine Fish in UK Waters  
David Rawson, DSc, University of Bedfordshire

2:40  QAC 04 Quality Control for Large Archived Collections: Increasing the Value, Decreasing the Cost  
Kathi Shea, SeraCare Life Sciences, Inc.

3:00  BSS 10 DNA Stabilization in Tissues, Cells and Whole Blood  
Rolf Muller, Biomatrica

3:20  BSS 14 The Influence of Tissue Sample Size on RNA Integrity  
Marcel Kap, BSc, Erasmus MC

3:40  QAC 13 Biospecimen Reporting for Improved Study Quality (BRISQ)  
Helen Moore, PhD, National Cancer Institute

4:00pm – 4:30pm  Break & Visit the Exhibits  
Exhibit Floor (Ground/1st Floors)  
Supported by: GenVault

4:30pm – 6:30pm  Contributed Papers – Sessions III & IV (Concurrent Sessions)

4:30pm – 6:30pm  Session III: Biobanking Diversity  
Willem Burger Zaal (3rd Floor)  
Co-Chairs: Anne Thompson, PhD, Victorian Cancer Bank, Carlton, Australia and Bill Grizzle, MD, PhD, University of Alabama at Birmingham, Birmingham, Alabama, USA

4:30  GRS 01 New Technology for Room Temperature Storage of DNA  
Jacques Bonnet, Institut Bergonié

4:50  GRS 04 The Future of Bio-sample Storage is Here to Stay – Not in the Cold but at Room Temperature!!!  
Rolf Muller, Biomatrica

5:10  HSR 08 Creation of a Local Biospecimen Collection Network at the Translational Genomics Research Institute  
Lora Nordstrom, PhD, Translational Genomics Research Institute

5:30  HSR 20 Addressing the Challenges of a Complex Disease Through a Repository-Centered Strategy: The Design and Implementation of the Accelerated Cure Project Multiple Sclerosis Repository  
Hollie Schmidt, Accelerated Cure Project for Multiple Sclerosis
5:50  HSR 34 Essential Factors for Establishing a Tissue and Serum Repository: The Feist Weiller Cancer Center (FWCC) Experience
Patrick Adegboyega, MD, Feist Weiller Cancer Center, LSU Medical Center, Shreveport, LA

6:10  HSR 39 BIOBUS – Taking the Laboratory to the People
Robyn L. Woods, PhD, Monash University

4:30pm – 6:30pm Session IV: Challenges and Solutions in Biobanking Technology and Informatics
Fortis Bank Zaal (4th Floor)

Co-Chairs: Marianne Henderson, MS, Office of Division Operations and Analysis Division of Cancer Epidemiology and Genetics, U. S. National Cancer Institute, Bethesda, Maryland, USA and Edward Suh, DSc, Translational Genomics Research Institute, Phoenix, Arizona, USA

4:30  RAT 07 Automated Processing of Biological Samples. The Experience of the InterInstitutional Multidisciplinary Biobank (BioBIM)
Fiorella Guadagni, MD, PhD, IRCCS San Raffaele Pisana

4:50  RAT 01 Using Automation to Improve Storage and Handling of Biospecimens in Legacy Collections
Karen E. Pitt, PhD, National Cancer Institute

5:10  NIN 05 The DNA Bank Network - A Shared Portal for Non-Human Biorepositories, Providing Live References to DNA and Specimen Data
Holger Zetzsche, PhD, Botanic Garden and Botanical Museum Berlin-Dahlem

5:30  NIN 07 An Interactive Web Portal to Facilitate the Worldwide Networking Between Biobanks and Key Players in the Biomarker Field
Pascal Puchois, PhD, Trans-Hit Biomarkers

5:50  RIF 05 Development of an Electronic Management System and Agenda for Controlling Sample Processing & Retrieving in the Biobank Laboratory
Jose Claudio Casali-da-Rocha, MD, PhD, Brazilian National Cancer Institute

6:10  RIF 16 Advances in Sharing Biorepository Information Through the Common Biorepository Model (CBM)
Andrew Breychak, BA, Sapient Government Services

5:30pm – 6:30pm Vendor Meeting (Exhibitors Only)
Van Beuningen Zaal (3rd Floor)
Friday, May 14, 2010

GENERAL INFORMATION:

7:30am – 2:00pm Registration/Information
Registration Desk (Ground Floor)

PROGRAM INFORMATION:

7:30am – 8:20am Breakfast (Concurrent Sessions)

Automated Repositories
 Hudic Zaal (3rd Floor)
 Leader: Andy Zaayenga

Biorepository Funding & Promotion
 Van Beuningen Zaal (3rd Floor)
 Leaders: Sara Loud & Hollie Schmidt

Biospecimen Science
 (open meeting; all meeting attendees are welcome)
 Schadee Zaal (3rd Floor)
 Leader: Fay Betsou, DSc

Rights to & Control of Human Tissue
 Mees Zaal (4th Floor)
 Leaders: Ty Hoover MD, JD, FCLM & Rajiv Dhir, MD

Continental Breakfast (for all attendees)
 Willem Burger Foyer (3rd Floor)

8:30am – 10:30am Education & Training Workshops
(Concurrent Workshops; See workshop descriptions on page 91)

8:30 Potentials and Pitfalls in Establishing a Global Network to Identify Bio-Specimens for Research
 Willem Burger Zaal (3rd Floor)
 Rivka Ravid, PhD, Brain Bank Consultants

8:30 Expanding the Role of the Consumer in Biobanking
 Fortis Bank Zaal (4th Floor)
 Liz Horn, Genetic Alliance

9:30 New Tissue Preservation Technologies Improving Commercialization of Human Biospecimens
 Fortis Bank Zaal (4th Floor)
 Olga Potapova, PhD, Cureline, Inc & Irina Zaytseva, MBA, Cureline, Inc

10:30am – 11:00am Break
 Willem Burger Foyer (3rd Floor)

11:00am – 1:30pm Global Harmonization - (Ethical, Legal, and Social)
 Willem Burger Zaal (3rd Floor)

This session features speakers who present topics on local norms affecting harmonization, the management of differences between biobanks, such as species differences, scientific value, and regulations.
Co-Chairs: Anne Cambon-Thomsen, MD, INSERM, Paris, France, and Helen Morrin, Curator, Cancer Society Tissue Bank, Christchurch, New Zealand

11:00  Introduction

11:05  Millennium Seed Bank Partnership - Working Together to Save Plants Worldwide
Jayanthi Nadarajan, PhD, Royal Botanic Gardens KEW, Surrey, United Kingdom

11:35  Update on SciColl
Richard Lane, Natural History Museum, London, United Kingdom

12:10  The Ethical Challenge of International Exchanges for Existing and New Human Biobanks
Anne Cambon-Thomsen, MD, INSERM, Paris, France

12:40  Unique Cultural Aspects for Biobanking in New Zealand: Can We Join Global Biobanking Initiatives and Still Fulfill our Cultural Obligations?
Helen Morrin, Curator, Cancer Society Tissue Bank, Christchurch, New Zealand

1:10  Panel Discussion

1:30pm  Meeting Adjourns
Invited Speaker Abstracts
(listed in alphabetical order by author)

Quality Control in the Biobanking Process: New Solutions to Old Problems, Old Solutions to New Problems
Fay Betsou, DSc, HDR, Integrated Biobank of Luxembourg (IBBL), Luxembourg
Thursday, May 13th 8:35am – 9:05am

A global and cross-disciplinary overview of the Quality Control challenges and implications in the biobanking process will be presented and methodological approaches will be discussed.

The Ethical Challenge of International Exchanges for Existing and New Human Biobanks
Anne Cambon-Thomsen, MD, INSERM, Paris, France
Friday, May 14th 12:10pm – 12:40pm

Human biobanks useful for research have been set up in different contexts for a long time. A lot has already been published about the ethical issues raised by such biobanks. However research requires increasingly international exchanges with the development of large scale studies, especially in genomics and related approaches. The issues are sensitive for biobanks that have existed for a long time and for which the context of such exchanges were not foreseen at the time of informed consent. A number of aspects rarely addressed in the past are systematically reviewed in the information provided nowadays to potential participants. The presentation will concentrate on comparing the questions encountered in legacy biobanks as compared to prospective current ones for international exchanges. The evolution over time of the role devoted to informed consent, research ethics committees, patients/populations consultation as groups is important to analyse. Finding incentives to sharing samples and data for researchers and their institutions and adapted governance models is a key factor. The traditional distinct categories of samples seen as human body elements on the one hand and of associated data mainly considered as personal data, on the other hand may be challenged as the limits between categories may be changing over time. An analysis of various tools and initiatives to facilitate international exchanges of biobank contents, and the role of ethical considerations in such endeavors will be discussed.

GBIF: Building the Biodiversity Informatics Commons, Making Biodiversity Information Accessible to All
Vishwas Chavan, Global Biodiversity Information Facility, Copenhagen, Denmark
Wednesday, May 12th 9:05am – 9:35am

Mobilising global environmental datasets is increasingly made possible through IT developments, and in particular, mobilising the billions of analogue primary biodiversity-related records already in existence around the world is a critical component of establishing baseline knowledge of species and ecosystems, allowing time-series analyses of changes and modelling of future environmental trends to improve decision-making. However, progress in discovery and mobilisation of these primary biodiversity data to date has been slow and opportunistic in nature. The Global Biodiversity Information Facility (GBIF), a multi-lateral initiative (of currently 53 countries and 43 international organisations) established to help mobilise these data has catalysed agreements on many of the standards, protocols and infrastructure required to make disparate datasets compatible, discoverable and accessible worldwide. Over 190 million records from 8300 datasets from more than 300 institutions worldwide are now accessible through the GBIF data portal (data.gbif.org). However, less than 40% of these records are specimen-based. This calls for expediting digitisation and access to an estimated more than 2 billion specimens housed in natural history repositories worldwide. To this end GBIF is developing various strategies and tools, including a ‘Global Strategy and Action Plan for mobilisation of natural history collections data (GSAP-NHC)’, and, to facilitate discovery of biodiversity data resources, a ‘Global Biodiversity Resources Discovery System (GBRDS) and network of distributed metadata catalogues. GBIF’s Integrated Publishing Toolkit (IPT) and Harvesting and Indexing Toolkit (HIT) facilitate efficient sharing, hosting and discovery of biodiversity-related data and general dataset metadata. Thus, the global biodiversity commons is now a reality, allowing access to previously inaccessible records and datasets, and analyses which were previously impossible. With
‘proof of concept’ secured, in order to enhance our ability to analyse our world and find solutions, it is for members of professional societies like ISBER to take full advantage of this emerging infrastructure to expedite the progress in digitisation and mobilisation of natural history repositories data. The call is made for participation by all who hold and collect biodiversity information to make their data available via common standards and internet publication. In addition, the call is being made to all funding agencies, both public and private to mandate within their grants that the data are captured to these global standards and made freely available.

**Unique Cultural Aspects for Biobanking in New Zealand: Can We Join Global Biobanking Initiatives and Still Fulfill our Cultural Obligations?**

**Helen Morrin, Curator, Cancer Society Tissue Bank, Christchurch, New Zealand**

*Friday, May 14th 12:40pm – 1:10pm*

The need for specimen sharing to obtain relevant study numbers for health research, particularly for rare diseases, has highlighted the requirement for standardisation of biospecimen practices and resulted in a shift towards Global harmonisation in biobanking. This movement has produced ISBER’s “best practice” guidelines, standardised operating procedures, biopreservation research, biobanking networks, and complex data sharing and informatics systems designed for future data mining activities. Generic informed consent is also acceptable to many countries; all indicating that global specimen exchange is achievable. However, when indigenous peoples cultural perspectives are incorporated into country-specific ethical and legal policies differences arise that need to be addressed, and new biobanking models need to be evaluated. In New Zealand a unique aspect of developing our Cancer Society Tissue Bank (CSTB) was our ethical, legal and cultural requirement to address important principles contained within New Zealand’s founding document, The Treaty of Waitangi (1840). By consulting with our indigenous Maori population we have developed a partnership from our banks’ inception to incorporate cultural values into our operational protocols. This has allowed the CSTB to address such cultural issues as the desire for tissue to remain in New Zealand, appropriate tissue handling, specimen return or disposal, and the concept of collective ownership of DNA and the associated genetic information. This presentation outlines the culturally inclusive operational procedures we have developed that have contributed to our bank achieving inclusiveness of all ethnicities, and the implications for joining global biobanking initiatives.

**Millennium Seed Bank Partnership - Working Together to Save Plants Worldwide**

**Jayanthi Nadarajan, PhD, Royal Botanic Gardens Kew, United Kingdom**

*Friday, May 14th 11:05am – 11:35am*

The Millennium Seed Bank Project has, since 2000, successfully collected and conserved 10% of the world’s seed-bearing flora. The MSB Project was conceived, developed and managed by the Seed Conservation Department of the Royal Botanic Gardens, Kew, UK. Besides seed collecting, the aim was to develop bilateral research, training and capacity-building relationships to support and advance the seed conservation effort. Both the MSB Project and the new MSB Partnership (2010-2020) have been developed within the framework for international conservation collaborations agreed by signatories to the Convention on Biological Diversity (CBD). The CBD is a framework for the development of national biodiversity action plans, national policies, guidelines and national legislation regulating access to genetic resources, traditional knowledge and associated benefit-sharing on biological diversity. The MSB Project’s collecting programme worked with partners from about 50 countries. Each partner’s ‘Access to Benefit-Sharing Agreement’ reflects the terms and conditions of a partnership designed to reflect particular characteristics and needs; collecting, science, technology, information etc. Active science collaborations were also developed with over 100 institutions in 60 countries, including EU-funded COST Action 871 on the cryo-preservation of crop species in Europe and Darwin Initiative-supported projects on seeds with 16 countries in sub-Saharan Africa. MSBP through its bilateral agreements and support of partner institutions, ensures duplication of conserved seed collections at facilities all over the world, at the same time providing capital input, training and technical expertise for seed banking activities and the project has become a world focal point for seed conservation and scientific research.
Safeguarding Against “Identity Theft” in a Biorepository Setting: Implementing Standard QC Measures to Identify Sample Discrepancies

David A. Toke, PhD, Rutgers University Cell & DNA Repository (RUCDR), Piscataway, NJ

Thursday, May 13th 10:05am – 10:30am

Biobanking has become the mainstay for both basic science and clinical discovery programs and soon will be a critical component of routing clinical diagnostic platforms. Due to the recent growth in sample receipts across existing and newly formed biorepositories, the number of samples being collected and processed into high quality biomaterials has led to unforeseen challenges in the automation of sample preparation and more importantly quality control processes. In many research applications both whole blood and cell line derived DNA are genotyped soon after distribution at which time sample discrepancies ultimately arise. In order to quickly and efficiently resolve any sample discrepancies as well as play a proactive role in identifying sample registration and sample handling errors a good biorepository must implement a functional QC process that allows for both qualitative assessment of sample quality as well as provide key genetic information to confer sample identity. Topics to be covered will include: How to safeguard against identity errors, how to address the mistaken identity of samples, methods required to identify the source of error and most importantly the determination of sample validity for the ever expanding downstream applications for nucleic acid analysis.

Integrating Genetics, Genomics, and Biology Towards a More Personalized Medicine

Jeffrey Trent, PhD, FACMG, Van Andel Research Institute, Grand Rapids, Michigan, USA

Tuesday, May 11th 2:10pm- 2:40pm

Genome wide profiling of gene states (structure, expression, etc) has emerged as a means for molecularly defining disease. The next challenge is to match the specific molecular context of disease with the most appropriate therapy. Systems medicine is emerging as a new field of research, which seeks to identify contextual vulnerabilities that arise in disease context. Towards this end, TGen has developed and applied a number of genome wide and genome compatible technologies and strategies to both profile the disease context (structural and functional genomics), as well as profile context selective drug targeting (cellular genomics). Our group has focused primarily on cellular genomics using very high throughput RNAi to systematically knockdown genes, and determine the functional role of each gene in various cellular processes including cell growth, survival, molecular end points, and drug response. The computational ‘fusion’ of multidimensional data sets to integrate structural, functional, and cellular genomic information has proven to be a very powerful strategy for generating new predictive models of context dependent targeting. In oncology, this research has led to the discovery of context specific vulnerabilities, enabling us to prioritize pharmacologically and clinically relevant drug targets and support more personalized medicine oriented drug discovery. Additionally, we have shown that this approach can lead to the discovery of genes that are casually involved in determining specific response to cancer drugs. These genes are currently being advanced as candidate predictive markers to select patient populations that would respond to specific cancer drugs, and as putative combination targets to enhance response in patients that are not responding. Such information can improve and accelerate the clinical development of emerging cancer therapies. This strategy represents a new paradigm for both drug discovery and drug developments, and has the potential to someday impact on how therapeutic decisions are made.
The planning of the construction of a pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) started in February 2008 and should result in the implementation of BBMRI as an ERIC (European Research Infrastructure Consortium) legal entity at the end of 2010. BBMRI will build on existing sample collections, resources, technologies, and expertise, which will be specifically complemented with innovative components. In particular, BBMRI will comprise i) all major population-based and disease-oriented biobanks, ii) biomolecular resources, such as collections of antibodies and other affinity binders and a variety of molecular tools to decipher protein interactions and function, and iii) bio-computing and sample storage infrastructure. All resources will be integrated into a pan-European distributed hub structure-like network, and will be properly embedded into European scientific, ethical, legal and societal frameworks. BBMRI in its preparatory phase involves currently 260 institutions or organizations from 30 countries, either as direct participants in the project or as associated organizations. Although BBMRI will be located in Europe it aims at establishing close collaborations with biobanks and biological resource centres outside of Europe. This might be facilitated by the fact that BBMRI builds on the OECD best practice guidelines for biological resource centres. BBMRI is establishing contact with similar initiatives in OECD Member States and enhanced engagement countries to explore opportunities for future collaboration that follow the principles as defined in the concept for the OECD Global Biological Resource Centres Network (GBRCN) and further specified in the OECD best practice guidelines.
Exhibit Schedule & List of Exhibitors

Exhibit Schedule:

Tuesday, May 11, 2010, 4:30pm – 6:30pm
Wednesday, May 12, 2010, 8:00am – 4:30pm
Thursday, May 13, 2010, 8:00am – 4:30pm

List of Exhibitors:

AM Robotic Systems, Ltd (Booth # 3)
AM Robotic Systems offers laboratory automation to the life science research community and has developed a range of flexible bench top systems for blood fractionation. These systems aim to automate operations that are difficult to perform manually and they have also been designed for the preparation for storage of other sorts of samples, for example, urine and saliva.
www.amroboticsystems.co.uk

Angelantoni Industrie SpA (Booth #’s 30-31)
The Life Science BU of ANGELANTONI INDUSTRIE SpA manufactures a complete range of ultra freezers, blood banks, refrigerators and laminar air flow cabinets, isolator and the clean rooms assuring the best cold technology solutions for biological laboratories, universities, hospitals and industries. Angelantoni Industrie has produced an innovative robotic cryobank, SMARTFREEZER® working at -80°C and -180°C.
www.angelantoni.it

Aperio Technologies, Inc (Booth # 40)
Aperio is the leading provider of digital pathology solutions in hospital and reference labs, academic medical centers, and biopharma institutions across the world. Our comprehensive product line features our ScanScope® scanners, Spectrum™ image management (PACS) software, SecondSlide™ slide sharing service for pathology, and image analysis tools and services.
www.aperio.com

Artificial Intelligence in Medicine (Booth # 42)
AIM’s comprehensive biospecimen management system – TissueMetrix – now connects to NCI cancer bioinformatics grid (ca BIG) through the common biorepository model. TissueMetrix also exposes summary inventory data and contact details to the general public through a ‘Storefront’ web portal. Building value added specimen resources? See AIM in Booth 42 and discover why you should choose TissueMetrix to create collections, annotate specimens with clinical information, and track the chain of custody as your biospecimen repository solution.
www.aim.on.ca

Askin GMBH (Booth # 9)
The ASKION C-line ® system is an open and modular system to meet the growing requirements of quality bio-banking. It is used in the fields of biomedicine, medicine, biology, biomarker development, biotechnology and proteomics. Main advantages are an integrated sample management and a closed cooling chain for the specimen. This system consists of three components: ASKION C-line ® hermetic storage is a semi-automated, high-security cryo storage system. ASKION C-line ® work bench is a liquid nitrogen work bench with a deep-cool working space and an optional freeze and thawing system. ASKION C-line ® control is the control software for the system and the interface to the common LIS/HIS.
www.askion.com
Asterand plc (Booth # 34)
Asterand plc is a leading supplier of high quality human tissue and tissue-based services. Our comprehensive approach to human tissue and research services supports human drug discovery and translational medicine. Samples are collected from a global network according to standardized, ethical protocols. Therapeutic areas include arthritis, cancer, cardiovascular, and diabetes. Our products include custom and standard tissue procurement, tissue microarrays, and gene expression profiling. [www.asterand.com](http://www.asterand.com)

AutoGen, Inc. (Booth # 17)
The AutoGenFlex STAR is the finest automated system available for extracting DNA from large volumes of whole blood, cells and saliva. The STAR features a capacity for 40 samples per batch providing real productivity and its outstanding reliability makes it a system you can count on day after day. Backed by AutoGen's best in the industry customer support the AutoGenFlex STAR provides you with the tools you need to PREP WITH CONFIDENCE. [www.autogen.com](http://www.autogen.com)

Autoscribe Limited (Booth # 20)

Biomatrica (Booth # 48)
Biomatrica is a molecular biology company creating new technologies for room temperature stabilization, storage, archival and/or transport of nucleic acids. Our SampleMatrix™ platform of products now include ambient room temperature stabilization of purified genomic DNA and total RNA, as well as DNA in blood, tissues and cell lines. We also offer assay boosting reagents for PCR and STR experiments. Our laboratory sample management software provides a data management, inventory control, tracking and audit trail of all biological samples in storage. [www.biomatrica.com](http://www.biomatrica.com)

BioRep s.r.l. (Booth #’s 28-29)
BioRep is an independent “SERVICE PROVIDER”, offering biorepository services to public and private research institutes, to the highest standards of quality and safety. Thanks to an exclusive agreement with Coriell Institute for Medical Research, the oldest and largest biorepository of the world, BioRep is specialized in cell lines preparation, in nucleic acid extraction and long term storage in liquid nitrogen (-196° C) and in refrigerators -80°C of any kind of biosamples. BioRep and Coriell together constitute one of the few “Global Biorepository” able to serve the pharmaceutical industries for world wide clinical trials. In addition to the storage service, BioRep provides Cell Biology, Molecular Biology, Microbiology, Media preparation services developed in ISO9001/2008 certified laboratories. [www.biorep.it](http://www.biorep.it)

BioStorage Technologies Inc. (Booth # 32)
BioStorage Technologies, Inc. is the worldwide leader in sample storage, inventory management and cold chain logistics for the biotechnology and pharmaceutical industries throughout the research, clinical trial and commercialization phases of drug development. The company offers secure, temperature-controlled storage; real-time tracking of stored biological samples; and next-day return of biomaterials. BioStorage Technologies operates facilities in the United States and Europe. [www.biostorage.com](http://www.biostorage.com)
Brady Corporation (Booth # 25)
High performance labels, barcode printers (hand-held and bench-top), software, scanners and applicators. Brady has a full range of label sizes, materials and adhesives specifically designed for laboratory applications like vial and plate identification. Our labels are chemical and solvent resistant and can withstand exposure to liquid nitrogen, freezer storage, hot water baths, and autoclave process.
www.bradyid.com

Computype Inc. (Booth # 50)
Computype is a world leader in integrated Auto ID Solutions, with high quality products and services including: • Custom-engineered pre-printed and print-on-demand labels • Linear, 2D & RFID capabilities • Harsh Environment labels (Cryogenic, freeze/thaw etc) • Chemical resistant labels (Xylene, DMSO etc) • Hardware - scanners, PDT’s, printers, applicators/dispensers • Software • Bureau service for pre-labelled labware and tare-weighing.
www.computype.com

Cryo Bio System (Booth #'s 45-46)
Cryo Bio System provides innovative solutions to the scientific community, through a range of High Security storage products for Biorepositories, Biobanks and Biological Resources Centres for applications such as epidemiological studies. Our solutions include DIVA, a fully automated packaging system for liquid biological samples in CBS™ High Security straws.
www.cryobiosystem.com

Dataworks Development, Inc. (Booth # 5)
Developers of Freezerworks™ freezer inventory and sample management software. Fully user configurable. Track samples across multiple freezers and shipments in and out of the lab. Safeguard your data with powerful user and group security, 21 CFR part 11 compliance, and cryogenic-safe barcode labeling. Integrate using SOAP toolkit (read/write) and native SQL database. Configure for all freezers and tanks.
www.freezerworks.com

Elpro (Booth # 14)
ELPRO is a leading provider of temperature monitoring solutions for repositories and cold chain transportation. The ELPRO Central Monitoring System is an easy to use, reliable and scalable solution for all your temperature & humidity monitoring requirements in storage and production processes. For cold chain monitoring, ELPRO offers the unique Libero PDF Logger which provides a complete report at the destination without any software.
www.elpro.com

Fisher BioServices (Booth # 38)
Fisher BioServices Inc. (FBS) is a leader in support of clinical research in infectious diseases, chronic illness and cancer. We provide cold chain management, storage, and worldwide distribution of clinical trial materials (preclinical - Phase IV) and biological specimens. We offer customized collection kit assembly and molecular laboratory services, which include blood processing, cell separation, DNA/RNA extraction, and quantification.
www.thermofisher.com

FluidX (Booth # 22)
At FluidX our vision is to exceed our customers’ expectations and requirements for the high quality consumables, instrumentation and automation tools they need to help them succeed in their Life Science Research. We offer an ever-developing range of fluid handling systems, sample storage and tracking systems, sealing products and sample picking instruments. FluidX continually strives to offer superior products at competitive prices.
www.fluidx.co.uk
Fraunhofer Institut für Biomedizinische Technik (Booth # 10)
The Fraunhofer Institute for Biomedical Engineering (IBMT) engages in applied research into Cryo-technologies, Cryo-devices and Biocryophysics. Living samples (cells and tissue) are stored at temperatures below −130°C using a closed temperature chain and 100% sample identification in totally automatically operating facility. Biological competence for adapting freezing protocols or stem cell research is also provided.
www.ibmt.fraunhofer.de

GE Sensing & Inspection Technologies (Booth # 47)
The Validation software and hardware platforms you have trusted for years continues to expand the Kaye product line and offer you more value and security with your bottom line in mind. Safe time and money using Kaye wired and wireless thermal validation systems; wireless process validation and monitoring systems; centralized facility monitoring, alarm and reporting systems.
www.gesensing.com/kayeproducts/

GenoLogics (Booth #’s 18-19)
GenoLogics provides discovery and biomedical solutions that can be implemented across multiple labs and support translational medicine and systems biology initiatives. Our vision is to catalyze life sciences research with a collaborative data management software platform, advancing the early detection, prevention, and treatment of disease.
www.genologics.com

GenVault Corporation (Booth # 33)
GenVault is the leading global provider of next-generation technologies for room temperature storage and management of biosamples for genomic research. GenVault’s products enable extraction, recovery and preservation of DNA and RNA. With newly launched GenTegra™ DNA, and scalable archiving solutions, GenVault is pioneering new standards for biosample management.
www.genvault.com

Hamilton Storage Technologies (Booth # 12)
HST provides automated sample management solutions to customers in the life science industries. The company develops modular, scalable systems that automate sample storage, management and processing. Products include -80°C biobanking, -20°C high-throughput tube and plate management and liquid handling integration. Our systems are beneficial for biobanking and biorepository applications.
www.hamilton-storage.com

HighRes Biosolutions (Booth # 23)
HighRes Biosolutions is the leader in the design and construction of innovative robotic systems and laboratory devices used by pharmaceutical, biotech, government, medical and academic research laboratories. We enable biorepository science and accelerate drug discovery with highly flexible, expandable and modular integrated systems; bench-top devices and consumables that are easily configured (and reconfigured) to create research environments conducive to achieving breakthrough results.
www.highresbio.com

KBioscience Ltd. (Booth # 55)
KBioscience Ltd is a rapidly growing company in the biological repository and processing sector. Our facility is based just minutes north of London and contains a dedicated and highly efficient centre for DNA collection, storage, purification and SNP genotyping using proprietary in-house chemistry. The organisation has been established in such a way as to bring incredible quality of service at exceptional value.
www.KBioscience.co.uk
LabVantage Solutions Inc. (Booth # 24)
90 Day Risk Free SAPPHIRE BioBanking Solution: As part of the SAPPHIRE Laboratory Information Management Suite (LIMS), a zero-footprint configurable-off-the-shelf (COTS) solution, the SAPPHIRE BioBanking Solution provides a centralized solution with comprehensive functionality for biorepository management. The SAPPHIRE BioBanking Solution is now guaranteed to be delivered by LabVantage within a fixed duration of 90 days and at a fixed cost. More information is available at www.labvantage.com/solutions/riskfree/gbb/index.aspx?src=printscw.

LabWare, Inc. (Booth # 52)
LabWare is recognized worldwide as the leading supplier of enterprise Laboratory Information Management Systems (LIMS). We are a full service provider offering software, professional implementation and validation assistance and world class technical support to ensure our customers get maximum value from their LabWare LIMS™ and LabWare ELN™ solutions. www.labware.com

Linde Gas Cryoservices (Booth # 56)
Linde Gas Cryoservices and its team of highly qualified specialists in the field of low temperature technology offer extensive services in temperature controlled freezing, cryogenic storage and logistic management of biomedical and pharmaceutical material. Linde Gas Cryoservices is more than just an equipment supplier, and is offering full low temperature repository services in its self-owned and operated cryobank in Hedel, The Netherlands. www.linde-gascryoservices.com

Micronic Europe B.V. (Booth # 49)
Micronic is an independent organisation with its headquarters located in Lelystad, The Netherlands. Micronic’s class 7 clean room is also located here, in which all the products can be produced RNase, DNase and Pyrogene free. Micronic is an ISO 9001 and 14001 certified company. The Micronic sales, marketing and product support is organised at two sales offices; Micronic Europe BV and Micronic North America, LLC. Our products are applied worldwide in the (research) laboratories of university medical schools, forensics, agricultural, veterinary and governmental institutes as well as companies in the Biotech, Food, Chemical and Pharmaceutical areas. www.Micronic.com

Modul-Bio (Booth # 35)
Modul-Bio’s products portfolio includes:
- MBioLABEL®: traceability solutions for Life Sciences laboratories allowing biological samples identification for long term storage, from labelling to scanning
- MBioLIMS®: a flexible Laboratory Information Management System based on MBioLIMS Core and Plug-in modules. Solutions specially designed for biobanking laboratories.
Our solutions accelerate your research while providing long term data preservation and complete traceability. www.modul-bio.com

MVE-Chart Industries (Booth #'s 15-16 and 26-27)
MVE-Chart is the leading manufacturer of technical systems for biological storage of human tissue, cord blood, bone marrow, stem cell and other highly sensitive biotech and pharmaceutical applications. MVE-Chart offers the widest selection of aluminum storage units including vapor shippers and nitrogen handling equipment, and stainless freezers. For more information, please email info.biomed@chart-ind.com. www.chartbiomed.com

Nexus Biosystems (Booth # 44)
Nexus Biosystems provides high-integrity solutions for demanding Life Science applications. Nexus provides the Universal Store and Universal LabStore lines of Automated Biological and Chemical Compound Sample Storage, for highly-modular and expandable systems for -80°C, -20°C and ambient environments. Nexus manufactures and sells its’ XPeel Automated Seal-Removal Systems and the Aurora Microplate Products for sensitive fluorescence and cellular-imaging applications. www.nexusbio.com
OCIMUMBIO (Booth # 53)
Biotracker™ Biobanking is a fully scalable and customizable complete biobanking solution. Features include; Web-Based Requestor Module, Donor/Patient and Biospecimen Management with full Genealogy, Unlimited Meta Data Annotation, Controlled Vocabulary and Synonyms, Data and Location Management, TMA, CMA, caBIG® Bronze Certified, Regulatory Compliant (HIPAA, 21CFR11, GxP, CLIA), and much more. Biotracker™ Biobanking can be implemented on your network or as SaaS.
www.ocimumbio.com/lims

Perma Cryo Technologie GMBH (Booth # 8)
Perma Cryo Technologie GmbH was founded in April 2007 with the vision to set a new standard in cryo technology: electronically flagged samples, which are able to interact with cryo tank systems and other laboratory equipment by “knowing” their own workflow or storing important data on an integrated memory chip. This technology will reduce the likelihood of any mix-ups to 0%. Each sample (certified medical devices), comes with four major security features including two in-mold labels with 2D-barcodes, RFID transponder and a Perma Cryo® Memory Chip which allows data storage and interaction down to -196°C.
www.perma-cryo.com

Phase Forward (Booth # 51)
Phase Forward offers a global, Integrated Clinical Research Suite designed to enable like sciences companies of all types and sizes to automate and integrate the management of their entire clinical development process—from study initiation and regulatory submission through post-approval trials and pharmacovigilance studies.
www.phaseforward.com

Planer PLC (Booth # 4)
Planer, worldwide leader in controlled rate freezers, also supplies liquid nitrogen storage systems and the full range of laboratory products required to preserve and protect biological samples. Assure24seven, their web enabled Monitoring and Alarm solution, seamlessly integrates with KryoTrak inventory management. GLP, GMP, IQ and PQ are all supported.
www.planer.com

Progeny Software, LLC (Booth # 21)
Progeny LIMS is the ideal sample tracking and management solution. Available as a web or PC deployment, and able to integrate with clinical and genetic data, Progeny LIMS is easy to configure and use without expensive customization. Progeny LIMS has full chain of custody, security and is 21 CFR Part 11 Compliant. Visit us for a demo at ISBER!
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Qiagen Ltd (Booth # 39)
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www.qiagen.com

REMP (Booth # 11)
REMP, a Tecan Group Company, is a global leader supplying automated storage and retrieval systems for sample management in the Life Science industries. Solutions include systems, devices, consumables and software applications for sample management and biorepository applications. REMP was the first worldwide supplier to successfully install a large scale, fully automated biorepository operating at -60°C and -20°C, concurrently. Founded in 1986, REMP has over 100 employees worldwide.
www.remp.com
RTS Life Science, Ltd (Booth # 13)
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www.rtslifescience.com

RURO, Inc. (Booth # 43)
FreezerPro by RURO is a next generation, Web-based software application for managing, tracking and auditing frozen samples and their associated data in laboratories and biorepositories of just about any size. RURO Inc, headquartered in Frederick, Maryland, specializes in development and production of state of the art computer software for research, biotechnological, pharmaceutical, healthcare and government laboratories in the US and worldwide.
www.ruro.com/freezerpro

Sanyo E&E Europe BV (Booth # 1)
SANYO E&E Europe BV, a division of SANYO Electric Co., Ltd., manages sales, logistics and technical service of SANYO laboratory products throughout Europe (including Russia and Turkey). Sanyo has established a worldwide reputation as a manufacturer of high-quality and innovative medical and laboratory equipment over the past thirty years, using the latest applied theories and ideas about refrigeration, compressors and energy efficiency that directly benefit our customers.
www.sanyo-biomedical.com

Soventec (Booth # 7)
Soventec is provider for software development services and solutions in automation and workflow management for cryobiological labs and biobanks. The LabOS ChameleonLab platform fills the gap between LIMS and device automation on an abstracted layer and provides an intuitive user interface for automated, semi-automated and manual workflows.
www.soventec.com

STARLIMS (Booth # 6)
STARLIMS® is an exceptionally flexible information management system that helps you maximize the value of specimens, meet stringent regulations and promote collaboration. STARLIMS archives, traces and manages specimen data, along with clinical studies, laboratory testing workflows, donor data, legal consent data and more. All this information is accessed online, through this award-winning Web-based solution based on 20 years of expertise.
www.starlims.com/markets/biorep.htm

Thermo Scientific (Booth #’s 36-37)
Thermo Fisher Scientific is the world leader in serving science, enabling our customers to make the world healthier, cleaner and safer. Our brand Thermo Scientific offers customers a complete range of high-end analytical instruments as well as laboratory equipment, services, consumables and reagents to enable integrated laboratory workflow solutions. We offer the most convenient purchasing options to customers and continuously advance our technologies to accelerate the pace of scientific discovery.
www.thermo.com

Trinean (Booth # 57)
TRINEAN produces the DropSense96, the first high throughput droplet plate reader. Combining the DropSense96 with its microfluidic disposable, the DropPlate16/96, allows quick and precise UV-VIS full spectral analysis of 1-3 µl samples of DNA/RNA/proteins. Unique features are a large measurement range (no sample dilution) and elimination of sample evaporation. The DropSense96 is compatible with liquid handlers for a full automated workflow.
www.trinean.com
Tri Star Technology Group, LLC (Booth # 54)
TriStar High-density Tissue Micro arrays comprise thousands of clinically well-defined tissue samples and can substantially accelerate the validation of potential new biomarkers. IHC, FISH or RNA in-situ hybridization (ISH) is used to relate target expression/amplification to prognosis, progression, drug treatment & response. Focus areas include Cancer and Neurodegenerative diseases. Arrays, biological samples and contract research services are provided.
www.tristargroup.us

Vitro S.A. (Booth # 2)
Since 1989, Vitro has pioneered the discovery and development of new reagents, software and techniques – translating them into innovative solutions. This continues with Bio-e-Bank, the complete biobank management system, developed in partnership with Spain’s premier DNA and tumour banks. Bio-e-Bank offers proven data security, sample traceability and process integrity in an intuitive and scalable system. It tracks, annotates and manages samples from reception, through processing to storage. Integrating with your existing HIS and LIMS systems, it helps streamline your processes and helps ensure compliance.
www.bio-e-bank.com

Wheaton Science Products (Booth # 41)
Wheaton Science Products offers a variety of containers for biospecimen storage. This offering includes high recovery vials, cryogenic vials and ampules, glass microtubes, and freezer boxes for automated and manual systems. In today’s world of sample management, sample integrity means everything. With the new Wheaton CryoELITE® Cryogenic Vial, sample tracking is simple and permanent with the unique 2D Data Matrix bar code bottom insert.
www.wheatonsci.com
Abstract Presentation Schedule

Lightning Round Poster Session (Poster Discussion) Schedule:
Wednesday, May 12th
2:00pm – 3:30pm
Willem Burger Zaal (3rd Floor)

Poster Presentation Schedule:
Posters are located on the Willem Burger Foyer (3rd Floor). Presenters are asked to stand beside their posters at the following times:

Wednesday, May 12th
10:00am – 11:00am and 3:30pm – 4:30pm

Thursday, May 13th
10:30am – 11:30am

Contributed Papers Session Schedule:
Thursday, May 13th 2:00pm – 4:00pm
Concurrent Sessions:

Contributed Papers I – Legal, Social and Hot Topics
Willem Burger Zaal (3rd Floor)

Contributed Papers II – Biospecimen Science
Fortis Bank Zaal (4th Floor)

Thursday, May 13th 4:30pm – 6:30pm
Concurrent Sessions:

Contributed Papers III – Biobanking Diversity
Willem Burger Zaal (3rd Floor)

Contributed Papers IV – Challenges and Solutions in BioBanking Technology and Informatics
Fortis Bank Zaal (4th Floor)

NOTE: Posters must be removed by 2 PM on Thursday, May 13th. Posters left on the boards after this time will be discarded. ISBER is not responsible for any posters left on the boards.
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Banking of Mesenchymal Stem Cells for Tendon Repair in Race Horses

Maura Ferrari¹, Sabrina Renzi¹, Lorenzo Sesso², Maurizio Comali³, Serena Carlin⁴
¹Istituto Zooprofilattico Sperimentale di Brescia, Brescia, Italy; ²University of Milan, Milan, Italy; ³Veterinary Clinic, Merano, Bolzano, Italy; ⁴University of Padua, Padua, Italy

Background - Mesenchymal stem cells (MSCs) are frequently used in veterinary medicine to repair orthopaedic injuries, particularly in race horses. MSCs can be isolated from different tissues, but the most commonly used for clinical applications are derived from adipose tissue or bone marrow. A branch of our culture bank was dedicated to the storage of MSCs, in order to treat tendon injuries in horses. Methods – MSCs have been isolated from fat tissue and bone marrow, propagated in vitro not more than four passages and tested for multi-potentiality. Before freezing, every batch was subjected to safety controls. Only the batches free from contaminations (viruses, eubacteria and mycoplasma) were banked. MSCs were used not only for autologous but also for allogeneic implantation. For implantation, cells were suspended in autologous Platelet Rich Plasma (PRP) and inoculated into the damaged tendon. After MSCs treatment, horses were subjected to a rehabilitative period and to ecographic controls. A sample of every batch was conserved in the bank to be preserved either for a subsequent treatment or in case of complaint. Results – Currently the MSC bank consists of 100 batches of cells. Each ampoule contains an average of 7x10⁶ MSCs. Ecographic examinations showed good tendon regeneration and some of the treated animals have started competitions. Conclusions – The MSC bank at IZSLER is organized in accordance with quality parameters. The prepared cells have shown to be useful for clinical application regarding tendon repair.

Wildlife Gene Specimen Banks – Essential Infrastructure for the Assessment and Monitoring of Endangered Wildlife in Southern Africa

Pete Goodman¹, Bettine Van Vuuren², Jacques Flamand³, Eric Harley⁴, Paul Bartels⁵
¹Ezemvelo KZN Wildlife, Cascades, Kwazulu Natal, South Africa; ²Stellenbosch University, Matieland, Western Cape, South Africa; ³WWF-SA, Cascades, Kwazulu Natal, South Africa; ⁴University of Cape Town, Observatory, Western Cape, South Africa; ⁵National Zoological Gardens of SA / NRF, Pretoria, North West Province, South Africa

Populations that are founded from a small surviving parent population that has gone through a numerical bottleneck, can, if not properly managed, end up suffering from a decline in genetic diversity. This in turn could lead to inbreeding depression and a loss of fitness which if severe enough could lead to population extinction. The main objective of managing such a population is to have a meta-population exchange strategy that minimizes loss of heterozygosity and inbreeding. The establishment of a number of Genetic or Gene Specimen Banks in southern Africa has, as one of its outputs, facilitated the setting-up of genetic management standards and informing management as to the ongoing genetic status of selected endangered wildlife populations e.g. Black rhinoceros, Diceros bicornis minor. Specimens derived from currently abundant species would in turn also be valuable should a catastrophic decline in numbers befall the species, such as occurred with the Indian white-backed vulture Gyps bengalensis. The purpose of Gene Banks also includes archival banking; forensics investigations; contributing to the International Barcode of Life (iBOL) Initiative; biodiversity discovery; game ranch management; identifying hybrid species. Field officers are tasked with the logistics of collecting the appropriate specimens and data and transporting them to the Gene Bank. The Gene Bank is tasked with sample processing, management and control, as a national asset of the country and to the benefit of society.

National Animal DNA Bank – Infrastructure Partner within a Network of Biobanks in South Africa

Ronwe Wolmerans¹, Ben Greyling¹, Paul Bartels²
¹Agricultural Research Council, Irene, Gauteng, South Africa; ²National Zoological Gardens of SA / NRF, Pretoria, North West Province, South Africa

Introduction: Access to DNA derived from livestock and wildlife play a vital role in molecular genetics and forensics. The ARC, a consortium member of BioBankSA, collects, processes, banks and distributes a representative range of value-enhanced biomaterials from key wildlife and indigenous livestock species for research and biotechnology development. Methods: Tissue and blood specimens are submitted by the owners of animals, DNA extracted and an aliquot banked for future use. Results: Samples held include 65 wildlife species, 10 livestock species, including different breeds and a number of avian and fish species. The National Animal DNA Bank has about 13,000 samples, each uniquely identified by a barcode ID number. Information pertaining to the samples is stored in a database and allows for easy access and value adding. Dynamic operational policy ensures protection of ownership on the one hand while promoting availability and access of samples for
research purposes. Access and release of sub-samples to beneficiaries is mediated through a peer-reviewed evaluation process. Conclusion: A number of projects have culminated from samples originating from the National Animal DNA bank and includes technology development for forensic identification of a range of wildlife species, including rhino, impala, kudu, sable antelope and buffalo. DNA samples, representative of the species diversity of southern Africa, will be added to the collection, so increasing its value and use, to the benefit of society.

ASR 04

Securing Components of Southern Africa’s Biodiversity in a Biological Resource Bank – Contributing to Biodiversity Conservation & Biotechnology Development

Paul Bartels¹, Ilse Luther¹, Shoni Nemakonde¹, Kim Labuschagne¹
¹National Zoological Gardens of SA, NRF, Pretoria, North West Province, South Africa

Introduction: Biomaterials play a pivotal role in biodiversity conservation and biotechnology development. A unique, one of a kind wildlife / indigenous livestock Biological Resource Bank (BRB) has been established in South Africa. Method: Biomaterials are collected from a variety of species, processed and banked in the BRB. Different tissue-types making up the BRB include fibroblast cell cultures, gametes, embryos, skin, DNA, hair, feathers, shells, blood and muscle. Tissue is stored under different conditions, including room temperature, refrigeration, mechanical freezers and Liquid Nitrogen freezers. The BRB represents a knowledge-hub and is expanding to meet the growing biodiversity communities’ needs of biomaterial access, processing, curation, research (Science of Collections) and distribution for trans-disciplinary research, including molecular genetics, reproduction, epidemiology, health, forensics, species discovery (Barcode of Life) and environmental pollution. The knowledge-hub further engages stakeholders in technology transfer, knowledge generation, human resource development and access and benefit sharing (ABS) practices. The BRB is the custodian of the biomaterials, on behalf of the legal owners of the animals, from which the biomaterials were collected. Results: The BRB has 45,000 samples from more than 450 species and together with the samples banked at the BioBankSA consortium partners, represents a significant resource for the national, regional and global research communities. Conclusion: Biomaterials are national assets and the BRB plays a pivotal role in the securing of such assets and the use thereof for ethical research, to the benefit of society.

BSS 01

Do you have an Idea for an Innovative Technology to Advance the Biospecimen Sciences? Resources from the US National Cancer Institute’s Program for Innovative Molecular Analysis Technologies (IMAT)

Mark Lim¹, Carolyn Compton¹
¹U.S. National Cancer Institute, NIH, Bethesda, MD, USA

The US National Cancer Institute's Program for Innovative Molecular Analysis Technologies (IMAT) offers several funding opportunities to support those innovators who are developing novel technologies that have the potential for making a high impact in cancer research and patient care. As an investigator-initiated program, the research community has the burden of identifying the unmet need and pairing it with an innovative technological solution that has the potential for broad impact. There is one targeted area that IMAT has a very specific solicitation and it is in the area of biospecimen science. The overall goal of these solicitations is to develop technologies capable of interrogating and/or maximizing the quality and utility of biospecimens or their derived samples for downstream molecular analyses. These opportunities will support the development of tools, devices, instrumentation, and associated methods to assess sample quality, preserve/protect sample integrity, and establish verification criteria for quality assessment/control and handling under diverse conditions. Supported technologies are expected to have a potential to accelerate and/or enhance the research in cancer biology, prevention, diagnosis, treatment, epidemiology, and cancer health disparities, by reducing pre-analytical variations that affect biospecimen and/or sample quality.

BSS 02

Comparison of DNA Isolation Techniques from Saliva and a Novel Alcohol-Free Mouthwash Collection Method for Obtaining High-Quality Genomic DNA

David Goerlitz¹, Trent Jackson², Doaa Saleh³, Mohamed Abdel-Hamid³, Christopher Loffredo²
¹Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA; ²Georgetown University, Washington, DC, USA; ³Cairo University, Cairo, Egypt; ⁴Minia University, Minia, Egypt

Background: Participation rates in population studies might be enhanced by offering saliva as an alternative to blood collection but there may be low DNA yield, high costs, and alcohol-based mouthwash which is
offensive to some populations. Our method yields high-quality genomic DNA from buccal cells that is non-invasive, cost-effective, and acceptable to individuals who abstain from alcohol. Methods: We compared five DNA isolation kits using saliva, and evaluated quality for alcohol-free mouthwash vs. passive collection in 70% ethanol. We also tested temperature and prolonged storage effects on yield by UV spectrophotometry, agarose gel electrophoresis, and RT-PCR. Results: Mean DNA yields varied among test kits. Oragene and EpiCentre kits yielded the most DNA followed by EZNA, Norgen and Qiagen. EpiCentre, Qiagen and Norgen kits all produced DNAs with high purity, while Oragene and EZNA DNAs contained protein impurities. Norgen failed in RT-PCR. Immediate saliva sample processing collected in alcohol-free mouthwash yielded the most DNA; time delay in processing and temperature did not significantly alter DNA yield or purity. Conclusions: The best method for DNA isolation from saliva with respect to DNA yield, quality, and cost is “swish and spit” with 10ml Crest Pro-Health alcohol-free mouthwash and DNA isolation with the EpiCentre Master Pure DNA kit. This method is cost effective compared to the Oragene kit. This method yielded repeated success in our current NIH-funded study of gender differences in bladder cancer risk factors in Egypt, where many recruited subjects abstain from alcohol use.

BSS 03

Idiopathic Pulmonary Hypertension Human Tissue Biobank

Katherine Sexton 1, William Grizzle 1
1 University of Alabama at Birmingham, Birmingham, AL, USA

Background: Idiopathic pulmonary hypertension (IPH) is characterized by elevated pulmonary arterial pressure culminating in right ventricular failure. The pathophysiology has not been elucidated and research has been frustrated by a lack of quality, well-characterized tissue samples. The Pulmonary Hypertension Breakthrough Initiative (PHBI) was established to characterize the genotype, cellular basis, and biomolecular pathways of IPH and to fund a network of ten lung transplantation centers, two tissue processing centers and a coordinating center. Methods: As one of the tissue processing centers, our laboratory operates the PHBI Biobank. This is a disease-specific biobank for IPH tissues. Standard operating procedures were designed for the collection, processing, and storage of samples. Lung transplantation centers enroll and obtain consent for the collection of tissues, and clinical histories from participants prior to transplantation. Blood is obtained for genotyping or processing prior to banking. Following lung explantation, fresh samples are shipped immediately. Execution of the standard operating protocol yields over 100 aliquots of tissue that are frozen or preserved using multiple techniques to accommodate analysis of cells, protein, DNA, and RNA. All fixed and/or frozen samples are sent to the Biobank where they are bar-coded, linking them to annotated clinical data. Results: To date, tissue has been obtained from 51 lung transplants and >1000 samples have been distributed. Conclusion: This biobank, which collects and distributes specimens from transplant sites across the United States, has increased the opportunity for a generation of new information about pulmonary hypertension. Similar models could be established for other rare diseases.

BSS 04

Increased Stability of RNA in the Presence of GenTegra Matrix

Michael Barnes 1, Monica Tsoras 2, Susan Thompson 1
1 Cincinnati Children’s Hospital, Cincinnati, OH, USA; 2 Cincinnati Children’s Hospital Medical Center, Cincinnati, OH, USA

Background: Storage of RNA can be problematic with temperature fluctuations, freeze-thaw cycles, and shipping potentially causing degradation of samples. We tested a new technology for the ability to stabilize RNA at 22°C or 56°C for extended time periods. Methods: RNA (n=4) was prepared from peripheral blood mononuclear cells (PBMCs). Samples were stored at 22°C and 56°C in GenVault’s GenTegra RNA matrix or -80°C, 22°C or 56°C in water. After storage, RNA integrity numbers (RIN) were determined using the Agilent Bioanalyzer 2100. Samples were labeled using NuGEN WT-Ovation Pico and assayed on Affymetrix Human Exon 1.0 ST Array to assess matrix interference in this downstream application. Results: RNA stored in water at -80°C for two weeks, had a RIN of 9.6 compared to decreased quality in RNAs stored in water at either 22°C or 56°C (RIN: 7.2 and 3.1, respectively). By comparison, RNA samples stored with matrix at 22°C or 56°C were protected (RINs of 9.6 and 8.6, respectively). Finally, transcriptome profiling indicated that RNA stored in matrix at 56°C performed as well as RNA stored in water at -80°C as demonstrated by similar present calls (59% and 60%) and background values (115 and 130) measured by microarray. Conclusions: The GenTegra matrix offered significant protection of RNA integrity when compared to RNAs stored in water. Further, matrix did not interfere with the performance of downstream applications such as NuGEN labeling and subsequent profiling on Affymetrix exon arrays. Technologies for room temperature storage hold promise for improved sample preservation.
BSS 05

**Standard Preanalytical Coding for Biospecimens: Defining the Sample PREanalytical Code (SPREC)**

Fay Betsou1, Sylvain Lehmann2, Garry Ashton3, Michael Barnes4, Erica Benson5, Domenico Coppola6, Yvonne DeSouza7, James Eliason8, Barbara Glazer9, Fiorella Guadagni10, Keith Harding11, David Horsfall12, Cynthia Kleeberger13, Umberto Nanni14, Anil Prasad15, Kathi Shea16, Amy Skubitz17, Stella Somiari18, Elaine Gunter19

1Integrated Biobank of Luxembourg, Luxembourg; 2CNRS, Montpellier, France; 3Patterson Institute for Cancer Research, Manchester, UK; 4Cincinnati Children’s Hospital Medical Center, Cincinnati, OH, USA; 5Damar Research Scientists, Fife, Scotland, UK; 6Moffitt Cancer Cancer, Tampa, FL, USA; 7University of California, San Francisco, San Francisco, CA, USA; 8Michigan Neonatal Biotrust, Detroit, MI, USA; 9Quintiles Laboratories, Marietta, GA, USA; 10IRCCS San Raffale Pisana, Rome, Italy; 11Damar research Scientists, Fife, Scotland, UK; 12Hanson Institute, Adelaide, Australia; 13Social and scientific Systems, Durham, NC, USA; 14University of Rome La Sapienza, Rome, Italy; 15University of Arizona Health Sciences, Tucson, AZ, USA; 16Seracare Life Sciences, Gaithersburg, MD, USA; 17University of Minnesota, Minneapolis, MN, USA; 18Windber Research Institute, Windber, PA, USA; 19Specimen Solutions LLC, Tucker, GA, USA

Management and traceability of biospecimen preanalytical variations are necessary to provide effective and efficient interconnectivity and interoperability between Biobanks. Therefore, the ISBER Biospecimen Science Working Group developed a “Standard PREanalytical Code” (SPREC) which identifies the main preanalytical factors of clinical fluid and solid biospecimens and their simple derivatives. Implementation of the SPREC is expected to facilitate and consolidate international multicenter biomarker identification research and biospecimen research in the clinical Biobank environment. The SPREC is easy to implement and can be integrated into Biobank quality management systems and databases. Its flexibility allows integration of new novel technological developments in future versions. The SPREC is simple, straightforward and easy to implement, even for Biobanks in developing countries and those with limited resources since it can be hand-written or incorporated into a linear or two-dimensional barcode. The SPREC is flexible, making it possible to add new elements and/or new preanalytical options and corresponding coding characters. The value of SPREC-01 is also being proposed for use in non-human biorepository sectors with a view to encouraging a wider debate as to its value across different thematic biobanking sectors.

BSS 06

**An Immunological Fingerprinting Method for Differentiation of Serum Samples in Research-Oriented Biobanks**

Fay Betsou1, Katy Beaumont2

1Integrated Biobank of Luxembourg, Luxembourg; 2Biobank de Picardie, Saleux, Picardie, France

An immunoenzymatic serum fingerprinting method was developed which allows researchers to establish a serum sample fingerprint through determination of IgG titres of three different specificities. Three widespread antigens were selected for their capacity to induce long lasting humoral immune responses. This fingerprinting method can be used to differentiate between two serum samples and allows to assess if two serum samples come from the same primary blood specimen or not. The precision of the method was sufficient to confer it a 99.5% specificity. This method can be used as a quality control method for biobanked serum samples. The serum fingerprinting method does not allow discrimination between individual donors of serum samples as the same donor may have different IgG titres against a specific antigen over time. The method allows discrimination between individual donors at a given time or between primary blood specimens. This method offers a novel, easy to implement and specific tool to overcome one of the rarely recognized challenges of biobanks, in terms of quality control and quality assurance.

BSS 07

**Tissue Microarrays: A Cross-Over Validation Tool for Research**

Marina Cardano1, Giuseppe Diaferia2, Manuela Maffè3, Maurizio Falavigna4, Ida Biunno5, Pasquale DeBlasio2

1Doctorate School of Molecular Medicine; 2Biorep srl, Milano, Italy; 3Integrated Systems Engineering srl, Milano, Italy; 4National Research Council, Segrate, Milano, Italy

Background: Genomics, transcriptomics, and proteomics have increased the importance of tissues in the discovery and validation of prognostic, diagnostic and therapeutic biomarkers. Human tissue has become a strategic and unavoidable tool for all –omics technologies including high-throughput in situ proteomics to study signal transduction and protein-protein interactions. Tissue microarray (TMA) systems allow for the study of hundreds of samples (paraffin embedded tissues or cells) on a single slide for hystochemical analysis. The “Galileo CK4500” (www.isenet.it) is a high-throughput semiautomatic and computer-assisted TMA platform with the unique feature of picking cores of interest in a tissue or cell block and extract nucleic acids for subsequent molecular biology analysis. Methods: Harvested and
agarose-re-suspended Neural Stem Cells (NSCs) were fixed in PFA (4%) and treated like the human glioblastoma xenografts tissue donor block selected for the specific study. Cores of cells or tissues (previously selected) from the donor blocks were placed by the arrayer either in a second paraffin block or in appropriate vessels to be processed for nucleic acid extraction. Results: TMA and CLMA (Cell Line Microarray) technology were used to analyze glioblastoma xenografts and NSCs, to verify stemness and tripotency. From the cores DNA, RNA and microRNAs were successfully extracted. Conclusions: The Galileo CK4500 platform is a powerful pathology tool to simultaneously screen a huge number of tissues or cell lines treated in different conditions or with different phenotypes. This technique will be particularly useful to obtain immunophenotypical information and to perform epigenetic studies in specific selected areas of a biological sample.

BSS 08

Global Methylation Surveys of Colorectal Cancer for Cancer Discovery in Archival Paraffin Tissue Samples: Split Sample Strategy to Support Experimental Evidence

Galen Hostetter1, Bodour Salhia1, Michael Syring1, April Watanabe1, Lora Nordstrom1, Michael Bittner1, Jeffrey Trent1, John Carpten1

Translational Genomics Research Institute, Phoenix, AZ, USA

Background: Formalin-fixed paraffin-embedded (FFPE) tissues offer a valuable resource in cancer research for both biomarker discovery and clinical validation. In reality, existing sample procurement methods have been collected tissue under less than optimal conditions with uneven documentation of collection parameters, contributing to the 'pre-analytic variable' phase of a given research sample. In our experience, FFPE-extracted DNA possesses remarkable stability and sample processing permits successful application to high resolution CGH microarrays. The epigenome encompasses DNA modifications that though reversible can be stably transmitted. Epigenetic changes in cancer are poorly understood. Methods: Twelve CRC samples and matched normal tissues were collected in 2006 and obtained from an established commercial vendor. Time to preservation was reported < 25 minutes. DNA extractions for all samples were performed by the Maxell 16 automated DNA extraction system. Sample DNA integrity was determined by gel electrophoresis, 260/280 spectrophotometer and sample baseline integrity by RIN value. Sample DNAs underwent bisulfite conversion and were applied to the Infinium HumanMethylation27 BeadChip array. Results: FFPE tissues showed variable DNA fragmentation with several samples showing significant bands above 12 kb. Mirror frozen sample DNAs were of high quality. RIN values ranged from 5.5 to 8.7 and > 30% were <7 suggesting sub-optimal collection and cautionary for potential transcriptome analyses. FFPE/frozen tumor pairs showed high concordance on the Infinium methylation array. Conclusions: High density assays to determine DNA methylation patterns using FFPE samples are highly concordant to fresh frozen counterparts and supports the use of archival specimens for use in high density methylation arrays.

BSS 09

Pre-Analytical Procedures for DNA Studies: The Experience of the Interinstitutional Multidisciplinary BioBank (BioBIM)

Raffaele Palmirotta1, Annalisa Savonarola1, Giorgia Ludovic1, Maria Laura De Marchis1, Barbara Leone1, Vincenzino Perrone1, Francesco De Angelis1, Antonella Spila1, Fiorella Guadagni1

IRCCS San Raffaele Pisana, Rome, Italy

Background: Standard operating procedure (SOP) optimization for DNA extraction from stored samples is of crucial importance in a biological repository, considering the large number of collected samples and because their future application may not be known. Methods: Whole blood was collected into different Vacutainer tubes (EDTA, Lithium-heparin, NaCit, CTAD and Fluorure-Oxalate) and stored at different times and temperatures to optimize SOP of the BioBIM. DNA extraction was performed using an automated method, a commercial (Qiagen) and an in-house kit. After quantification, DNA quality was tested evaluating different PCR length products and qRT-PCR. Results: No significant differences were observed among DNA recovery in samples collected into different anticoagulants with respect to the three selected extraction methods. Conversely, DNA recovery tended to decrease over blood storage time at RT and 4°C, whereas blood storage at -80°C preserved DNA integrity for all anticoagulants used with results comparable to those of a freshly drawn sample. PCR amplifications testing were all satisfactory regardless of the fragment length, samples time storage and anticoagulant used, with the exception of reactions carried out in the presence of Lithium-Heparin. DNA quality was investigated performing qRT-PCR, which showed a progressive decrease over time with a slight improvement after 24 h sample storage. Strikingly, using qRT-PCR on Lithium-Heparin samples were amplifiable even though with a lower efficiency. Conclusions: DNA extraction from stored blood samples requires that all efforts should be made to prevent degradation, preserve molecular integrity and to avoid the presence of any possible inhibitor. Partially supported by Grant ACC-WP 3/1b.
BSS 10

DNA stabilization in Tissues, Cells and Whole Blood

Rolf Muller¹, Steven Wilkinson¹, Sohela de Rozieres¹, Laurent Coulon¹
*biomatrica, San Diego, CA, USA

Background: Current methods for storing and shipping human and animal blood, tissue or cells for clinical, forensic and biomedical research needs are costly and can be insufficient for reliable molecular diagnostics requiring preservation of high-quality genomic DNA. Mammalian tissues are commonly shipped on dry-ice or in liquid nitrogen which are costly and often not practical for the collection of samples in the field.

Method: We have applied synthetic chemistry to create a formulation that stabilizes genomic DNA in mammalian blood, tissue and cultured cells at room temperature. The recovered DNA stored at room temperature in this medium (called DNAgard™) was then subjected to different downstream applications such as PCR, qPCR and sequencing analysis.

Results: We will present data demonstrating that DNAgard™ preserves the integrity of genomic DNA in tissue and cells stored for over 60 days at room temperature, and provides DNA yields comparable to frozen controls. Genomic DNA integrity is also preserved in samples stabilized with DNAgard during extended exposure to extreme heat (45-50°C), with DNA remaining intact for 1 month in tissue samples and for two months in cultured cell samples. Tests exploring the capacity of this product as a shipping application demonstrate that DNAgard™ preserves the integrity of genomic DNA in human and animal blood, tissue and cell samples when exposed to extreme fluctuations in temperature.

Conclusion: In conclusion, the recovered DNA stored at room temperature in DNAgard is perfectly suitable for numerous downstream applications including qPCR, as well as techniques requiring intact DNA, such as sequencing and long-fragment PCR.

BSS 11


Catherine Cormier¹, Joshua LaBaer²
¹DNASU Plasmid Repository, Tempe, AZ, USA; ²Virginia G. Piper Center for Personalized Diagnostics, Tempe, AZ, USA

The Protein Structure Initiative Material Repository (PSI-MR; http://psimr.asu.edu) provides centralized storage and distribution of information and samples for the 80,000 protein expression plasmids created by PSI researchers. These plasmids are an invaluable resource that allows the research community to dissect the biological function of proteins whose structures have been identified by the PSI. Researchers can search for and request plasmids from the PSI collection through the repository’s distribution website, DNASU (http://dnasu.asu.edu). Each PSI plasmid is linked to the PSI Structural Genomic Knowledgebase (PSI-SGKB; http://kb.psi-structuralgenomics.org/) and numerous other biological databases, which facilitates cross-referencing of a particular plasmid to protein annotations and experimental data. Thus far over 25,000 PSI plasmids are in the process of full-length sequence validation and annotation at the MR, and nearly 17,000 are already available from DNASU.

In addition to distributing materials, the MR has sought to simplify the MTA process in order to decrease the time it takes for institutions to deposit or receive plasmids. To achieve this goal, the MR pioneered two documents, the depositor’s agreement, which sets forth the terms enabling the MR to distribute deposited plasmids from outside institutions, and the expedited process MTA, which eliminates the need for researchers to wait for their institutions to sign an MTA. In the future, the MR will continue to make PSI plasmids and data available to researchers and will expand its expedited MTA network so that researchers can receive PSI plasmids without delay.

BSS 12

The AIDS and Cancer Specimen Resource (ACSR): A Resource for Bioinformatic Studies on HIV Infection and Associated Disease Processes

Susanna Lamers¹, Debra Garcia², Michael McGrath²
¹BioinfoExperts Consultants, Thibodaux, LA, USA; ²AIDS and Cancer Specimen Resource (ACSR), San Francisco, CA, USA

Background: The NCI-funded AIDS and Cancer Specimen Resource (ACSR) has stored HIV-infected human biospecimens from HIV-related or associated diseases from 1992-2010. These preserved tissues are an underutilized resource, particularly for the computational biologist who requires laboratory space, skills, and experienced personnel to generate genetic data from unprocessed tissues. The objective of our study was to use ACSR specimens to quickly develop a wide-ranging bioinformatic study focused on disease evolution. Methods: Seven multisite tissue autopsies from the ACSR were identified that correlated to HIV-associated disease pathologies, including lymphoma, dementia, cardiovascular disease and mycobacterium avium complex. All 55 tissues sampled were of sufficient quality for DNA extraction. Because the experimental protocols used to generate HIV sequence data were straightforward and well-defined, these were outsourced to commercial facilities.

Results: High-quality DNA was extracted from all
tissues; however, due to the varied nature of HIV infection in specific tissue types, HIV copy number varied. We generated 1731 3.3kb HIV sequences and demonstrated the intact nature of the stored specimens. The data was subsequently analyzed by experts in the field of bioinformatics without the need for in-house DNA isolation, PCR, cloning or sequencing. Genetic data were used to study HIV genetic evolution, HIV micro RNAs, and in three-dimensional structural modeling of HIV proteins. In all three studies, specific findings were linked to HIV disease pathology. Conclusions: At a minimal cost, the data enabled a series of independent bioinformatic studies, formed the foundation for multiple future projects, and provided public data for other researchers.

BSS 13

Standard Operating Pre-Analytical Procedures for Serum Low Molecular Weight Protein Profiling

Francesco Di Girolamo1, Jhessica Alessandroni1, Paolo Somma1, Michela Semeraro1, Francesca Iacovone1, Fiorella Guadagni1
1IRCCS San Raffaele Pisana, Rome, Italy

Background: Pre-analytical procedures may have a profound influence on Low Molecular Weight (LMW) proteome profiling. Methods: Blood samples were obtained from six consenting donors and collected in eight 4-mL Vacutainer CAT tubes. Four samples (from each donor) were immediately treated with protease inhibitor (PI). Blood was allowed to clot for different times at RT, thereafter, serum samples were divided into six aliquots (three of which added with PI 80 µL) and immediately stored at RT, +4°C (1, 2, 3, 6, 12, and 24h) or -80°C (up to 1 year) for subsequent analysis. Serum samples were fractionated using manual and automated functionalized magnetic beads (RP C18) for the capture of LMW proteins and analyzed by MALDI/MS system. Resulted mass spectra profiles were processed and CV values for each corresponding peak were calculated. Results: Automation allowed an increased LMW peak recovery of 16.2%, as well as a better reproducibility compared to manual procedure; clotting times up to 2 hours resulted in minimal changes in serum LMW profiling; serum samples (with or without PI), obtained from PI-free whole blood, were stable up to 1-hour storage at 4°C, but PI addition was required for RT storage; addition of PI on whole blood and/or serum samples had relatively minimal effects on serum proteome profiles up to 1-year storage at -80°C. Conclusions: Our study outlines the influence of pre-analytical factors on serum LMW proteome profiling, thus contributing to standardize methods for serum pre-analytical procedures and collection for future proteomics studies. Partially supported by Grant ACC-WP 3/1b.

BSS 14

The Influence of Tissue Sample Size on RNA Integrity

Marcel Kap1, Bas de Jong1, Peter Riegman1
1Erasmus MC, Rotterdam, South-Holland, The Netherlands

Background: The EC FP7 project SPIDIA aims to standardize the pre-analytical phase of diagnostic procedures, according to the principles of evidence based biobanking. To contribute in providing guidelines and protocols for optimal collecting, handling and storage of tissue samples one of the dogmas in biobanking is investigated. With this initial study we investigated if RNA quality decreases faster in small biopsies than in larger samples. Methods: Small (<10mm³), medium (±100 mm³) and large tissue fragments (±500mm³) of pig liver were frozen with 0, 5 and 15 minutes time-lag after harvesting. Samples were snap-frozen using cooled isopentane in liquid nitrogen. Sections were cut for RNA isolation using the Tel-test RNA Bee kit. RIN values were obtained using Agilent Bioanalyzer 2100 RNA nano chips. Results: Large samples were frozen immediately after preparation showed an average RIN value of 7.4 (5.2-8.6, n=6), medium samples 7.2 (6.6-7.5, n=3) and small samples 6.8 (5.5-8.2, n=5). Large samples frozen after 5 minutes of ischemia showed an average RIN value of 5.4 (3.4-8, n=6), medium samples 6.1 (4.3-7.5, n=5) and small samples 5.1 (3.3-6.2, n=4). Large samples frozen after 15 minutes of ischemia showed an average RIN value of 6.8 (6-7.5, n=2), medium samples 6.8 (6-7.8, n=4) and small samples 6.2 (5.8-6.9, n=3). Conclusions: Data from this initial study indicate no correlation between sample size, ischemia and decrease in RIN value. For allowing final conclusions, larger studies will be performed and other RNA quality parameters (PCR performance, other tissue types, profiles, procedures) will be investigated.

BSS 15

Improved Peripheral Blood Mononuclear Cell (PBMC) Sample Handling with the Use of the MVE Cryo Cart

Joseph Kessler1, Kristine Davis1, Latasha Gillis1, Cheryl Moyer1, Lisa Kierstead1, Cynthia Morrisey1
1PPD, Wayne, PA, USA

Background: Peripheral Blood Mononuclear Cells (PBMC) used in clinical assays are temperature-sensitive, and their integrity during inventory and retrieval is critical for quality results in functional assays. The current PBMC inventory and retrieval procedures were compared to modified procedures using the MVE Cryo Cart, through evaluation of temperature stability, processing time, ergonomics and cost savings. Methods: Aluminum, stainless steel, and
plastic freezer boxes were filled with vials of serum, which represented the PBMC sample matrix. Freezer boxes were placed in a LN2 unit and temperature profiles were continuously monitored with various sample retrieval and handling conditions. Results: Samples evaluated in any freezer box type with the current vial retrieval practice, demonstrated > 121°C temperature (warming) profiles during the 15 minute retrieval time. Samples evaluated with the modified procedure using the MVE Cryo Cart demonstrated a temperature (warming) profile of 9°C, 11°C and 15°C in aluminum, stainless steel and plastic boxes respectively. Additionally, the MVE Cryo Cart maintained acceptable sample temperature ranges with the various freezer boxes for up to 11 hours. Conclusions: Sample temperature stability during the retrieval process was improved with the MVE Cryo Cart compared to current retrieval methods and the aluminum storage box was evaluated as most suitable for maintaining temperature, improving ergonomics and cost savings. Modifying the current PBMC retrieval methods to include using aluminum storage boxes and the MVE Cryo Cart will ensure sample integrity for downstream testing.

BSS 16

PBMC Network: Successes and Challenges

Joseph Kessler1, Barbara Meyer1, Holly Lash1, Lisa Kierstead1
1PPD, Wayne, PA, USA

Background: The need for establishing a more consistent, effective method for collecting functional Peripheral Blood Mononuclear Cells (PBMC) for the analysis of T cell responses has been recognized within the vaccine research community. A PBMC Network service was created with Esoterix Inc, a LabCorp Company to coordinate activities across select clinical programs for the acquisition of viable, high quality PBMCs. Methods: The PBMC Network evaluated the practice of collecting PBMC such that isolation, processing and freezing are completed within 6-12 hours. All processing laboratories used a consensus SOP, which defined these major steps: 1. Isolating PBMC using Accuspin™ tubes, wash, lyse RBC 2. Counting total cell number and determining number of vials to freeze 3. Freezing at 1x10⁷ cells per vial (maximum 20 vials) at -70°C in StrataCooler™ 4. Storing > 24 hours at -70°C, and shipping weekly overnight on dry ice 5. Ensuring optimal temperature during handling, storage and shipping. Individual processing laboratory technicians participated in a two day workshop which included classroom lectures, lab demonstrations and finally hands-on preparation. Labs were qualified based on assessment of PBMC samples for cell quality parameters as well as functionality in the IFN-gamma ELISPOT assay. Results and Conclusions: Laboratories located in the vicinity of various clinical sites have been successfully trained and qualified to process PBMCs within 6-12 hours of blood collection using a consensus SOP. Further evidence with clinical samples supports the superiority of using a consensus SOP and PBMC Network compared to non-Network processing.

CCP 01

Comparison of Three Density Gradient Separation Methods for Peripheral Blood Mononuclear Cell Isolation

Heather Siefers1, Leah Marchesani1, Netasha Johnson1
1SeraCare Life Sciences, Frederick, MD, USA

Background: Reliable results for PBMC isolation from whole blood are dependent on careful separation techniques performed by experienced laboratory technicians. The most employed method is density gradient centrifugation. Preparation tubes containing porous polyethylene barriers have been recently developed to facilitate efficient, reproducible results while decreasing labor and skill level requirements. Methods: PBMCs were isolated from whole blood using three density gradient centrifugation methods: Ficoll-Paque™ underlay, Leucosep® and Lymphoprep™ tubes. Isolated PBMCs were counted by Hemacytometer using ACK lysis buffer and Trypan blue to calculate total cell yield. PBMCs were cryopreserved, thawed seven days post-cryopreservation, and counted for calculation of percent recovery. Results: PBMCs isolated from preparation tubes were more sensitive to ACK lysis buffer compared to Ficoll-Paque™ underlay, resulting in under-representation of the total cell yield; cell counts were most accurate using Trypan blue only. The average cell yield (millions) was: Ficoll-Paque™ 11.9, Leucosep® 14.3, Lymphoprep™ 12.8, while the post-thaw recovery yield was: Ficoll-Paque™ 9.4 (79%), Leucosep® 10.2 (71%), and Lymphoprep™ 9.2 (72%). Total processing time per sample (minutes) was recorded at: Ficoll-Paque™ 89, Leucosep® 70 and Lymphoprep™ 62. Conclusion: The Leucosep® tube produced comparable to superior results requiring less processing time and technician skill-set than the traditional Ficoll-Paque™ method. The Lymphoprep™ tube yielded the lowest post-thaw cell count; percent recovery was similar for the preparation tube methods. Completion of cell proliferation analysis is in process to compare cell functionality.
CCP 02

An Efficient, Cost Effective Method for the Generation of Immortalized Human Cell Lines from Small Quantities of Cryopreserved Whole Blood

Deborah Blick¹, Jim Cooper¹, Natalie Baker¹, Pippa Bracegirdle¹, James Biggins¹, Edward Burnett¹
¹Health Protection Agency, Salisbury, Wiltshire, UK

Background: The conversion of a blood sample from an individual participant in a biobank to a lymphoblastoid cell line ensures a permanent, expandable and renewable supply of genetic and other cellular material, including DNA, without any requirement to return to the donor. However, the current method, involving the separation and cryopreservation of peripheral blood lymphocytes (PBLs) can be considered expensive and time consuming and relies on relatively large volumes of blood. We describe here the development of a simple technique for the Epstein Barr virus (EBV) transformation of small volumes of cryopreserved whole blood. Methods: Aliquots of whole blood (cryopreserved in 10% v/v Dimethyl sulphoxide (DMSO)) were exposed to EBV, and the resulting transformed cells expanded and cryopreserved. No separation steps were carried out. Bench top flow cytometry was used to assess cell viability and transformation where conventional microscopy techniques proved difficult. Results: A total of 48/50 cryopreserved blood samples were successfully transformed at the first attempt giving a transformation success rate of 96%. Aliquots of 1.5ml and 800µl of blood transformed with equal success and flow cytometry proved critical to the assessment of transformation. Conclusions: We have developed a robust, efficient and cost effective technique, suitable for high throughput generation of lymphoblastoid cell lines from small volumes of cryopreserved whole blood without the requirement to pre-isolate PBL’s. This presents biobanks with the opportunity for storing small amounts of blood for the future generation of material representing important disease collections.

CCP 03

Trehalose, A Non Toxic Molecule To Cryopreserve Stem Cells

Sara Simona Dessi¹, Giuseppe Diaferia¹, Ida Biunno², Pasquale DeBlasio¹
¹Biorep srl, Milano, Italy; ²National Research Council, Milano, Italy

Background: In general, cells including stem cells are frozen in medium containing high concentration of cryoprotective molecules such as Dimethyl Sulphoxide (DMSO) in addition to animal proteins. An important consideration should be taken in using non-toxic levels of DMSO on stem cells during preservation processes since several reports have underscored that in hESC the pluripotency capacity diminished in a reversible manner (Katkov LL et al., 2006; Adler S. et al., 2006) in addition to cell quiescence induction in a dose dependent and reversible manner (Sahgal. et al.2005). It has been reported that DMSO affects the epigenetic system by acting on the three DNA methyltransferases (Dnmts) and on five wide DNA methylation profile, the ES and embryonic bodies undergo changes in their phenotypic behavior (Iwatani M. et al.,2006). A non toxic alternative protectant is Trehalose, proven to stabilize stem cells during freezing, the challenge is to find a way to introduce this big glucose disaccharide in the cells. Materials and Methods: We used the HEK293 and NSC46 (murine neuronal derived stem cell) and different methods to internalize trehalose in the cells. Results: It is possible to vehicle trehalose in these cells using the pore channelling capacity of ATP and appropriate extra/intracellular trehalose concentration ratio. Good cell recovery was obtained in both cell lines. Conclusion: We show that it is possible to use trehalose as cryoprotectant reagent.

CCP 04

Managing of a Stem Cell Biorepository

Giuseppe Diaferia¹, Ida Biunno², Pasquale DeBlasio¹, Monica Girardi¹, Valeria D’Orazio¹, Sara Simona Dessi¹, Marina Cardano¹,³, Aby J. Mathew⁴
¹Biorep srl, Milano, Italy; ²National Research Council, Segrate, Milano, Italy; ³Doctorate School of Molecular Medicine, Milano, Italy; ⁴BioLife Solutions, Inc., Bothell, WA, USA

Background: Stem cells have acquired a great deal of attention as they promise to be new vehicles for gene therapy. It is then important to optimize culture conditions, cryostorage protocols and monitoring systems to obtain ready-to-use cells for clinical applications. BioRep is a partner in two European Financed projects (FP6 and FP7) with the aim to establish a cell bank hosting neural derived stem cells and define the proper procedures to limit the unreproducibility of their use. Methods: BioRep regularly performs a series of tests to assess the presence of contaminants in the cultures including the presence of viral particles. Cells are cryopreserved and banked in liquid nitrogen tanks connected to a central monitoring alarm system. Routinely, the cells are assessed for their pluripotency status and differentiation capabilities, chromosomal stability and viability. Results: A set of standard operating procedures (SOP) have been generated relating to each step of stem cell culturing, processing and storage with the objective to guarantee the freezing of cell with highly reproducible characteristics. Using GMP freezing medium free of animal proteins (Cryostor CS10) in addition to a controlled rate cooling system, it is possible to achieve remarkable cell
viability and low apoptotic level. Conclusions: Joining the stem cell biology expertise of the academy with the technology standards of the industry has allowed the development of reagents and processes to generate safe and effective stem cell lines. In this way, several neural stem cell lines have been established and made available to the scientific community.

**CCP 05**

**New CryoSolutions And Cryopreservation Strategies Used In A Mesenchymal Stem Cells (MSCs) Bank**

Maura Ferrari¹, Sabrina Renzi¹, Sara Dessì², Giuseppe Diaferia², Pasquale De Blasio², Ida Biunno²

¹Istituto Zooprofilattico Sperimentale di Brescia, Brescia, Italy; ²Biorep, Milan, Italy

Background – Optimization of cryopreservation protocols to maintain the quality of MSCs is an important task for stem cells banks. To allow long-term storage, MSCs are slowly cooled and stored at -196°C in liquid nitrogen. Unfortunately, despite the use of well standardized protocols, the percentage of living cells after thawing is low. In order to use MSCs for regenerative medicine, it is important to find a cryopreservation solution able not only to reduce cell death but also free of animal proteins, in order to reduce zoonoses risk. Materials and Methods – Rat, sheep (models) and horses MSCs were isolated from bone marrow and adipose tissue and in vitro cultured. Each MSCs sample was frozen in three different cryoprotectant solutions (BioLife Solutions). After thawing and re-seeding, cell viability was assessed for three consecutive days and cell counts were performed at 24-h intervals. Results – Cell viability differences were observed not only among the three different cryopreservation reagents used but also according to the species from which the MSCs were derived. Equine MSCs were much more sensitive to the freezing process than rat and sheep derived cells. Conclusions – The possibility for long-term storage for MSCs and other types of cells in a frozen state which are suitable for immediate clinical application could provide immense benefit in regenerative medicine. Moreover, identification of more effective cryoprotectant solutions deprived of animal proteins could improve the quality of the freeze/thaw process and reduce cost/benefit ratio.

**CCP 06**

**Use of Aluminium Wrap for Tissue Cryopreservation: Effect on Processing and Retrieval Times**

Huizhen Sam¹

¹Singapore Health Services Pte Ltd, Singapore

Background: Due to shortage of storage space, we have been exploring the possibility of storing 3 fragments of tissue per cryovial. The main problem with such a move is that frozen tissue fragments tend to stick together, making it difficult to separate during tissue withdrawal and raising the fear of unwanted thawing. To prevent tissue fragments from adhering to each other, we consider wrapping each fragment in aluminium foil prior to cryopreservation. In this study, we consider the processing time during tissue acquisition and withdrawal with and without wrapping tissue fragments in aluminium foil. Method: 60 fragments (3-5mm³) of non-neoplastic breast tissues were divided into two study groups, 30 in each group. 3 fragments were placed into one cryovial, with and without aluminium foil wrapping. The time taken for tissue acquisition and tissue withdrawal using 1 to 10 cryovials was recorded. Results: The average time taken at tissue acquisition to process tissues wrapped in aluminium foil is 780 secs (range: 92 to 1825 secs) compared to an average time of 402 secs (range: 38 to 903 secs) without aluminium foil wrap. The average time taken for tissue retrieval is 4 secs per fragment (range: 3 to 5 secs) with aluminium foil wrapping compared to an average time of 6 secs (range: 5 to 7 secs) without aluminium foil wrap. Conclusion: Our preliminary data show that wrapping tissue fragments in aluminium foil prior to cryopreservation doubles the processing time with 8 or more cryovials (p<0.001) but with only modest reduction in tissue retrieval time.

**CCP 07**

**Cryo-Banking of Cells and Tissues from Freshwater and Marine Fish in UK Waters**

David Rawson¹, Tiantian Zhang¹, Tiziana Zampolla¹

¹University of Bedfordshire, Luton, Bedfordshire, UK

Background: Specimen cryo-banking can ensure a record of species genome and proteome, and in the case of future extinctions this may be the only source of such information. A major determinant of value of any such cryo-bank is the quality of the material held, which in turn is determined by the protocols used in their processing. Cryopreservation protocols exploiting cryoprotectants and storage below glass transition temperature, enables long-term preservation of molecular components and viable cells from tissue explants. Methods: A biological resource bank of freshwater (FW) and marine fish from UK waters is being established. For all species banked - three tissue treatments are performed: (i) muscle tissue, cryopreserved using protocols to ensure long-chain DNA protection; (ii) fin clippings, cryopreserved to give viable cell retention for cell line culture; (iii) blood samples, held on Whatman FTA cards. Results: Following a series of collection surveys in 2009, from lowland rivers in England, and the Irish and Celtic Seas, tissue samples were processed from 122 species, 19 freshwater and 103 marine. Cell line cultures have already been established for 20 species
and cryobanked. Cell lines from the remaining species will be established during 2010. Conclusions
Cryobanking of bulk tissue and viable cell lines, provides for future genomic and proteomic applications, and also ensures that withdrawals do not deplete the resources bank. Protocols for cryopreservation and cell culture have been established and will be reported.

CCP 08

ICE® system: an unique sample biobanking solution.

Christophe Leboeuf1
1Biosapling Systems, Saint Ouen l'Aumône, France

The revolutionary ICE® tube system integrates both a datamatrix code and an RFID tag that remains active in liquid nitrogen and -80°C freezers. Dual security tabs on the cap of the ICE® tube guarantee the integrity of the contents. The first ensures the container was not opened before being filled, and the second ensures it was not opened after being filled. With this system, we can configure lab software to store reliable sample information in the RFID tag of each tube. We have developed a unique plastic insert which facilitates the storage and retrieval of several separate, very small tissue sample biopsies in a single ICE® tube. 81 ICE® cryotubes are stored in a unique, custom-designed cryobox with industry standard dimensions: no need to change your -80°C freezer and nitrogen cryobank infrastructure.

ER 01

Knowledge, Transfer and Skills Development During the Transportation and Movement of Fish

Josias Masharakane Seabi1
1National Zoological Garden of S.A, Gauteng, South Africa

A survey was conducted in the National Zoological Garden of South Africa during the month of September 2009 to January 2010 to assess the transportation of fish in the Aquarium. The purpose was to collect baseline information between the zoo keepers and educators on how to transport or move fish in the Aquarium. Details about the movement and transportation of fish were shared for the well-being of fishes being transported, including transportation within institution premises and transfers from one institution to another. Skills, training and experience were shared among the keepers to ensure the well-being of fish such as medical requirements, container size, size of the tanks, temperature and life support system. The other changes in an animal’s normal behavior could be expected as a result of being moved and transported, and every precaution was taken to ensure the safety of the animals such as recognizing the territorial behavior, ages, sex and health. The implications of these appropriate steps (such as use of tranquilizers), which is taken to reduce the stress levels of fish and water quality is discussed. The major handicap in the development of transporting or moving fish in the Aquarium is skill shortage among workers. In conclusion this paper will discuss how staff interact and share experience and knowledge within the community of zoo keepers, aquarist and zoo educators. Key words: fish, keepers, stress, transportation, skills transfer.
New Technology for Room Temperature Storage of DNA

Sophie Tuffet¹, Delphine Coudy¹, David de Souza¹, Jacques Bonnet², Marthe Colotte¹
¹Société IMAGENE, EVRY Cedex, France; ²University of Bordeaux, Bordeaux, Aquitaine, France

Background: One of the challenges regarding DNA repositories is the exponentially increasing number of samples to be preserved making classical freezer storage unreliable and prohibitively costly. An appealing solution is room temperature storage of dehydrated DNA but we recently showed that storage in air is inadequate for optimal DNA conservation at room temperature. Indeed, we showed that solid-state DNA degradation is greatly affected by atmospheric water and oxygen and that these conditions generally lead to DNA loss by aggregation after a few weeks storage. We also confirmed that there is no airtight plastic ware. However, we found that, protected from water and oxygen, DNA primary structure is extremely stable and that the secondary structure is preserved or fully restored upon rehydration, except possibly for small fragments. Methods: DNA chain breaks were quantitated by plasmid relaxation or denaturing electrophoresis. DNA denaturation was estimated by hyperchromicity measurements. Results: From the above observations, we developed a high throughput fully automated process where DNA samples are desiccated in glass inserts which are then enclosed into small laser-sealed capsules under anoxic and anhydrous atmosphere. Traceability is insured by engraving a 2D data matrix code on the capsules. This process has been applied to DNA samples prepared by different techniques from various organisms. Accelerated aging studies established the high stability of these samples. Conclusion: We developed an original procedure which, by ensuring a full and permanent protection of DNA from water and oxygen, allows safe and autonomous room temperature storage with no maintenance and energetic cost.

QIAsafe DNA Blood: A New Technology for Ambient Temperature Storage

Thomas Doed†¹, Sohela de Rozieres², Rita Kist¹, Dirk Heckel¹, Rolf Muller²
¹QIAGEN GmbH, Hilden, Germany; ²Biomatrica Inc., San Diego, CA, USA

Background: Conventional storage and shipment of biospecimens poses space, cost and energy problems. Biomatrica, Inc. has developed sample matrix technology to store, ship and archive samples at room temperature based on the natural principles of anhydrobiosis (“life without water”). QIAsafe DNA Blood, a product co-developed by QIAGEN and Biomatrica, allows the dry storage and shipment of whole blood at room temperature preserving DNA. Methods: Blood was stored for up to 9 months at room temperature or 45°C (equivalent to approx. 3 years of room temperature storage) in QIAsafe DNA Blood along with frozen and unprotected controls. After storage DNA from blood was purified according to manufacturer’s instructions followed by downstream applications to demonstrate integrity, yield and performance (e.g., agarose gels, PCR, and sequencing). Results: DNA yields and integrity from blood stored with this technology are comparable to frozen controls (-20°C or -80°C) and superior to those samples collected on dry filter paper. Isolated DNA can be recovered using Scope mouthwash and Oragene®, are good sources of high quality DNA. Whole genome amplification can be used as an alternative to freezers and does not alter DNA quality. Conclusions: Non-invasive collection methods, such as mouthwash and Oragene®, are good sources of high quality DNA. Whole genome amplification can be used to maximize DNA yield from these samples. Room temperature storage technology is a sustainable alternative to freezers and does not alter DNA quality or performance in downstream analysis.
be used in many downstream applications including PCR, qPCR, genotyping, and DNA sequencing, giving equivalent results to DNA which has been isolated from frozen blood. Conclusions: QIAsafe DNA Blood allows ambient temperature transport and storage of blood samples for subsequent DNA purification. DNA is of high quality and yield which will enable biobankers to perform downstream applications from archived samples. This technology does not require cold storage and thereby eliminates the risk of freezer breakdown, and at the same time reduces energy costs and carbon emissions.

GRS 04

The Future of Bio-sample Storage is Here to Stay – Not in the Cold but at Room Temperature!!

Rolf Muller1, Judy Muller-Cohn1, Omo Clement1
1Biomatrica, San Diego, CA, USA

Background: Biological sample preservation and integrity is of concern to every biological scientist. Samples and reagent quality determines the quality of our research results. New technologies have evolved to study systems biology and high through-put discovery, while our ability to manage bio-specimens has not evolved as much over the past hundred years. Scientists are required to protect their biological samples and reagents from degradation in a cold chain that can be unreliable. The costs for maintaining these cold chains are growing as well as their deleterious impact on the environment due to the large amounts of CO2 emissions from the fluorohydrocarbons in the refrigerants in these cold freezers. The future of biobanking and bio-repositories of biological specimens will require the adoption of novel technologies that addresses all of these known deficiencies.Method: We will present technologies and methods that are derived from extremophile biology, organisms that can survive stasis for >100 years, while applying these molecular stabilization principles towards transporting and storing a wide range of biological samples, from purified gDNA and RNA, to more complex mixtures in blood, tissue and cell lines at ambient room temperature. Results: Long-term stability data for DNA of 30 years and RNA of 12 years (accelerated stability) will be presented as well as the progress into complex samples and protein stabilization at room temperature. Conclusion: Room temperature technology has a tremendous impact on the future of biobanking in relation to sample quality and economics of scale for sustainable sample management.

HSR 01

Fresh Tissue Dispersal and Research Blood Collection at UC Davis Cancer Center Biorepository

Irmgard Feldman1, Stephanie Soares1, Regina Gandour-Edwards1
1University of California Davis, Sacramento, CA, USA

Background: The Cancer Center Biorepository (CCB) at UCD was created in 2004 for the procurement and storage of fresh, frozen specimens. Responding to researcher interest in fresh (unfrozen, unfixed) specimens, to allow cell culture and gene expression studies, we have developed a protocol to disperse specimens between 20 min - 3 hours after resection. Additionally, we developed a protocol to obtain research blood samples via the clinical laboratory, thereby eliminating the need for a dedicated phlebotomist. Method: We employ three means to facilitate collection and dispersal of fresh specimens: 1. List surgeons and other clinicians on CCB protocol to allow patient pre-op consent and order subsequent blood draws. 2. Add previously approved CCB paragraph for research tissue collection to clinician’s protocol-specific consent form. 3. Researcher obtains exempt IRB protocol that allows acquisition of coded specimens via the CCB. After consent is obtained, CCB orchestrates notification of interested researchers, preparation of coded vials and patient information, and notification of grossing room and pathologist. On arrival from surgery, the pathologist determines the suitability of tissue for research, these are stored in RPMI media, and researcher contacted for pickup. Results: To date, we have dispersed >170 fresh specimens (breast, brain, kidney, bladder, lung, prostate, colon and pancreas) and increased our serum/plasma collection from 33 specimens in 2008 to >900 specimens in 2009. Conclusions: We have developed effective means to obtain fresh tissues for rapid dispersal to researchers. We continue to refine methods to increase volume, improve efficiency and logistics.

HSR 02

The Value of a Tumor Bank in the Development of Cancer Research in Brazil: 12 Years of Experience of the A C Camargo Hospital

Antonio Campos1, Andre Silva1, Louise Mota1, Eloisa Olivier1, Diogo Patrao1, Helena Brentani1, Fernando Soares1, Ricardo Brentani1
1Hospital A C Camargo, Sao Paulo, Brazil

Background: The A C Camargo Hospital Tumor Bank (ACCHTB) was established in 1997 to provide human tissue samples for the Human Cancer Genome
Project, an initiative by the Sao Paulo Research Foundation and the Ludwig Institute for Cancer Research. It culminated with the identification of a million gene sequences of the most frequent tumors in Brazil. Since then, it has accelerated the improvement of cancer research done at A C Camargo Hospital (ACCH). In 2009, it provided biological samples for twenty-seven research projects and contributed to 15% of the theses and dissertations of our Postgraduate Program. Methods: We analyzed, from 1997 to 2009, the number of publications by ACCH’s authors and collaborators, the average impact factor of publications for each year, the sort of publication (regional versus international journals), and the contribution of the ACCHTB for each factor. Results: Along with a significant increase in the number of publications (from 107 in 1997 to 200 in 2009), there has been an increase in the average impact factor of publications (from 2.08 to 4.187) and a shift from predominantly regional to predominantly international publications (90% of publications in international journals in 2009). Conclusion: The possibility of using high-quality biological human samples, provided by ACCHTB, has made possible for scientists and collaborators to access to state-of-the-art equipment for genomic analyses, which had an impact in the quality of cancer research done at our Institution. The development of such initiatives by other institutions can improve cancer research in Brazil.

HSR 03
The Susan G. Komen for the Cure Tissue Bank at the IU Simon Cancer Center: The Source for Normal Breast Tissue

Susan Clare1, Theresa Mathieson2, Connie Rufenbarger1, Jill Henry2, Jie Sun2, Patricia Mitchum2, Robert Goulet1, Valerie Jackson1, Erkia Rager1, Patricia Kennedy1, Monet Williams Bowling1, Barbara Savader3, Stephen Westphal1, Robert Pennington1, Katherine Walker1, Hadley Ritter3, Richard Berg3, Roger Bangs4, Eric Wiebke1, Brittney-Shea Herbert1, Anna Maria Storniolo1

1Indiana University School of Medicine, Indianapolis, IN, USA; 2Susan G Komen for the Cure Tissue Bank at the IU Simon Cancer Center, Indianapolis, IN, USA; 3Indiana University School of Medicine, Carmel, IN, USA; 4Clarian Arnett Physician Group, Lafayette, IN, USA

Background: Our efforts to prevent and treat breast cancer are significantly impeded by a lack of knowledge of the biology and developmental genetics of the normal mammary gland. This ignorance has been the consequence of the lack of access to richly annotated, high quality normal breast specimens. To provide the specimens that will enable the study of normal mammary development and to provide normal controls for breast cancer research, the Susan G. Komen for the Cure® Tissue Bank at the IU Simon Cancer Center (KTB) was established. The KTB is a repository of specimens from volunteer donors with no clinical evidence of breast malignancy. Methods: Donors are recruited from the general population of the State of Indiana. The KTB banks fresh frozen and formalin-fixed, paraffin-embedded (FFPE) breast tissue, DNA, whole blood, serum, plasma and cell lines derived from the tissue. These specimens are richly annotated with detailed information regarding the donors’ reproductive history, medical history, family history, and medications. All of this information is recorded in an Oracle-based, searchable database. Specimen data is linked to image data, e.g. mammograms and H & E sections, and to molecular data. Results: As of 1/1/2010, the KTB and its predecessor, Mary Ellen’s Bank, have available fresh frozen breast tissue (10 gauge cores) from 807 individual donors and FFPE from 408, DNA from 6752, serum from 1642 and plasma from 3079 donors. Conclusions: The KTB is a unique and invaluable research resource which is now open for business and accessible to researchers across the globe.

HSR 04
Institutional Tissue Bank = Building Blocks for Personalized Medicine

Yehudit Cohen1, Amir Onn1, Raanan Berger1, Shlomo Noy1, Iris Barshack1

1Affiliated to the Tel-Aviv University, Sackler School of Medicine, Tel Hashomer, Ramat Gan, Israel

Background: Sheba Medical Center (SMC) is the largest medical center in the Middle East. Our patients present with significant demographic diversity including ethnicity, socio-economic condition and religion, which provides an opportunity for the collection of a wide variety of biosamples. Vision: Our goal is to establish an Institutional Tissue Bank (ITB) in order to provide researchers with high-quality and well-annotated biospecimens. The ITB will enable SMC to be at the forefront of translational-research field, building a foundation for the Translational-Research & Personalized Medicine Program. Methods: Collection and preservation of human tissues from patients with cancer and other diseases. Following Institutional Review Board (IRB) approval and signing an Informed Consent Form (ICF), the specimens are collected by a designated pathologist, at the operating room. Tumor and tumor-free specimens are collected, only when there is sufficient amount of tumor, in excess of the routine needs. Blood samples are collected prior to surgery/procedure. Specimens are processed immediately (10-30 minutes for tissues and up to a few hours for blood) and preserved in small aliquots. Clinical/pathological/follow-up data is collected in a designated database. All ITB activities are according to well established & validated procedures. Results: Since activation on January 2009, we have obtained biosamples, from over 450 patients (colon/rectum n=40, pancreas n=25, brain n=155, liver n=30, stomach n=20, thoracic n=20, kidney n=65, bladder n=20).
n=15, Gynecology n=20, orthopedics n=10, children n=50, Head & Neck n=20). These building-block samples are soon to be used in research for the development of ‘targeted therapy’, facilitating pharmacogenetic studies.

**HSR 05**

**Biobanking Solution Adapted to the Needs of Sites Participating in Clinical Trials Conducted in Collaboration with the Pharmaceutical Industry**

Julie Méthot¹, Céline Lefebvre¹, Steve ArsenaULT¹, Daniel Gaudet¹
¹ECOGENE-21 Clinical Trial Center, Chicoutimi, Quebec, Canada

**Background:** Managing investigational products (drugs or biodrugs) in conformity with Good Clinical Practice (GCP) requirements is a challenge that the sites participating in clinical trials with the pharmaceutical industry are not necessarily prepared to assume.

**Methods:** The Ecogene-21 clinical research center along with the Genome-Quebec/Chicoutimi Hospital Biobank are developing a GCP toolbox for the management of investigational products and biological samples. The toolbox is adapted to the scale and the needs of the clinical sites participating in clinical trials and includes: (1) the technologies and standard operating procedures from reception of the investigational product to distribution and use by the participant, storage conditions (temperature, humidity, security, access), drug accounting, return or destruction procedures if required; (2) samples management (from sample collection to shipping or use); (3) training of qualified personnel and coordination by a pharmacist; (4) development of technologies and automated storage systems.

**Results:** In the last year, the toolbox has been tested in 12 clinical trials (phase I to III). A transdisciplinary, GCP-trained, team with experience in biobanking, technology development/assessment and clinical trials accompanies the process. All deviations to storage conditions, procedures or study protocols were noticed and rapidly solved, thus facilitating the monitoring of the studies and improving the site capacity to follow the audit trail.

**Conclusions:** Clinical sites conducting clinical trials require reliable GCP systems to manage investigational products and biological samples. We have developed, evaluated and implemented an adapted biobanking approach and new technologies to cover these needs.

**HSR 06**

**Biospecimen Accessioning and Processing for the Mayo Clinic Biobank**

Jason Carnahan¹
¹Mayo Clinic, Rochester, MN, USA

The Mayo Clinic Biobank serves as a source of non-disease controls for numerous research projects having the goal of improving disease outcomes. Participants in the biobank complete a health questionnaire, allow access to medical records, and provide blood samples from which DNA, serum, and plasma are prepared and archived. Within the Biospecimens Accessioning and Processing (BAP) Laboratory, blood samples are accessioned into Mayo’s Research Laboratory Information System (RLIMS), a custom LIMS built on the Sapphire platform (LabVantage). RLIMS will track the progress of the sample thru the laboratory and drive the process of preparing derivative material per a specific IRB protocol. RLIMS is interfaced with the Electronic Medical Record in a prospective and HIPPA compliant manner to couple the biospecimen with the participant’s medical record, maximizing the sample’s utility for biomedical research. BAP utilizes a combination of effective staffing levels at peak times and automation to provide high quality processing and sample storage services to the Biobank and other research customers. With its current automation and information technology, the BAP laboratory accessioned 43,000 samples in 2009, extracted DNA via the AutoGenFlex STAR platform from almost 33,000 samples, and plated over 45,000 samples in 96 well-plate format for downstream analyses. BAP monitors its efficiency using process workflow modeling to identify workflow bottlenecks with current and projected volumes. This modeling process also enables modeling of future states of the laboratory, including introduction of additional automated equipment to assess the need for increased automated equipment, staffing, and/or space to meet anticipated demand.

**HSR 07**

**Isolation of microRNAs and other small RNA species from PAXgene® Blood RNA Tubes**

Thorsten Voss¹, Mogens Kruhoffer², Maren Wengeler¹, Franziska Heese¹, Ralf Wyrich¹
¹QIAGEN GmbH, Hilden, NRW, Germany; ²AROS Applied Biotechnology A/S, Aarhus, Denmark

**Background:** The RNA content and profile of unstabilized blood specimens are altered post-phlebotomy due to RNA degradation and gene induction. The need for stabilization of cellular RNA for accurate gene expression profiling in blood is widely
accepted, and the PAXgene® Blood RNA System is commonly used to address this problem. This system was designed to isolate high molecular weight RNA species, such as mRNA. We have now developed a chemistry that maximizes yields of small RNAs like miRNAs from PAXgene Blood RNA Tubes as well. Methods: Blood was collected into PAXgene Blood RNA Tubes from consented healthy adults, and miRNA was isolated using the PAXgene Blood miRNA Kit. Yield and quality of small RNA species were determined using an Agilent 2100 Bioanalyzer and gel electrophoresis. Purified RNA was analyzed for genomic DNA contamination and PCR-inhibition. miRNAs were quantified by qRT-PCR as well as in a low-density array format. Results: Using miRNA protocols enrichment of small RNAs in total RNA was demonstrated by electrophoretic analysis. Higher miRNA contents could be confirmed with qRT-PCR assays detecting miR-10a, 16, 30b, 192 and let7a. Little gDNA (< 1%) was present in eluates which showed no RT-PCR inhibition. There was no interference with assays for the mRNA transcripts FOS and IL1B. Conclusions: The PAXgene Blood miRNA Kit produced high quality enrichment of these RNA species from the PAXgene Blood RNA Tube. miRNAs isolated by this method are ready for direct use. The PAXgene Blood miRNA Kit is intended for research use only. Not for use in diagnostic procedures.

HSR 08

Creation of a Local Biospecimen Collection Network at the Translational Genomics Research Institute (TGen)

Lora Nordstrom1, Galen Hostetter2, Stephanie Bucholtz1, Heather Cunliffe1, Robert Griego2, April Watanabe1, Catherine Mancini1, Lora Nordstrom1, Galen Hostetter1, Stephanie Bucholtz1, Heather Cunliffe1, Robert Griego2, April Watanabe1, Catherine Mancini1, Kelly Enders3, Amber Henson3, Jodi Black4

1Translational Genomics Research Institute (TGen), Phoenix, AZ, USA; 2Skin Cancer Specialists, LTD., Mesa, AZ, USA; 3Banner Good Samaritan Medical Center, Phoenix, AZ, USA; 4NHLBI, NIH, Bethesda, MD, USA

Background: Scientists at TGen perform genomics and proteomics research to understand the molecular mechanisms of a variety of human diseases. As TGen is a research institute that does not directly treat patients, partnering with clinical sites is essential for obtaining high quality biospecimens and clinical data. A model has been implemented to streamline the development of collaborations with local healthcare entities, which serve as TGen collection sites. A cornerstone of this model is the presence of jointly-hired clinical research coordinators (CRCs) at several collection sites. Methods: As the logistics of working with multiple healthcare systems can be challenging, more efficient processes have been developed for ethics review and contracting. Hiring, training and monitoring the work of the joint CRCs is coordinated between staff at TGen and the clinical site. To facilitate clinical and biospecimen data collection, a custom, online biospecimen management system (BIOMAP) has been implemented. Results: Two joint TGen CRCs perform collections at one large medical center and two more will be hired in Spring 2010. Active biospecimen collection studies are ongoing at six additional healthcare sites. To date, 3,013 samples have been collected from all clinical sites, with 1,367 samples collected at the site with joint CRCs. The new BIOMAP system has been instituted, which facilitates specimen tracking and QC reporting across all collection sites. Conclusions: The combination of streamlining administrative processes, joint CRCs at collection sites, and the use of an online biospecimen management system has significantly improved the collection and tracking of biospecimens at TGen.

HSR 09

Collection and Use of Pathology Data by the Breast Cancer Tissue Bank

Jane Carpenter1, Rosemary Balleine2, Nirmala Pathmanathan3, Christine Clarke4

1University of Sydney at Westmead Millennium Institute, Westmead, NSW, Australia; 2Westmead Institute for Cancer Research, University of Sydney, Westmead, New South Wales, Australia; 3Westmead Hospital, Westmead, NSW, Australia

Background: The Breast Cancer Tissue Bank (BCTB, www.abctb.org.au) is a repository of biospecimens and information, designed to support breast cancer research. Material is collected and stored at multiple sites and the project is co-ordinated by a central management team. Diagnostic pathology reports are an important source of data for the BCTB. In addition, a standardized pathology dataset is being collected through a process of centralized pathology review. A third level of pathology data is derived from content review of individual tissue samples provided to researchers. Methods: Strategies employed to collect pathology data include: 1. Collection of diagnostic pathology reports from many different pathology services/companies, with extraction of data into BCTB designed database fields. 2. Establishment of a digital image library including a high resolution image of a representative H&E stained section from each BCTB case. Review of these images is performed by a single experienced breast Pathologist to establish a standardized central pathology review dataset which again is captured in the database. 3. Pathologist review of individual frozen and formalin-fixed paraffin embedded tissue blocks for tissue content prior to dispatch to researchers. Results and Conclusion: Pathology data forms a substantial component of clinical and specimen inventory information collected by the BCTB. In addition, centralized pathology review is providing an image library and standardised dataset that enhance the research resource. A combination of data extraction and dedicated pathology review...
processes is used by the BCTB to optimize research use of breast cancer tissue samples.

HSR 10

Institutional Tissue Bank (ITB)- Challenges for a Newly Established Repository

Yehudit Cohen¹, Iris Barshack¹, Raanan Berger¹, Shlomo Noy¹, Amir Onn¹
¹Affiliated to the Tel-Aviv University, Sackler School of Medicine, Tel Hashomer, Ramat Gan, Israel

Background: Our newly established ITB at Sheba Medical Center (SMC) was launched in January 2009, to provide researchers with high-quality and well-annotated biospecimens, essential for accelerating biomedical research and medical-product-development. Since its initiation, we encountered and overcame major challenges: 1- Institutional Review Board (IRB) approval- Israeli genetic regulations require the submission of separate applications to each field. Accordingly, our ITB is divided into sub-banks controlled by one central-administration. 2- Surgeons’ collaboration- In order to improve the willingness of surgeons to collaborate with the ITB, each sub-bank is represented by the head of the relevant department, as a Principal Investigator. 3- Patient recruitment- Since SMC is a general hospital and most patients are not oncological, the sorting of relevant patients is complex. We mainly depend on departmental-secretaries. 4- Signing Informed Consent Form (ICF)- Only M.Ds are allowed to conduct genetic studies and to have patients sign an ICF. Therefore ICFs are signed at the pre-operation-clinic, few days prior to surgery. 5- Proper infrastructure & designated manpower - Our preservation tanks can accommodate ~30,000 biosamples. A sterile biological-hood is located in the operating-room for various uses. Current staff includes: a pathologist, a technician, a database-manager and a scientific-director. 6- Intelligent database- We are currently building a database integrating clinical/demographic/other data from many sources. In addition, Israel is building a national-program for tissue banking of biosamples from all cancer patients. A National-Tissue-Bank would facilitate pharmacogenetic studies and the development of ‘targeted therapy’. Conclusions: The establishment of an ITB requires a concentrated effort of a multi-disciplinary team composed of para-medical, medical & scientific professionals.

HSR 11

Risk Assessment and Analysis - Setting Up a Tissue Biobank Facility for Clinical Studies

Douglas McKechnie¹, Kerry Heathcote¹, Christopher Womack¹
¹AstraZeneca, Macclesfield, Cheshire, UK

Background: As part of its global biobanking infrastructure, the AstraZeneca (AZ) R&D site at Alderley Park (AP) expanded its already established human cancer bank to include samples from all R&D areas on site. The new site biobank was fully commissioned in November 2009 and stores human biological samples (HBS) collected principally from AZ clinical trials, but also samples from AZ sponsored research collaborations and commercial suppliers. Methods: The facility was designed to provide safe, secure storage primarily for frozen samples together with sample reception and preparation laboratory space and a small office. Risk assessment and analysis included the following factors dictated by legislation, regulation and AZ policies and procedures: Health and safety - laboratory design and user requirements – ultra low temperature (-80°C) samples storage and sample preparation • Legal Compliance - Good Clinical Practice and UK Human Tissue Act (2004) – licensing and ethical approvals • Governance – Quality systems for laboratory and sample management – HBS life cycle management. Results: Budget approval to full commissioning was completed in one year within which time we were able to transfer existing on site samples for long term storage and receive samples stored externally from two clinical studies. Transfers of additional clinical samples are underway and at the time of writing 5 out of 14 freezers are full. The laboratories are fully functional. Conclusion: Risk identification and management underpins regulated storage of human tissue in a centralized site biobank established to increase the utility of samples collected in AZ clinical trials.

HSR 12

RNA Quality Control of Human Sample Repository of Chinese Cancer Patients

Menghong Sun¹, Yuhu Xin¹, Guangqi Qin¹, Huan Chen¹, Yanzi Gu¹, Daren Shi¹, Xiaoyan Zhou¹, Xiang Du¹
¹Fudan University Cancer Center, Shanghai, China

Background: The Institutional Tissue Bank (ITB) of Fudan University Shanghai Cancer Center was established in 2006 as central repository of human tissue samples for cancer research. Variant samples including blood, tumor tissue, and body fluids are collected. It is important to keep undeniable high quality samples and reliable tracking. Methods:
Altogether 17,000 samples have been banked in the ITB by the end of 2009. From the whole bank, 41 samples including tumor and normal tissue were randomly chosen for RNA quality control. Total RNA was extracted from RNAlater reserved tissue using Trizol or Qiagen RNA extraction kit. Thirty-four RNAlater reserved tissue samples were extracted using Trizol and the other 7 using Qiagen Kit. RNA qualification and quantification was performed using GE Nano Vue (classic) and Agilent 2100 Bioanalyzer (Chip). Results: Twenty-one out of 34 samples showed satisfactory RNA quality and quantity in the cases using Trizol. Seven out of seven samples showed satisfactory RNA quality and quantity in the cases using Qiagen kit. All 41 RNA samples were checked using Chips and 12 with dual methods. Conclusion: RNA was well preserved in our bank. There was good consistency between two readings using dual Chip and classic systems. However, it is of important to observe the peaks for 18s and 28s obtained from Chips. It might be possible that some factors would influence the report of Chip by cutting some qualified samples eligible for further study off.

HSR 13

Australian Brain Bank Network: Challenges of Achieving Financial Sustainability

Fairlie Hinton1, Antony Harding2, Donna Sheedy2, Robyn Flook3, Allison Eckert4, Caroline Casley5, Jillian Park, Australia; 4The University of Queensland, 1Mental Health Research Institute, Parkville, Victoria, Australia; 5Royal Perth Hospital, Perth, Australia; 6Alfred Hospital, Prahran, Victoria, Australia

Background: The Australian Brain Bank Network (ABBN) www.nnf.com.au/abbn was formed in 2003. Building on previous grants, an Australian National Health and Medical Research Council (NHMRC) Enabling grant scheme (2004-2009) transformed a group of Australian brain banks into a truly national and comprehensive network supporting neuroscience research. Our aim has been to achieve long-term financial sustainability. Method: A review of the income as total grant money and the costs for collection, processing, characterization, storage and distribution of tissue, was performed, on the basis of 192 brains per annum. Results: The ABBN (2004-2009) has been successful in receiving a number of: 14 Australian, 6 NHMRC and 3 international grants of which all or part of the funding has been directed towards infrastructure and operational costs. The introduction in 2006 of a cost recovery policy for services associated with tissue requests resulted in AU$16,951 per annum. The total income was AU$1,017,000 per annum. Real costs for collection, processing, characterization, storage and distribution of tissue was AU$20,000 per brain. The difference between income and costs was AU$2,823,000 per annum shortfall. Conclusion: Despite some financial success this represents a fraction of the total cost needed to maintain the infrastructure of the ABBN. A recent submission to the NHMRC resulted in securing partial funding until 2014. We face an ongoing challenge along with increasing costs to achieve long-term financial sustainability.

HSR 14

Quality Bio-Specimen Storage Ensures Success in High Throughput Research

Lee Peng Karen-Ng1, Sok Ching Cheong1, Wan Maria Nabillah Ghani1, Mannil Thomas Abraham2, Wan Mahathir Wan Mustafa2, Keng Kiong Tey2, Norma Jalil2, Zainal Ariff Abdul Rahman2, Abdul Rashid Ismail3, Rosnah Binti Zain1
1Oral Cancer Research & Coordinating Centre (OCRCC), Kuala Lumpur, Federal Territory, Malaysia; 2Department of Oral Maxillofacial Surgery, Kuala Lumpur, Federal Territory, Malaysia; 3Department of Community Dentistry, Kubang Kerian, Kelantan, Malaysia

Background: An oral cancer biobank was developed where collections of tumor and normal tissues were done and DNA, RNA were extracted for molecular studies. This report is to highlight the benefit and usage of a high quality biobank. Method: Tissues obtained from tumours and normal sites were processed for extraction of DNA and RNA. Only samples with high tumor cell content (>75%) and high-quality mRNA (RIN>7) were selected and subjected to transcriptome sequencing. Result: Since 2004, we have collected specimens from 390 cases and 55 controls. To date, we processed 137 cancer and 33 normal samples. Of the 170 samples, 108 were processed for RNA extraction while 62 were not processed as they were either connective tissue, adipose/muscle, salivary gland, no tumour or <10% tumour cells. RNA was found to be of good quality with an average RIN>7. DNA was only extracted from 89 tissues as there were insufficient tissues after RNA extraction. RNA from 15 samples were used for Next Generation Sequencing transcriptome profiling. This high throughput sequencing showed that 48 genes were differentially expressed between cancer and non-cancer samples, where 17 were found to be down regulated while 31 were highly expressed. Meanwhile 36 SNPs were observed to be common in all tumour but not in normal samples where 13 were found to be novel. Conclusion: Good practice of specimen collection and processing leads to high quality nucleic acid content which enable us to carry out high throughput research which translates into novel knowledge in oral cancer research.
HSR 15

Standardization of Tissue Collection Procedures by the Australian Brain Bank Network

Antony Harding1, Fairlie Hinton2, Donna Sheedy3, Robyn Flook4, Allison Eckert5, Caroline Casely6, Jillian Kni7, Catriona McLean3

1The University of Sydney, Sydney, New South Wales, Australia; 2Mental Health Research Institute, Parkville, Victoria, Australia; 3Flinders University, Bedford Park, South Australia, Australia; 4The University of Queensland, Brisbane, Queensland, Australia; 5Royal Perth Hospital, Perth, Western Australia, Australia; 6Alfred Hospital, Prahran, Victoria, Australia

Background: The Australian Brain Bank Network (ABBN) www.nnf.com.au/abbn was formed in 2003 to coordinate the collection of post-mortem human brains and related information across Australia. The Network now consists of eight banks located in five Australian states with a centralised management structure. The ABBN facilitates research into neurological and psychiatric disorders, and normal aging. The ABBN aims to standardize across sites the tissue collection, processing, storage and distribution protocols.

Methods: A national survey was conducted to examine four major components of brain banking: Donor recruitment; brain retrieval; diagnostic procedures and tissue storage to ensure that tissues are of the highest quality and can be used in current and prospective studies. Results: The survey resulted in 33 recommendations, 17 criteria warranting immediate review and 16 for future review. All were minor adjustments to existing protocols to standardize and maximize tissue quality across brain banks. A set of recommended guidelines for enhancing brain banking were developed in line with State and National ethics and legislation and which were compliant with international standards of brain banking.

Conclusion: With declining autopsy rates, it is imperative that the ABBN ensures that the stored consented brain tissue available for research is of highest quality. Implementation of National guidelines for banking of brain tissue, across the Network, is imperative in achieving this aim.

HSR 16

Challenges in Managing a Biobank and an Accompanying Databank for Research: A multicentre collaboration

Wan Maria Nabillah Ghani1, Lee Peng Karen-Ng1, Ishak Abdul Razak1, Raja Jallaludin Raja-Latifah1, Sok Ching Cheong1, Abdul Rashid Ismaill1, Norlida Abdullah1, Rosnah Binti Zain1

1Oral Cancer Research & Coordinating Centre (OCRCC), UM, Kuala Lumpur, Federal Territory, Malaysia; 2Oral Cancer Research Team, Cancer Research Initiatives Foundation, Subang Jaya, Selangor, Malaysia; 3Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia; 4Ministry of Health Malaysia, Putrajaya, Federal Territory, Malaysia

Background: To facilitate research through sharing of limited resources, an oral cancer biobank and databank was developed. The aim of this report is to highlight problems faced in managing an oral cancer biobank/databank. Method: Specimens and data were obtained from participating referral centres. These were stored temporarily at each respective centre before being centralized at Oral Cancer Research & Coordinating Centre (OCRCC), University of Malaya.

Results: Since 2004, data was collected from 620 cases and 280 controls along with 390 tumor and 55 normal tissues. Blood samples were also collected from 266 cases and 266 controls. DNA/RNA was extracted from some specimens to facilitate molecular/genetic research. A major challenge in data collection is the ability to randomly check accuracy of data. The main problem identified in managing the bank is the lack of a formal body to vet application for usage of data/specimen. Lack of policy on authorships and acknowledgements evokes unfairness for original parties involved in the development of the bank. Lack of funding to carry out specimen collection and processing cast doubt on the continuity of the biobank. The establishment of a Central Advisory Committee (CAC) to govern policies related to data/specimen usage was proposed, while a minimal fee for specimen processing for research was suggested. Conclusion: A check and balance system is needed to ensure accuracy of data. There is a need for a standard operating procedure for request to use data/specimen and a formally structured governing body to make decisions to avoid dissatisfaction and dispute among researchers.

HSR 17

Survey of Biobanks at a Swiss University Hospital

Christine Currat-Zweifel1, Serge Leyvraz1, Daniel Simeon-Dubach1, Jean-Daniel Horisberger1, Ivan Stamenkovic1

1Centre Hospitalier Universitaire Vaudois (CHUV), Lausanne, Canton de Vaud, Switzerland; 2Foundation Biobank Suisse, Bern, Canton de Bern, Switzerland

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Wan Maria Nabillah Ghani1, Lee Peng Karen-Ng1, Ishak Abdul Razak1, Raja Jallaludin Raja-Latifah1, Sok Ching Cheong1, Abdul Rashid Ismaill1, Norlida Abdullah1, Rosnah Binti Zain1

1Oral Cancer Research & Coordinating Centre (OCRCC), UM, Kuala Lumpur, Federal Territory, Malaysia; 2Oral Cancer Research Team, Cancer Research Initiatives Foundation, Subang Jaya, Selangor, Malaysia; 3Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia; 4Ministry of Health Malaysia, Putrajaya, Federal Territory, Malaysia

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1Centre Hospitalier Universitaire Vaudois (CHUV), Lausanne, Canton de Vaud, Switzerland; 2Foundation Biobank Suisse, Bern, Canton de Bern, Switzerland

Background: To facilitate research through sharing of limited resources, an oral cancer biobank and databank was developed. The aim of this report is to highlight problems faced in managing an oral cancer biobank/databank. Method: Specimens and data were obtained from participating referral centres. These were stored temporarily at each respective centre before being centralized at Oral Cancer Research & Coordinating Centre (OCRCC), University of Malaya.

Results: Since 2004, data was collected from 620 cases and 280 controls along with 390 tumor and 55 normal tissues. Blood samples were also collected from 266 cases and 266 controls. DNA/RNA was extracted from some specimens to facilitate molecular/genetic research. A major challenge in data collection is the ability to randomly check accuracy of data. The main problem identified in managing the bank is the lack of a formal body to vet application for usage of data/specimen. Lack of policy on authorships and acknowledgements evokes unfairness for original parties involved in the development of the bank. Lack of funding to carry out specimen collection and processing cast doubt on the continuity of the biobank. The establishment of a Central Advisory Committee (CAC) to govern policies related to data/specimen usage was proposed, while a minimal fee for specimen processing for research was suggested. Conclusion: A check and balance system is needed to ensure accuracy of data. There is a need for a standard operating procedure for request to use data/specimen and a formally structured governing body to make decisions to avoid dissatisfaction and dispute among researchers.
biobanks follow the Swiss Academy of Medical Sciences (SAMS) guidelines on biobanks. Eighty-three services (FBM: 15, CHUV: 68) were contacted. Twenty did not respond, 35 had no collection of human biospecimens. 28 services had 37 research biobanks and 6 collections for diagnosis and treatment; the latter were excluded from further analysis. Fifty-seven percent of biobanks store > 1,000 biospecimens. One third of biobanks stored tissue (92% fresh frozen, 46% FFPE, 31% DNA, 23% RNA, and 23% frozen cells), 65% stored blood components (58% serum, 63% plasma, 46% frozen cells, 38% DNA, 17% RNA, and 4% whole blood). The majority of biobanks have accepted the SAMS guidelines. Forty-one percent of biobanks used the biospecimens and data only for their own research, almost half share biospecimens and data, but only a quarter use a material transfer agreement. The data collected in this survey will allow biobank infrastructure optimization at the CHUV and will improve research support.

HSR 18

**Biobanking to Bridge Research: The NIHR Cardiovascular and Respiratory Biomedical Research Units at the Royal Brompton & Harefield NHS Foundation Trust**

Sara Giesz¹, Tracy Higgins², Emma Holder², Lydia Harris¹, Eric Alton², Dudley Pennell³
1Royal Brompton & Harefield NHS Foundation Trust, London, UK; ²Imperial College London, London, UK

Background: The Royal Brompton & Harefield NHS Foundation Trust (RBHT), in partnership with Imperial College London, was awarded NIHR Biomedical Research Unit (BRU) status for both Respiratory and Cardiac research programmes. The Respiratory BRU incorporates clinical research facilities for advanced lung diseases. The Cardiovascular BRU encompasses advanced facilities for cardiac imaging, interventional cardiology and genetics. Methods: A research Biobank has been established across both BRUs. The Biobank prospectively collects, processes, and stores specimens, together with clinical data, consented for donation to research by patients undergoing treatment at RBHT. A dedicated collection team ensures all possible samples are procured. Access to samples is done equitably, based on prioritization and availability and is open to all researchers. Results: Each year, RBHT serves >90,000 outpatients and >26,000 inpatients representing specialized cardiovascular and respiratory disease cohorts. The Cardiovascular BRU has stored >2100 samples in the Biobank since August 2009. The Respiratory BRU will store multiple samples from an estimated 8,000 patients annually. Access to the Biobank is governed by recognized leaders in cardiovascular and respiratory research who form the core of each BRU. Conclusions: The Biobank facilitates access to an extensive range of specimens from highly unique patient populations. As a shared core facility between the Respiratory and Cardiovascular BRUs, operations are harmonized providing a well-organized, proficient resource to enhance research opportunities between both academic and clinical institutions and thus, stimulate development of novel treatments for respiratory and cardiovascular disease. The processes and infrastructure created enabled increased access, efficiency, and collaboration within a transparent, equitable and ethical framework.

HSR 19

**The Integral Role of Global Cold Chain Management in Ensuring the Integrity of Biospecimens**

Jeff Clark¹
¹BioStorage Technologies, Inc., Indianapolis, IN, USA

As clinical research trends towards globalization, the process of transporting human biospecimens has become increasingly complex. Regulatory requirements, quality control concerns, import and export guidelines and maintaining the visibility of temperature-sensitive biomaterials pose distinct challenges to organizations collecting biospecimens on an international scale. Without careful consideration for cold chain logistics, compliant storage, information management and audit trails, researchers risk specimen degradation and losing valuable clinical information. As a result, information provided will impart attendees with invaluable insight into logistical strategies and highlight in-depth measures that help ensure the on time, compliant transportation of valuable biospecimens. Specific topics that will be addressed, include: •Maintaining Regulatory Compliance •Adhering to Custom Regulations •Specific Aspects of Maintaining Visibility of the Cold Chain •The Role of Validated Packaging for Extended Transit Times •Standards for Labeling and Documentation. The presenter will also address the process of developing a comprehensive cold chain strategy, taking into account best practices for the labeling and handling of specimens.
HSR 20

Addressing the Challenges of a Complex Disease through a Repository-Centered Strategy: The Design and Implementation of the Accelerated Cure Project Multiple Sclerosis Repository

Hollie Schmidt1, Sara Loud1
1Accelerated Cure Project for Multiple Sclerosis, Waltham, MA, USA

Despite decades of research, the etiology and pathophysiology of multiple sclerosis remain very poorly understood. This lack of progress and understanding is due primarily to MS being a complex, heterogeneous disease. A multitude of factors contribute to initiating and driving the disease, and the specific factors involved vary from person to person. Determining how to prevent, treat, and cure MS requires strategies specifically tailored to the challenges of investigating a complex, heterogeneous disease. The Accelerated Cure Project MS Repository is the cornerstone of such a strategy. It collects longitudinal blood samples (RNA, DNA, plasma, serum, and lymphocytes) from MS subjects and controls, characterized with over 40 pages of information about each subject. Samples and data are shared with scientists in many disciplines investigating the causes and mechanisms of MS – who in return provide their experimental data to the Repository to be incorporated in the database. Combining clinical and epidemiological information with genetic, gene expression, proteomic, and other types of experimental results creates a rich and multifaceted dataset that can yield new insights into the biology of MS. The Repository currently has 2,000 sets of samples and data collected through a network of nine clinical sites across the US, has supported over 30 research projects, has recovered several experimental data sets, and is now developing an informatics and data analysis plan for extracting new findings from the Repository database. This presentation will describe the design, status, and future directions of the MS Repository.

HSR 21

Managing Supply and Demand for the Neuroscience Research Community

Donna Sheedy1, Jillian Kril1
1The University of Sydney, Sydney, New South Wales, Australia

Background: The New South Wales Tissue Resource Centre (TRC) of Australia, collects human brains from forensic institutes and associated pre-consented donor programs. The primary focus is supporting research of substance abuse of alcohol and schizophrenia. Recent tissue requests for genetic research projects have indicated the requirement of large cohorts to substantiate findings. The challenge for this bank is the ability to meet these needs while working within finite financial and infrastructure support. Aim: The goal of this study was to evaluate the collection process and assess the acquisition rates, the current research cohorts and to identify the cases that are under utilised or do not meet criteria for research. Results: There have been 660 brains collected since 1994. Of these, 510 cases are assigned to the research cohort while 150 cases have not met inclusion criteria due to pathological or clinical measures. The research cohorts are further subclassed by DSMIV, alcoholic liver disease and smoking history. The female gender is under represented in each group; control - 27%, schizophrenia-36% and substance abuse of alcohol-23%. The yearly collection rate average has increased from the first 5-year period of 38 cases to 60 cases for 2008-2009. Conclusion: Strict inclusion criteria and insufficient clinical information has excluded a number of cases from the research cohort. A review of collection protocols has indicated access to medical records in a shorter timeframe and a more rigorous review of available information is warranted to reduce the limitation of usage.

HSR 22

Human Biobanks as a Key Player in the Search for Biomarkers in Neurological Disorders

Rivka Ravid1
1Royal Dutch Academy of Arts and Sciences, Amstelveen, noord Holland, The Netherlands

Background: The diagnosis of most neurological disorders is severely hampered by the absence of reliable biomarkers that can be measured in body fluids such as blood, urine and cerebro-spinal fluid (CSF). Biomarkers search strongly depends on specimens collected from living donors as well as autopsy material collected and store by Biobanks and tissue banks. Methods: Biomarkers validation copes with data fluctuation due to the huge variability in biomarkers between individuals and the rapid post-mortem changes. We are currently using amyloid and Tau as early diagnostic markers in the pathology of dementia and in differential involvement in Alzheimer’s disease (AD), Lewy Body dementia (DLBD), Vascular dementia, fronto-temporal lobar degeneration (FTLD) and non-neurological controls. Results: Due to the overlap in pathophysiological hallmarks of the various disorders syndromes, we identify common markers in blood and CSF. We also determine CSF-total and phosphorylated tau and CSF- Aβ42 in blood and CSF, both in living donors and in rapid autopsy material, in combination with imaging techniques to assist in diagnostic procedures. Conclusions: Although it is clear that no single biomarker can
discriminate between AD and other dementias, a judicious combination of several biological markers may substantially increase the sensitivity and specificity of the diagnosis. If the results from a panel of biomarkers are added to the findings derived from a classical work-up, diagnostic accuracy can be further increased. Biobanks using internationally accepted SOPs, play a major role in the collection of large numbers of high quality specimens for Biomarker identification.

**HSR 23**

**Multi-site Tissue Banking Linked to a Centralised Application Process**

Joanne Edgar¹, M Thompson¹, Zoe Squire¹

¹Victorian Cancer Biobank, Carlton, Victoria, Australia

Background: The Victorian Cancer Biobank (Biobank) is a consortium formed in 2006 by five parties including 4 pre-existing tissue banks. Each member agreed to a centralised application process to streamline the access to specimens, this required the introduction of a structure that gave custodianship of all biospecimens to the Consortium whilst retaining a sense of shared management and decision making over their allocation for research. Methods: During 2007, the Consortium Committee developed terms of reference for an Access Committee to oversee access to samples. The Committee includes representatives from the Consortium members and independent members with expertise in research and human ethics. An Applications Manager was appointed to work with researchers and support the committee. Results: Initial challenges were encountered when “rolling over” existing projects from local to central management and supporting different types of research. The application process was revised and developed further to cater for such challenges. Since the formation of the Access Committee the Victorian Cancer Biobank has processed 47 new applications. After implementing this process the Biobank has distributed approximately 1100 biospecimens to these new and rolled over projects. Conclusion: Overcoming the sense of ownership of tissue samples has probably been the most significant challenge associated with a centralised access policy. The successful centralisation process has streamlined access to biospecimens and reduces the duplication of resources required for approving applications and distributing biospecimens. The adaptability of the model has enabled us to move forward with supporting clinical and translational research by providing both services and products.

**HSR 24**

**South Australian Brain Bank – Flexibility in Tissue Banking: Investing in the Future**

Robyn Flock¹, William Blessing¹, Jim Manavis², Barbara Koszyca³, Wei Gai¹, Peter Blumbergs³

¹Flinders University, Bedford Park, South Australia, Australia; ²IMVS, Adelaide, South Australia, Australia; ³IMVS/SA Pathology, Adelaide, South Australia, Australia

Background: Established in 1986, the South Australian Brain Bank collects and stores post-mortem human neurological tissues for use in research. In 1993, with the development of the Australian Brain Bank Network, a modified methodology was needed, to ensure flexibility in line with changing technologies. Methods: Whole brain perfusion fixation via cerebral arteries is ideal when histological and immunohistochemical studies are the primary research goal. With careful storage in buffered formaldehyde, these tissues remain useful decades after collection. Evolving technologies required tissue that had not been chemically treated, so we modified a method (1) whereby one half of each brain (chosen randomly or according to case specific pathology) is immersion- or perfusion-fixed for diagnostic studies. The contralateral hemisphere is dissected into 10mm coronal slices that are rapidly frozen and stored at -80°C. Results: The completion of the Human Genome Project in 2003 resulted in a propensity for genetic studies, increasing the demand for fresh frozen tissue. The modification to our protocol ten years earlier has enabled us to facilitate a variety of new national and international research studies. Conclusions: Careful preservation and storage of human tissues ensures its viability for both current and prospective research. This is particularly important when storing rare or inherited neuropathologies. Flexibility in this process is crucial to keep ahead of emerging technologies. Reference: 1. Vonsattel, et al, An improved approach to prepare human brains for research, J Neuropath Exp Neurology 54 (1): 42-56, 1995.

**HSR 25**

**Quality Studies of DNA in the Norwegian Mother and Child Cohort Study (MoBa)**

Siri Baekken¹, Liv Paltiel¹, Anita Haugan¹, Mariam Bakkerud¹, Kari Harbak¹

¹Norwegian Institute of Public Health, Oslo, Norway

Background: The MoBa study is a nationwide population-based pregnancy cohort where biological samples from mothers, their partners and newborns have been collected from more than 100 000 pregnancies. The samples were collected at participating hospitals, and sent by mail to the central biobank where DNA was extracted and stored at -20
Background: The Biobank at NIPH collects and stores cord blood samples in Tempus™ blood RNA tubes (~52,000 tubes have been collected). Long-term storage of samples before extraction may affect the quality and integrity of RNA contributing to artifacts in gene expression (GE) analysis. We have evaluated the effects of storage on the stability of RNA in blood in Tempus tubes. Methods: Cord blood from three placentas (3 ml blood/tube, 45 tubes) and whole blood from three healthy adults (3 ml/tube, 172 tubes) were drawn in Tempus tubes and stored overnight at -20 °C and then at -80 °C during long-term storage. RNA was extracted and analyzed after 0, 1, and 2 years. RNA quantity and quality were examined using Nanodrop™ spectrophotometer and Agilent Bioanalyzer. The stability of the GE profile of seven genes (18S rRNA, FOS, IL-1β, IL-8, MYC, TP53, and CDKN1A), was analyzed by qRT-PCR (7500Fast, Applied Biosystems). Results: In general, long-term storage had no significant effects on RNA yield and quality. The expression levels of the seven genes were not altered by storage, except some differences in MYC expression levels. We are now conducting analysis of data from four-year stored samples. Conclusions: Our results suggest that the storage of blood in Tempus tubes for up to two years has no significant effects on the RNA quality and yield. This suggests that blood samples in large biobanks – frozen in suitable collection tubes for RNA stabilisation – can be used for GE studies even after years of storage.
Conversion of novel non-invasive colorectal cancer screening tests, a biorepository of blood, urine and tissue linked to comprehensive risk factor and outcome data is being developed. Methods: The biorepository is located at the Forzani & MacPhail Colon Cancer Screening Centre (Calgary, Canada), an endoscopy unit providing colon cancer screening colonoscopies. Biorepository participants complete comprehensive questionnaires on their health and lifestyle, family history, diet, use of medications and nutritional supplements and provide blood and urine samples. Blood is fractionated into serum, plasma, whole blood and buffy coat and stored at -80°C. Participants undergo colonoscopy with removal of all polyps. Normal colonic biopsies are obtained on a subset. Formalins-fixed tissue is available from all polyps removed. Subsequent linkage to the provincial cancer registry will identify interval cancers. Samples can be obtained based on specific participant characteristics or neoplasia status. The goal is to recruit 1,000 asymptomatic, average risk participants annually. Results: Over 650 individuals have been recruited to date.

HSR 30

Public Support for Tissue Banking

Patrick Adegbuyega¹, Mylinh Smith¹, Christi Eugene¹
¹Feist Weiller Cancer Center, LSU Medical Center, Shreveport, LA, USA

Background: In this emerging genomic research era, availability of tissue samples is an essential key for the success of basic translational research, hence the establishment of biorepository units for tissue and serum banking. However, the success of the biobanks is largely dependent upon the goodwill of the public. Therefore we carried out this study to evaluate the support of an American general public for tissue banking for biomedical research; and to assess the willingness of patients to donate their tissue samples for future research. Method: The study consists of patients who underwent surgical resection of a tumor at an American public university medical center between October 2006 to December 2009. The patients were solicited to donate their tissue samples to be banked for unspecified future biomedical research. They were also provided with the options to opt-out of the program whenever they choose to do so, with no questions asked (opt-out plus consent
Building a State-of-the-Art Biobanking Infrastructure: The Genome Quebec and Chicoutimi Hospital/Ecogene-21 experience

Nancy Tremblay1, Céline Lefebvre1, Martin Lambert1, Daniel Rivard1, Daniel Gaudet1, Steve Arsenault1  
1Genome Quebec and Chicoutimi Hospital/Ecogene-21 Biobank, Chicoutimi, Quebec, Canada; 2Chicoutimi Hospital/University of Montreal, Chicoutimi, Quebec, Canada

Background: Implementing a biobank represents an important challenge and many elements need to be addressed, among which personnel, governance, technologies, automation, workflows, versatility, throughput, redundancy and capacity. The GQ Biobank is an infrastructure comprising different off-the-shelf systems operated by highly qualified personnel using standardized procedures. Methods: The GQ Biobank includes technological platforms implemented to process and store a variety of sample types in various conditions and on different sites. Refrigerators and freezers: Primarily used for temporary to mid-term storage, this platform accommodates a wide range of needs for many different specimen types at temperatures ranging from 80°C to 4°C. Cryopreservation: Comprised of several liquid nitrogen cryocontainers, it is primarily used for long-term storage of several sample types within straws or cryovials. Controlled ambient temperature storage: Fully automated, this platform is suitable for long-term storage of a variety of samples such as DNA, RNA and proteins. Sample processing: Diverse sample handler systems and validated manual procedures were implemented to process and track hundreds of samples every day. R&D: Development of new technologies, robotics, information systems and procedures. Training: Development and maintenance of qualifications of highly qualified personnel. Results: The GQ Biobank provides short and long-term storage solutions with flexibility regarding storage conditions and sample types, and a capacity of tens of millions of samples. Conclusion: By selecting or developing a combination of storage technologies that minimize operating costs and maximize versatility, the GQ Biobank constitutes a sustainable infrastructure having the potential to grow according to the needs of users of today and tomorrow.

HSR 32

The Canadian Tumour Repository Network (CTRNet): Development Plans to Advance the Discipline of Biobanking in Support of Cancer Research

Rebecca Barnes1, Spencer Gibson2, Anne-Marie Mess-Masson3, Michael Sawyer4, Brent Schacter2, Lois Shepard5, Peter Watson1, Brent Zanke6  
1BC Cancer Agency, Victoria, BC, Canada; 2University of Manitoba, Winnipeg, MB, Canada; 3FRSQ Cancer Research Network; Centre de recherche CHUM, Montreal, QC, Canada; 4Alberta Cancer Board, Edmonton, AB, Canada; 5Queen's University, Kingston, ON, Canada; 6Ontario Institute for Cancer Research, Toronto, ON, Canada

Founded in 2003 through funding from the Canadian Institute for Health Research, CTRNet's mission is to improve capacity and quality of cancer biospecimens and associated data through standardization and improvement of biobanking processes. CTRNet does not fund or direct tumor banks but seeks to leverage its expertise and effort in creating national standards and harmonization mechanisms to increase the ability of cancer researchers to utilize these resources. Specific achievements include developing a comprehensive set of policies and SOPs; creating a database to support all aspects of cancer biospecimen annotation and biobank operations (Advanced Tissue Information Management-ATiM); and launching a web-based biospecimen catalogue to enhance access. CTRNet has also contributed to harmonization of international biobanking and benefited from linkage to similar initiatives in the international community.CTRNet is entering the next phase of its development. Plans include: 1) Expanding its scope and size through broader membership of existing biobanks and assisting development of new Canadian biobanks; 2) Maintaining and improving existing policies/SOPs and developing new ones; 3) Facilitation of purpose-designed prospective collection including developing a densely annotated Biospecimen Science Research cohort to enable future analyses on influences of pre-analytic variables on biospecimen quality; 4) Developing Certification, Training and Education programs in conjunction with ongoing centralized sample quality assurance services for all member banks; and 5) Refining ATiM and the biospecimen catalogue to enhance capabilities for tracking specimen release, utilization and costs.CTRNet continues to focus on developing the necessary infrastructure for high-quality and high-capacity biobanking in support of cancer researchers' changing biospecimen needs.
HSR 33

Biospecimen Use and Emerging Techniques in Cancer Research Over Two Decades

Peter Watson¹, Alexandra Cole¹, Rebecca Barnes¹
BC Cancer Agency, Victoria, BC, Canada

Background: Cancer biospecimens hold the key to unlocking the mechanisms of cancer development and progression. The demand for tissue biospecimens has increased threefold over the last 20 years, with the most significant demand for formalin-fixed paraffin-embedded tissues (FFPE). We set out to address the hypothesis that emerging research techniques drive these observed biospecimen trends.

Methods: We analyzed 262 publications encompassing papers published at five-year intervals (2008, 2003, 1998, 1993, and 1988) in the journal, Cancer Research. We categorized publications for tissue biospecimen utilization, biospecimen format type (Frozen, FFPE and fresh), extract type (RNA, DNA, protein and cells) and assay techniques.

Results: We observed that the mean number of techniques performed per publication did not change over the last 20 years. However, significant changes in the proportions of techniques using a specific extract type were observed. These changes correlated with the proportion of techniques which require FFPE tissue. Significant changes were also observed in types of techniques. Further analyses will be performed to look at the relationship between trends in techniques and biospecimen format.

Conclusions: Techniques such as the TMA, PCR, RT-PCR and increased use of cell lines are likely driving the observed shifts in tissue biospecimen formatting. Conclusions from this report are intended to assist biobanks in understanding historical trends and to project future trends in biospecimen needs that will materialize as a result of emerging technologies. Consideration of research trends and emerging technologies will aid biobanks in decisions around priorities for biospecimen accrual and optimal preservation format.

HSR 34

Essential Factors for Establishing a Tissue and Serum Repository: The Feist Weiller Cancer Center (FWCC) Experience

Patrick Adegboyega¹, Christi Eugene¹, Mylinh Smith¹
¹Feist Weiller Cancer Center, LSU Medical Center, Shreveport, LA, USA

The need for high quality human tissue and serum samples for translational research is increasing, but access to such samples continues to elude many researchers. Therefore, FWCC established a Tissue and Serum Repository (TSR) that provides for all interested investigators, equal access to human tissue and serum samples. Method: The following factors were put in place: 1. A full-time pathologist dedicated to tissue banking program. 2. Personnel for recruiting and consenting patients. 3. Couriers for timely transportation of surgical specimens from operating rooms to pathology dissection suites. 4. Interdepartmental cooperation between FWCC, Department of Pathology, and surgeons. 5. Active involvement of surgery and operative room nurses. 6. Reliable computer-based tissue inventory system. 7. A histopathology laboratory. 8. Funding underwritten by the FWCC.

Results: • Co-operation between all stakeholders. • High recruitment rate: 97% (2,116 of 2,191 patients) assented to donate their tissue sample for future biomedical research. • Timely transportation of surgical resection specimens from operating room to pathology dissection suite. • Expert handling of specimens to ensure diagnostic workup of the specimens is not compromised. Not a single complaint received from pathologists—with more than 2,000 specimens examined for potential tissue banking over a 40 month period. • Free access of the TSR personnel to surgical resection specimen. • Prodigious banking of tissue samples for future biomedical research with 16,430 pieces of frozen tissue samples banked.

Conclusion: The FWCC tissue and serum banking model is an efficient and workable model for successful establishment of a Tumor and Serum Repository.

HSR 35

Biobanking Transgene Products and Biodrugs in Clinical Trials: From Drug Production to the Patients

Julie Méthot¹, Céline Lefebvre¹, Steve Arsenault¹, Daniel Gaudet¹
¹ECOGENE-21 Clinical Trial Center, Chicoutimi, Quebec, Canada

Background: The term “biodrug” refers to bioactive substances used for disease prevention or treatment. Biodrugs include vaccines and monoclonal antibodies against microorganisms or complex diseases (cancer, diabetes, ...), transgene products (gene replacement therapy), viral capsids or bio-shuttles used for drug delivery, siRNA (anti-sense therapy), protein transcription factors, nutrients and other bio-particles.

The number of trials assessing the innocuity and efficacy of biodrugs is exponentially increasing. The storage and management of biodrugs, from pharmaceutical production to clinical sites and patients’ delivery raise very specific challenges. Methods and results: The Ecogene-21 clinical trial center and the Genome-Quebec/Chicoutimi Hospital Biobank are developing a good-clinical practice (GCP)-certified toolbox for the management of biodrugs in clinical trials (from Proof of concept to phase I-III studies). The toolbox covers the critical path from shipment by the pharmaceutical industry to the clinical site and from the site to the
patient: handling and transportation, storage conditions, bio-sample preparation and administration, drug excess recovery and bio-wasting. Standard operating procedures (SOPs) covering the audit trail, automated biobanking technologies and information systems were developed by a transdisciplinary, GCP-trained team with experience in clinical trials, technology development and biobanking. The toolbox has been tested in phase I/II and II/III gene therapy (associated adenoviral capsid), anti-sense therapy and nutritional trials. This allowed the step-by-step improvement of the SOPs and the development of adapted technologies. Conclusions: To assess the efficacy and innocuity of transgene products or adapted technologies.

HSR 36

The Netherlands Twins Register: Establishment of Shared Biological Resources for Longitudinal Population Studies of Adult Twins and Families

Ryan Winters1, Andrew Brooks1, Michael Sheldon1, David Toke1, Amrik Sahota1, Diane Huynh1, Qi Wang2, David D’Ambrosio2, Paul Van Hummelen2, Jay Tischfield1, Dorret Boomsma3, Gonneke Willemsen3, Eco de Geus3, Douglas Fugman1
1Rutgers University Cell and DNA Repository, Piscataway, NJ, USA; 2Bionomics Research and Technology Center, Piscataway, NJ, USA; 3VU University, Amsterdam, The Netherlands

Background: The Netherlands Twin Register is a longitudinal study of adult twins and their family members, started in 1987 by Prof. Boomsma and colleagues, to provide biological specimens for a variety of behavioral and epidemiological genetic analyses. Over 22,000 participants were enrolled through the 1990’s. From 2004 through 2008 blood samples were collected from over 8,400 participants for DNA and RNA extraction, plasma isolation, and cryopreservation of lymphocytes. In 2009 the NIMH awarded funding to the Rutgers University Cell and DNA Repository to convert the CPLs into lymphoblastoid cell lines, extract genomic DNA, extract RNA from stored frozen PaxGene blood tubes, and amplify cDNA in order to establish shared biological resources. Methods: CPLs were thawed and transformed into culture on a layer of irradiated MRC5 cells and expanded for cryopreservation of LCL stocks and DNA extraction. Cultured cells were extracted on a Qiagen AutoPure LS DNA extractor. Total RNA was isolated on a Qiagen Universal liquid handling system using a modified Qiagen RNAeasy protocol. The total RNA and miRNA fractions are stored independently in a Microtic 2D tube storage system. A small amount of total RNA was utilized to linearly amplify cDNA that will be distributed for qPCR, microarray, RNAseq and other gene expression applications. Conclusion: These biological resources and extensive phenotypic data will provide an invaluable resource for the investigation of genetic determinants in mental and physical health.

HSR 37

Response Rate for the Expanded Breast Cancer Registry and Tissue Repository (EBCR) at the University of New Mexico Cancer Center (UNM CC)

Angela Meisner1, Therese Bocklage1, Anne Marie Wallace1, Melanie Royce1
1University of New Mexico, Albuquerque, NM, USA

Background: The EBCR began recruiting breast cancer patients in 2006 from the UNM CC. Clinically annotated sera, plasma and DNA at baseline and 1 and 5-years thereafter, as well as excess fresh frozen tumor and normal breast tissue at surgery are collected. Methods: Eligibility criteria include diagnosis within 1 year of definitive surgery at any stage, 18 years old or older, and expected follow-up at UNM CC. All eligible patients have at least 24 hours to consider participation. We reviewed race/ethnicity and zip code from all eligible patients in the UNM CC eVelos system. Results: From 2006 to 2009, 429 eligible patients were approached. Within race/ethnic group 12.6% non-Hispanic white, 14.0% Hispanic, 37.0% Native American refused participation. Patients who refused were more likely to live in the Albuquerque metro area (77.1%) and northeastern New Mexico/northern Arizona (17.2%). The latter region corresponds with a large Native American population. Reasons for refusal: not interested (51.4%), passive refusal (15.7%), ‘too overwhelmed’ (10.0%), confidentiality concerns (4.2%), and other (18.7%). Response rates fluctuated by year and recruiter: 2006=93.2% (A), 2007=84.5% (A,B), 2008=69.1% (B,C), 2009=72.2% (C,D,E). Most recruiters were Hispanic and fluent in both Spanish and English. All were female, and of similar age, experience and training. Conclusion: Our analysis confirms previous literature that Native Americans are more likely to refuse participation in research than other race/ethnic groups. Differences in a recruiter’s style affect the response rate. We plan to investigate new ways to train recruiters, encourage more active physician involvement, and follow-up with the Native American community.

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HSR 38

Best Practices for Ensuring the Integrity of Samples Collected for Long-term Medical Research

John Mills¹
¹BioStorage Technologies, Indianapolis, IN, USA

There are now over 250 biobanks in Europe, which represents a dramatic increase over the last decade. This has been driven by the realization that well annotated and properly consented samples can give significant insights into the etiology of diseases and their treatment. Such samples can only retain their value if their integrity is uncompromised and since they may be kept for many years, temperature sensitive samples must be maintained in specialized environments. The curator of these collections is responsible for the implementation of standardized best practices and procedures, and should embrace advances in cold chain and monitoring technologies. Such Good Storage Practice will be highlighted in the poster presentation, including:

- Excellence in cold chain logistics with correct packaging and temperature monitoring.
- Assurance of adequate equipment temperature mapping and maintenance.
- Well defined data collection policies and appropriate sample annotation.
- A fully scalable inventory management system with an automated auditable history in compliance with 21 CFR Part 11.
- Aliquoting of samples that are likely to be examined repeatedly.
- Digitized temperature monitoring that links temperature history immediately to the sample.
- Internal inventory audits by QA department.
- Business continuity planning ranging from redundant equipment to emergency backup power.
- Full attention to all aspects of health and safety in the repository. Ultimately the conclusions drawn from the analysis of stored samples will have impact on patient treatment and safety. It is therefore an ethical responsibility to ensure standards of excellence are maintained in storage practice.

HSR 39

BIOBUS – Taking the Laboratory to the People

Robyn Woods¹, Emily Parker¹, John McNeil¹
¹Monash University, Melbourne, Victoria, Australia

Background: The ASPREE Healthy Ageing Biobank aims to collect biospecimens from up to 10,000 healthy Australians who are 70 years of age or older and who have agreed to participate in the ASPREE study. ASPREE (ASpirin in Reducing Events in the Elderly) is a double-blind, placebo-controlled clinical trial of low dose aspirin for primary prevention of major disease in the elderly. The biospecimens will provide the opportunity to evaluate new preventative biomarkers associated with outcomes of interest, over time. This is the only Biobank in the world to be focussing on older persons. To obtain samples of the highest quality bloods need to be collected, processed and stored within 4 hrs. If Biobank participants are not willing to come to a specialist laboratory, we need to take the laboratory to the people. This is particularly an issue for older persons. A mobile laboratory (the ‘BIOBUS’) is to be commissioned that will also serve as a mobile assessment clinic in both metropolitan and rural areas.

Methods: A Mercedes Benz Sprinter van will be outfitted with non-porous bench tops and flooring, refrigerated centrifuge, mobile LN₂ vapor phase storage tank which is safe to transport, back-up generator, clinical examination table and many other laboratory features and equipment.

Conclusion: The BIOBUS will provide the necessary link between the research laboratory and the community for ASPREE and further community-based trials. This is particularly advantageous for studies involving older people who do not have the mobility or confidence of younger people to attend new environments.

HT 01

Using Automation and Lean Transformation to Drive Efficiency in the Lab

Nicole Nelson¹
¹Brady Corporation, Milwaukee, WI, USA

Background: Do more with less… gain efficiency in your lab through automation, labeling and lean transformation. The healthcare community is in the process of adopting barcode technologies and lean practices at an increasing rate to replace the use of manual data entry and wasteful practices. Methods: Learn how labs can save time, improve efficiency and reduce errors to meet biobanking best practices, improve patient safety and track chain of custody by using visual clues, bar coding, sample labeling and quality improvements. There is a simple way to navigate through the challenges of setting up a barcode system. In addition to these implementation challenges, we will cover solutions to lab labeling for processing and storage environments that are extreme and can create real obstacles. Highlights from NCI Best Practice Whitepaper on Specimen Tracking will be covered. Beyond automation, labs can use lean tools and methodology to increase productivity by streamlining the flow and reducing waste through understanding waste, process mapping and 5S techniques. Results: Using hands on exercises and examples of labs you will see how they have made improvements to their work-flow and sample tracking that will provide real benefits back to your constituents such as physicians, hospitals and to the patient community. We will highlight these rewards by implementing a coherent process for labeling samples in the laboratory. Conclusion: By focusing on the overall picture, turn around time or cycle length is
immensely reduced and the results are increased quality and worker optimization in the lab.

**HT 02**

**Disease Advocacy Organization-initiated Biorepositories and Registries – an Exploratory Survey**

Elizabeth Horn1, Tierney Mancuso1, Sharon Terry1
1Genetic Alliance, Washington, DC, USA

Background: Disease advocacy organizations (DAO) are actively involved in establishing and managing biorepositories and registries. Methods: To gain a better understanding of their roles and to assess training needs, Genetic Alliance BioBank conducted an exploratory survey in December 2009, and 37 DAOs responded. Results: Approximately one-third have biorepositories (33%) or registries (41%), and many have been in operation for more than 5 years (50% biorepositories, 75% registries). These resources are DAO-established (67%) and owned (53%). DAOs are involved in recruiting participants (94%), obtaining informed consent (61%), providing financial support (56%), and fundraising for financial support (56%). DAO-initiated biorepositories collect a variety of sample types, including blood (72%), frozen tissue (56%), formalin-fixed tissue (50%), cell blocks (28%), and cell lines (22%), while 81% would like to collect additional sample types. Samples are primarily used for DNA/genomics analysis (64%) compared to protein/immunohistochemistry studies (14%) or RNA expression studies (7%). Most samples are stored in university labs (57%), but some are stored in commercial labs (21%), non-profit organizations (21%), or government labs (7%). DAOs who do not currently have these resources are interested in creating biorepositories (65%) or registries (86%). When asked about training needs, fundraising strategies (79%), public relations strategies (65%), and examples of successful advocacy-initiated registries and biorepositories (62%) were among the most requested. Conclusions: DAOs are playing integral roles in biorepositories and registries. It is important to understand these roles and provide training opportunities to assist DAOs in navigating the scientific landscape.

**HT 03**

**Southeast Tissue Alliance: The Role of Cadaveric Tissue Recovery and its Relationship to Post Mortem Tissue Research**

Lisa Miranda1, Norman Seavers2, Michael Scott2
1Biobusiness Consulting Inc, Lowell, MA, USA;
2Southeast Tissue Alliance, Gainesville, FL, USA

Post mortem tissue procurement has been well utilized for a number of applications including brain related research, medical education, tissue allograft for transplantation, ocular therapies, and other biomedical innovations. Tissue provided through post mortem procurement offers substantive options for a range of biomedical research applications. Normal & diseased post mortem tissues suitably supplement sometimes scarce surgical tissue collections for organs i.e. prostate, breast, and metastatic bone and offer opportunities for biomarker as well as biospecimen science related research. It is, however, vital that there are controls for post mortem interval related ischemia and other acquisition variables, and that the samples are assessed for quality, and annotated appropriately. Careful orchestration is required to support fresh, frozen and fixed tissue collection. Tissue recovery, both arduous and challenging, requires recovery technicians ideally certified tissue banking specialists (CTBS) on 24-hour call to manage prerequisite logistical hurdles. Constant communication is required with recovery team partners i.e. health care institutions, medical examiners and funeral facility personnel to 1) minimize recovery times 2) assure due diligence from consent through procurement and preservation, and 3) respect the funeral and closure needs of donor families. Experience demonstrates that staff responds best by understanding the value proposition behind the beneficence of donation for research. While the future appears bright for post mortem research applications, collaborative studies are still needed to define and validate tissue quality parameters. This role would be complimented via industry and academic partnerships allowing for shared expertise of lessons learned from cadaveric recovery, dissection and processing.

**HT 04**

**The Use of Biomarkers in Secondary Analysis – Research Models to Comparatively Organize Biomedical Information**

James McNally1, Martha Sayre1
1University of Michigan, Ann Arbor, MI, USA

Purpose: This poster presents results from a study that seeks to develop research models that allow for the comparative use of similar biomedical indicators across multiple data sets. While an increasing number of studies collect and release biomarker and biometric information in the form of secondary data it is often unclear if measures can be compared across studies due to differences in protocols, essays performed and results reported. This project attempts to introduce some structure within the existing body or research data. Methods: We perform a thorough review of existing secondary data sets in the public domain and categorize them according to how they are organized and presented as analysis variables. We examine the related published research literature using these
Six Degrees of Separation: Growing Research Intersections Between Bio-Data-Repositories and Traditional Bio-Repositories

Martha Sayre¹, James McNally¹
¹University of Michigan, Ann Arbor, MI, USA

This paper builds on work presented at the 2009 ISBER Meetings on the efforts by the National Archive of Computerized Data on Aging (NACDA) to build an understanding of the science underlying organization and preservation within a formal specimen repository. NACDA, the nation’s largest repository of secondary research data on aging and health is currently building a registry system to identify studies that use biomeasures and biospecimen data in their research design. Within our existing collection of 1,600+ studies we have identified studies utilizing biospecimen collection in over 500 individual surveys. With the growing number of federally funded social science based surveys now collecting biospecimens as part of their research design NACDA is actively building relationships with formal bio-repositories and building an understanding of how our methods intersect with traditional approaches to the archival sciences. Our core finding is that this process of understanding has only just begun and interacting with biospecimen researchers is central to our continued growth. The paper addresses our growing understanding of the commonalities that exist in our common approach to information and data management. Both bio-repository and data-repository researchers face similar challenges and objectives; working to strengthen these intersections among preservation specialists in serving our respective user communities will continue to strengthen multidisciplinary research on biomedical and biosocial issues. The growing collaborations between the biomedical and the social scientists argues that the preservation specialists who protect and maintain the product of these joint research efforts for future generations likewise need to strengthen their relationships.

Banked Mammalian Cell Cultures as a Wildlife Conservation Resource

Eric Harley¹, Paul Bartels²
¹University of Cape Town, Observatory, Western Cape, South Africa; ²National Zoological Gardens, Pretoria, Gauteng, South Africa

Introduction: A component of BioBank SA is a collection of mammalian skin fibroblast cultures secured in liquid nitrogen for trans-disciplinary use. Most of the specimens were collected from animals caught in the wild from various localities, predominantly in southern Africa, over the last 30 years. Method: Skin biopsies were cleaned, chopped into small pieces and placed into petri-dishes containing culture media, covered with a glass cover slip and cultured to confluence in a CO₂ incubator. Cells were placed into cryovials and frozen at -80 °C before being stored in liquid nitrogen. Results: Samples held include 20 different species of bovid, 7 different cetacean species, 5 felids, black and white rhinoceros, African Elephant, Hippopotamus, Hyaena, Plains and Mountain zebra, Small and large spotted genet, common molerat and chacma baboon. Conclusion: Uses include: molecular systematic studies (e.g. Science 317 (2007) 519 – 523.); molecular population genetic analyses where there are sufficient numbers of individuals stored (e.g Molecular Ecology 14 (2005) 2981-2990) - the value of wild-caught animals of known provenance being essential here; comparative metabolism (e.g. Comp. Biochem. Physiol. 110B (1995) 37-46); and hybrid identification here; comparative metabolism (e.g. Comp. Biochem. Physiol. 110B (1995) 37-46); and hybrid identification using karyotyping and/or microsatellites (e.g. Conservation Genetics, 6 (2005) 141-145). Examples in each of these categories will be given. Of especial relevance to conservation of endangered species is the potential of using cloning technologies on previously banked cells to retrieve different individuals from a population or species which has become recently extinct or is close to extinction.

A Persistent Dilemma - Legal /Ethical Issues Associated with Informed Consent and Genetic Testing in Dementia Research Biobanks

Rivka Ravid¹
¹Netherlands Institute for Neurosciences / KNAW, Amstelveen, noord Holland, The Netherlands

Background: International research codes require researchers to obtain the informed consent of subjects before starting a study. This requirement poses special challenges in conducting dementia research. The cognitive capacities of the patients vary widely; individuals in early stage of the disease can make their
own choices whereas individuals with severe impairment will be incapable of making the informed choice. Methods: Genetic research, e.g. linkage analysis studies, raise serious ethical problems and complexities; the collection of patient-related data for the researchers is often in conflict with the use and implications of this information for the providers, the families and the patients involved. Results: The links we find between genes and neurological diseases, create a heavy burden on physicians, health care workers, Bio-bankers and researchers. The outcome of studies in Huntington’s diseases, the Apo-E genotyping in AD and chromosome 17-Frontal temporal Dementia (17-FTD) pose a heavy load on the afflicted individuals and their families. Conclusions: Genetic testing often has a limited predictive value and should be accompanied by counseling for the families. It can be psychologically incapacitating, especially because currently there is no treatment or cure for most cases. Early diagnostic tests may prove extremely useful when treatment becomes available which makes the information obtained by genetic testing essential for the scientific effort to develop the right therapeutic strategies. As many of the molecular genetic studies are performed by international collaborative efforts, it would be advisable to have a global consensus on the legal/ethical codes of conduct.

**LE 02**

**General Consent to Store Human Biospecimen and Data for Future Research at Hospital Admission: A Pilot Project in Switzerland**

Daniel Simeon-Dubach¹, Nicole Probst-Hensch², Michelle Salathe³, Hans-Anton Lehr⁴, Jean-François Delaloye⁵, Bernice Elger⁶

¹Foundation Biobank-Suisse, Bern, Switzerland; ²University of Basel, Basel, Switzerland; ³Swiss Academy of Medical Sciences, Basel, Switzerland; ⁴CHUV, Lausanne, Vaud, Switzerland; ⁵University of Geneva, Geneva, Switzerland

Different types of biobanks located in or linked to hospitals store a great number of human biological materials. These specimens are of immense value for research, especially when linked to patient data. A major barrier to research involving these biospecimens is that often consent for the use of these biospecimens is not obtained when the specimen is taken or the consent is limited. A working group including all major stakeholders in Switzerland developed a standardized general consent form to be used routinely at admission or during hospitalization, in Swiss hospitals. It seems ethically sound and feasible to discuss with all patients whether they agree that their reversibly anonymised biospecimens and data may be used for future medical research, and without having to contact them again for any new research project. In our standard consent form we have deliberately not addressed the “right to know or not to know”. We will present arguments for this decision (i.e. non-predictability of research results generated with genome-wide array chips, questionable clinical “relevance” of novel findings, medical qualification of researchers, etc.) and we will discuss the potential role of IRBs and of the treating physicians in this complex scenario. The proposed informed consent form underwent an extensive review by major stakeholders in Switzerland including the medical, legal and administrative departments of the University hospitals. Implementation of this consent form will start in 2010. We will follow this process to identify possible barriers to this type of general consent research involving human biospecimens and data.

**LE 03**

**Challenge and Triumph Utilizing Fresh Human Tissue Samples in Oncology Drug Absorption Studies**

Iain Haslam¹, Tracey Randall¹, Derek O’Reilly², David Sherlock², Ambareen Kauser², Jacqui Aitchison¹, Chris Womack¹

¹AstraZeneca, Macclesfield, Cheshire, UK; ²North Manchester General Hospital, Manchester, Lancashire, UK

Background: Predicting the impact of intestinal absorption on overall fraction absorbed (Fabs) following oral dosing is a significant challenge in the drug discovery setting, given variability in commonly used pre-clinical species. Access to human intestinal tissue for laboratory investigations would allow direct assessment of gut absorption in man prior to clinical dosing. The challenge is logistical but preliminary laboratory results indicate that the endeavour is worthwhile. Methods: Whipples (pancreatoduodenectomy) surgery was identified as the most likely source of tissue suitable for study. The processes required to collect fresh intestinal tissue from resected samples in the operating theatre were not covered by existing procedures. Consent procedures were established, governance requirements were agreed with the hospital’s (Pennine Acute Trust) research and development (R&D) department and independent study specific ethical approval was obtained. Intestinal tissue was collected in a physiological preservation solution and couriered to the research laboratory for immediate Ussing Chamber investigations into drug permeability.

Results: The study took approximately 15 months to establish from initial enquiries to receipt of first sample. Subsequently 12 samples were obtained within a 5 month time frame. The tissue was assessed to be functionally viable with maintained integrity during transport and over the experimental time-course. Results have yielded strong correlations to equivalent results generated in rat small intestine. Conclusions: The study successfully established a method for acquiring and utilizing fresh human intestinal tissue for drug absorption investigations. Future studies will aim
to expand on the uses for the excised tissue to investigate other intestinal processes.

**LE 04**

**A Highly Effective Model for Reducing Delays in the Ethics Approval Process Related to the Acquisition and Use of Tissue Bank Materials**

Ida Rabbani¹
¹University of Calgary, Alberta, Canada

Background: Project reviews by Research Ethics Boards (REBs) can significantly delay research studies. Reviews by our REB can take up to 5 months, often requiring revisions. Our aim was to develop a strategy to reduce delays associated with ethics approval and enhance the function of our Intestinal Inflammation Tissue Bank (ITTB). Methods: A model was developed in which the REB allowed patients to be consented and have their tissue directly entered into the ITTB. We then developed three broad projects that encompass all foreseeable studies by our affiliated researchers. In short the projects were: 1) inflammatory regulators, 2) apoptosis-tight junctions and, 3) host-microbial interactions. REB approval was obtained for these projects. To initiate a new proposal, investigators are only required to submit a 1 page addendum to one of the above studies to the REB.

Results: Since instituting this model, 29 projects were submitted in 2.5 years, all of were approved without revision with an average time of 19 days. This marked reduction (versus 5 months with a 20% revision rate) was favorably accepted by both the REB and the researchers. Conclusions: This model has been highly successful, allowing consent and collection from over 850 patients and providing tissue for the above projects, resulting in numerous high level publications and successful grant applications over the last two years. Efficiency of the ITTB played a key role in securing an interdisciplinary team grant from the Alberta Heritage Foundation for Medical Research for the development of the Alberta Inflammatory Bowel Disease Consortium.

**LE 05**

**Utilization of Archival Clinical Paraffin Blocks for Subsequent Clinical Care: A Review of Existing Literature and Implications for Biobank/Research Access**

Tyron Hoover¹
¹World BioBank, Memphis, TN, USA

Background: Archival clinical formalin-fixed paraffin embedded tissue blocks (FFPE blocks, or paraffin blocks) are a vast potential resource for medical research. In the U.S., a main impediment to accessing clinical FFPE blocks for research are sample retention rules imposed on clinical pathology laboratories by CLIA and CAP, requiring block retention for specified periods (2 and 10 years respectively). Pathology laboratories often, and justifiably, point to these rules when choosing not to participate in research projects requesting clinical FFPE blocks. The question: Are there reported, non-anecdotal, studies demonstrating usage rates of archival clinical FFPE blocks for subsequent clinical care, for which ostensibly the regulations exist? Methods: Three sources were examined: (1) CLIA, (2) CAP regulations, and (3) existing medical literature (Pubmed). Results: CLIA provides no rationale for its retention requirements. CAP regulations, differing substantially from CLIA, provide no clues about usage rates or rationale for retention requirements. There are no studies in the medical literature reporting usage rates of archival clinical FFPE blocks. Conclusions: No published data exists regarding usage rates of archival clinical FFPE blocks. The rules requiring pathology laboratories to retain these were implemented decades ago, long before many current FFPE-based research methodologies existed. It is perhaps time to examine the benefit v. risk of releasing archival clinical blocks for research. First steps should include examination of current usage rates of archival blocks for subsequent clinical care and a subsequent reassessment of CLIA and CAP rules pertaining to retention requirements.

**LE 06**

**Cross-Border Exchanges of Human Biological Samples for Research Purposes: hSERN, a New Tool for Information on Regulation**

Gauthier Chassang¹, Aurélie Mahalatchimy¹, Emmanuelle Rial-Sebbag¹, Anne Cambon-Thomsen¹
¹Inserm, Toulouse, France

Exchanging (import/export) human biological samples is an important step for collaborative medical research within and outside Europe. Such exchanges must comply with heterogeneous National, European and International regulations. In this context, hSERN, “human Sample Exchange Regulation Navigator”, is a web based tool providing theoretical and practical information on legal and ethical requirements for transnational exchange of human samples for research uses. Initiated within the European GA₂LEN network of excellence (FP6) it is now further developed in connection with BBMRI (Biobanks and BioMolecular European Research Infrastructure). The beta version of hSERN is available online at http://www.hsern.eu/. This tool is dedicated to research institutions, to researchers and to anyone interested in the regulation of such exchanges. hSERN is based on the analysis of the relevant texts, namely: International regulation issued by several organizations (WHO, Council of Europe…), European Union’s regulation (such as Directive 2004/23/EC…) and national legal frameworks.
on medical research of the 27 Member States of the European Union; 4 countries are fully documented so far (Belgium, France, Spain and UK) and 7 others partially. Legal experts in each country are validating the information presented in a systematic way. The structure and functionalities of this tool and the issues encountered will be described. This tool is provided freely to the scientific community; it is oriented towards offering clear information on heterogeneous regulation and its systematic and transparent organization, as a first step of the global harmonization that is difficult to reach with so many variable regulations.

MR 01

A Molecular Collections Facility for the Natural History Museum (NHM) London

Jacqueline Mackenzie-Dodds1
1The Natural History Museum London, London, UK

Background: Molecular research at the NHM plays a major role in resolving questions on the diversity of life. Plants and animals are collected for traditional dry or alcohol preservation, and as a long term resource for molecular analysis. Molecular products are also extracted from ‘traditional’ collections. The NHM is developing new ‘molecular collections’ (in parallel to the ‘traditional’ collections) for future use beyond its own research programmes, making them accessible to the wider community and ensuring their long term value to science. Developments in the techniques of molecular biology, including next generation DNA sequencing, create exciting research opportunities and drive forward the need to preserve biological samples for study by future generations. Results: The NHM molecular collections have been managed by individual scientists and their research teams. New infrastructure, management and curation is now planned to accommodate existing and future collections and to integrate their development and management with the traditional collections. To ensure this, the NHM will build a central specialized storage facility within easy access of the NHM’s research teams and the traditional collections. Conclusions: Future-proofing the facility requires international legal compliance, identification of optimal storage methods, global standards, best practice and incorporation of new science and IT technologies. Exchange of knowledge in all these areas among partner institutions is vital to promote global sharing of genetic data. Our poster attempts to contextualize the current position of the molecular collections at NHM London within existing global networks of molecular initiatives.

NIN 01

STORE – Sustaining access to Tissues and Data from Radiobiological Experiments

Mandy Birschwilks1
1Federal Office for Radiation Protection, Neuherberg, Germany

The sharing of data and biomaterials from publicly funded experimental radiation science will yield substantial scientific rewards through re-analysis and new investigations. To that end, the STORE Consortium will create a platform for the storage and dissemination of both data and biological materials from past, present and future radiobiological research. The project will be completed by an assessment of viable financial models for long term support of a bioresource and Data Warehouse for radiobiology. The strategy to achieve these goals is multi-level: 1) To provide a “one-stop-shop” portal integrating international databases and other repositories currently active, such that the user can find material and data held remotely. 2) To archive primary (raw) data or pointers to data in public databases, from radiobiological experiments and studies. This resource will be open to individual investigators and to funding agencies as a potential central repository for data sharing. 3) To physically archive threatened material resources which are considered to be a valuable resource to the Community, and whose state of preservation is consistent with STORE benchmarks. 4) To provide a single point of access to the integrated biomaterial resources through standardized request procedures.STORE will provide a single online portal to radiobiological information that is presently distributed over scientific centres worldwide, and it will provide the necessary SOPs for the evaluation of archived tissue usability.

NIN 02

The European Radiobiological Archives: Online Access to Data from Radiobiological Experiments

Mandy Birschwiks1, Clemens Adelmann1, Soile Tapio2, Michael Gruenberger3, Paul Schofield3, Bernd Grosche1
1Federal Office for Radiation Protection, Neuherberg, Germany; 2Institute of Radiation Biology, Helmholtz Centre Munich, Neuherberg, Germany; 3University of Cambridge, Cambridge, UK

Today’s research is providing us more and more with the opportunity to quantify radiation risks at the individual level. New approaches allow the re-analysis of old data using new techniques. Thus, the retrospective analysis of earlier studies is an important resource for modelling and evaluating risk parameters.
The European Radiobiology Archives (ERA), together with corresponding Japanese and American databases, hold data from nearly all experimental animal radiation studies carried out between the 1950s and the 1990s, performed on different species and involving more than 400,000 animals. The concept and preliminary work on a computerized database to store and index this huge amount of data was started by G. Gerber and has now been transferred to a web-based database to maximize its usefulness to the scientific community and achieve compliance of data coding and structure with currently accepted semantic standards for anatomy and pathology. The accuracy of the primary data input was assessed and improved, thereby detected errors were corrected with a low mean-systematic error rate of only 1.7%. The majority of the original rodent pathology nomenclature was recoded to Mouse Pathology (MPATH) and Mouse Anatomy (MA) ontology terms or a combination of both. The database is accessible online at https://era.bfs.de, and has the potential of becoming a world-wide radiobiological research tool for numerous applications, such as the re-analysis of existing data and as an information resource for planning future animal studies.

NIN 03

Australasian Biospecimen Network Association: Ensuring Australasia Biobanking Networks into the Future

Jane Carpenter¹, Anita Matusan², Melissa Barber³, Lisa Devereux⁴, Joanne Edgar⁴, Marion Macnish⁵, Warwick Murphy⁶, Daniel Catchpoole⁷

¹Westmead Millennium Institute, Westmead, Australia; ²Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia; ³Baker IDI Heart and Diabetes Institute, Melbourne, Victoria, Australia; ⁴Victorian Cancer Biobank, Carlton, Victoria, Australia; ⁵University of Western Australia, Crawley, Australia; ⁶Company, Clayton, Victoria, Australia; ⁷The Kids Research Institute, The Children’s Hospital at Westmead, Westmead, NSW, Australia

Background: Personnel involved in the operation of tissue banks in Australia and New Zealand recognized that their relatively small population coupled with large geographical distance would benefit from the formation of a national alliance. Due to limited funding, such networks are often project- or clinical trial driven. As the Australasian tissue banking network expands, the need for a more formalized structure became apparent and an autonomous networking structure was established to ensure continuity, independent of funding or project goals. Methods: A voluntary informal network of tissue banks was established in 2002: The Australasian Biospecimens Network. Successful annual meetings; recommended SOPs; and involvement in several Federal and State government review papers have contributed to the biomedical research landscape in Australasia. With the value of the network apparent, the decision was taken to formally constitute the network into an association. Results: The Australasian Biospecimen Network Association (ABNA) was incorporated in July 2009. To date it has attracted 80+ subscribed Australian and New Zealand members from diverse biorepository backgrounds. ABNA allows tissue banking professionals to come together to share relevant non-confidential information to assist improvement of operational efficiencies, provide education and technical assistance to individuals establishing biorepositories and provide a structure and focus within the broad biobanking community of Australasia. Conclusion: The evolution of an informal network of tissue banking professionals to a formal association reflects the development and maturation of tissue banking in Australasia. ABNA provides the stability of an independent association underpinning an international network of biobanks. 1 AJMS 2007; 28, 1, 16-20.

NIN 04

Global Repository for HD Research

Pasquale De Blasio¹, Ida Biunno², Giuseppe Diaferia¹, Cinzia Pellizzaro¹, Michele Piovella¹, Scott Megill³, Joseph Giuliano⁴, Suzanne Robertson⁵, Steven Madore⁶, Mithra Mahmoudi⁷, Beth Borowsky⁷, Sherry Lifer⁷, Roderick Corriveau⁷

¹BioRep s.r.l., Milano, Italy; ²National Council of Research, Segrate, Milano, Italy; ³Coriell Institute for Medical Research, Camden, NJ, USA; ⁴CHDI Foundation, Princeton, NJ, USA; ⁵University of Rochester, Rochester, NY, USA

Background: Biobanks or biorepositories are increasingly seen as an essential tool in translating biomedical research into real improvements in healthcare. The CHDI Foundation has established a secure, global biorepository that stores and distributes quality-controlled and reliable biomaterials to support Huntington’s disease (HD) research in a broad spectrum of research endeavours. Methods: The Coriell Institute for Medical Research in USA and BioRep in Italy have joined their biobanking expertise and together constitute a “Global Biorepository” to serve biomedical research and worldwide clinical trials. HD collections at Coriell include the HD Community BioRepository, COHORT, and MITO-HD with specimens from United States, Canada and Australia. BioRep houses Registry (EHDN, European Huntington’s Disease Network) and TRACK-HD samples. For the Registry network, BioRep collects and processes samples from 16 European countries and will soon include samples from Korea, Singapore, Russia and Turkey. Results: Together Coriell and BioRep have banked samples from more than 5000 different individuals for HD research. These collections include: lymphoblastoid cell lines (LCL), genomic DNA samples extracted from whole blood and from LCL, RNAs, urine samples, plasmids containing HTT cDNA.
with CAG repeats of known lengths, antibodies that react with HD-relevant antigens, and striatal or PC12-based cell lines. BioRep has also started the distribution of DNA samples to any researchers that request the material through the EHDN portal.

Conclusions: The Global Biorepository for HD Research facilitates international collection of biospecimens. This effort aims to accelerate discovery of biomarkers and new therapeutic agents to slow or delay onset of the disease.

NIN 05

The DNA Bank Network - A Shared Portal for Non-human Biorepositories, Providing Live References to DNA and Specimen Data

Holger Zetzsche¹, Gabriele Droega₁, Birgit Gemeinholzer⁷
¹Botanic Garden and Botanical Museum Berlin-Dahlem, Berlin, Germany

The partner institutions of the DNA Bank Network share their DNA data via a central webpage (www.dnabank-network.org). Scientific customers can search for and order DNA samples. The webpage provides full online documentation of each record. For this purpose multiple databases are connected live. Therby dealing with redundancy and copies to be updated can be avoided and verifications or metadata analyses can easily be accomplished. Whereas data like taxon information, collection details and voucher images of the organism from which DNA or tissue was taken are contributed from specimen databases. DNA data such as extraction method, DNA purity and quality are provided by DNA databases. Additionally, links to inferred molecular data are placed if those are published in sequence databases. Here, the structure of the webpage’s underling data architecture is presented. GBIF’s wrapper software DiGIR/DarwinCore and BioCASE/ABCD is used to transfer specimen data from multiple sources. The DNA Module was newly developed as an open source software to enter and manage DNA sample data by the partner DNA banks. Using unique identifiers DNA and specimen datasets can be referenced. To transfer DNA data via BioCASE a DNA extension of ABCD schema (ABCDDNA) was developed. The webpage currently offers data of four DNA banks associated to major biological research collections such as the Bavarian State Collection of Zoology (Munich), the German Collection of Microorganisms and Cell Cultures (Braunschweig), Zoologisches Forschungsmuseum Alexander Koenig (Bonn) and the Botanic Garden and Botanical Museum Berlin-Dahlem. The webpage is open for cooperation with further DNA banks worldwide.

NIN 06

CIBERES: Pulmonary Biobank Consortium

Cristina Villena¹, Jaume Sauleda², Francisco Pozo³, Julio Cortijo⁴, Andrés Esteban⁵, Antoni Rosell⁶, Joaquim Gea⁷, Joan Albert Barbera⁸, Germán Peces-Barba⁹, Eduard Monso⁰, Jordi Rello¹¹, Alvar Agustí¹²
1Spanish Respiratory Research Network (CIBERES), Palma de Mallorca, Balearic Islands, Spain; 2Hospital Universitario Son Dureta-CIBERES, Palma de Mallorca, Balearic, Spain; 3Hospital Universitario 12 Octubre-CIBERES, Madrid, Spain; 4Consortio Hospital General Universitario de Valencia-CIBERES, Valencia, Spain; 5Hospital Universitario de Getafe-CIBERES, Getafe, Madrid, Spain; 6Hospital Universitario de Bellvitge-CIBERES, Hospitalet de Llobregat, Barcelona, Spain; 7Hospital del Mar-CIBERES, Barcelona, Spain; 8Hospital Clinic-CIBERES, Barcelona, Spain; 9Fundación Jiménez-Díaz-CAPIO-CIBERES, Madrid, Spain; 10Hospital Universitario Germans Trias i Pujol-CIBERES, Barcelona, Spain; 11Hospital Universitario Joan XXIII Tarragona-CIBERES, Tarragona, Spain

Background: In 2008 the Spanish Respiratory Research Network (CIBERES) promoted the creation of a network structure for the systematic collection of lung tissue samples and clinical information to facilitate respiratory research. Ten tertiary Spanish hospitals joined the initiative. The objective of this platform is to standardize the methodology to obtain and preserve lung tissue, to assure that tissue samples are linked to full clinical, functional and imaging information of the patient and to create a bridge between hospitals and researchers. Methods: The first step was to agree with all participating hospitals the common management and methodology to be used. After the standard operating procedures were agreed, common database software was launched and the persons involved were trained. At each hospital thoracic surgeons, pathologists, pulmonologists and local biobanks participate in the activity of the platform. Results: One year after its launching, the CIBERES Pulmonary Biobank Consortium includes 4,700 aliquots from 250 patients. All of them required thoracic surgery for clinical reasons, mostly lung cancer. Samples are available to the entire scientific community (www.ciberes.org), provided that samples are used in a specific research project approved by an ethics committee, and that investigators agree in returning their raw data to the platform. In this way, it will not only be a repository of tissue but a source of information for future investigations. Conclusions: The CIBERES Pulmonary Biobank Consortium has established a hospital-based network for the systematic collection and preservation of lung tissue samples coupled to relevant clinical information under strict quality control criteria.
An Interactive Web Portal to Facilitate the Worldwide Networking Between Biobanks and Key Players in the Biomarker Field

Pascal Puchois¹, Jean Marie Sueur², Melissa Thompson³
¹Trans-Hit Biomarkers, Montreal, Quebec, Canada; ²Biobank of Picardie, France; ³Matrix Clinical Research Management, USA

Academic research laboratories and their Offices of Technology Transfer (OTTs) along with private research laboratories from pharmaceutical and diagnostic companies have the pressing need to get easy access to retrospective clinical sample collections to facilitate the discovery and to accelerate the validation of new biomarkers. A survey indicated that identification and selection of biobanks can be “challenging” for those seeking quality biospecimen collections. On the other hand, biobanks have the critical need to find new resources. Establishing a partnership with scientists who are developing new biomarkers is one option for biobanks who also wish to establish scientific collaborations. Therefore, expanding their ability to get international visibility becomes important. A new communication tool has been developed to offer keys players in the biomarker field an easy way to interface with each other. A website has been built offering a variety of services such as: regulatory requirements for biomarker development, appropriate animal models from reputed preclinical CROs, biomarker licensing opportunities offered by worldwide OTTs. This new website is visited by private and public scientists. It is an interactive web based tool to facilitate networking and connection between “seekers” of sample collections and biobanks. Functionalities of this free website service will be presented as well as results of our experience. The usefulness of this tool for biobanks to gain exposure and international appeal for their collection and to introduce their expertise by utilizing web based technology will be discussed.

Brassica Resource Bank (BRB)

Hee Kyung Kim¹, Yong Pyo Lim¹
¹Chungnam National University, Daejeon, South Korea

The genus Brassica, phylogenetically related to Arabidopsis thaliana, is one of economically important crops and a botanical model of plant polyploidization and rapid phenotypic evolution. We established the Brassica Resource Bank(BRB) in order to supply basic plant materials for structural/functional genomics and breeding of Brassica. BRB has served various Brassica species, especially, general germplasm, inbred lines, and DNA stocks including BAC libraries and cDNA libraries. All germplasms of BRB have been propagated and maintained. Currently, BRB has collected 9,689 accessions for Brassica species, 91,446 clones for cDNA libraries, and 277,440 clones for BAC libraries, and 1,398 genetic markers. BRB has served more than 621,345 clones, 280 genetic markers and 4,023 lines to researchers in 10 countries since 2003. Information and other requests for genomic resources of Brassica are accessible at http://www.brassica-resource.org.

Germlasm Cryo-banking: Recalcitrant-seeded and Poor-seeding Plants in South Africa

David Mycock¹, Patricia Berjak², Norman Pammenter², Sershen Naidoo², James Wesley-Smith², Paul Bartels¹
¹University of the Witwatersrand, Johannesburg, South Africa; ²University of KwaZulu, Natal, Durban, South Africa; ³National Zoological Gardens of SA, NRF, Pretoria, South Africa

Introduction: South Africa has a rich flora but many species are under major threat. Many of the plant species are either poor seeders or produce recalcitrant (desiccation-sensitive) seeds and cannot be stored conventionally. There are particular problems associated with successful germlasm cryostorage of tropical and sub-tropical plants. Method: Excised embryonic axes, somatic embryos and excised shoot tips of several species were subjected to various cryopreservation protocols. Results: Variable success has been achieved, and currently, cryopreservation protocols have to be optimized on a per species basis; no generic methods can yet be presented. Our criterion for successful cryopreservation is >50% production of both roots and shoots. Success has been achieved with the poor-seeding important African food crops cassava (Manihot esculenta) and yam (Dioscorea rotundata), using somatic embryos and excised shoot tips, respectively. Of the vulnerable medicinal species, successful cryopreservation has been achieved with globular stage somatic embryos of two poor-seeding Haworthia species, and whole seeds of Warburgia salutaris. Embryos of a number of species of the Amaryllidacea, and the palm Phoenix reclinata (all monocots) have survived cryopreservation. A common feature among excised embryonic axes of tropical/subtropical dicotyledonous species is the lack of shoot development; this is ascribed to excision damage involving a burst of reactive oxygen species. Conclusion: Cryobanking can contribute to the conservation of indigenous recalcitrant-seeded and poor-seeding plant specie, although much development work remains to be done. The ultimate aim is to cryopreserve a representative sample of such germplasm for future ecological restoration.
QAC 01

Managing Biorepository Quality to Multiple Standards

Kent Treichler¹, Carla Chorley¹, Kathi Shea¹, David Olsen², Lindsay Holder³, Amy Stewart¹
¹SeraCare Life Sciences, Inc., Frederick, MD, USA; ²SeraCare Life Sciences, Inc., Milford, MA, USA; ³SeraCare Life Sciences, Inc., Gaithersburg, MD, USA

Background: Biorepositories are not regulated to a single specific standard, yet customers operate in highly regulated industries and expect systems in place that control each process performed. The scope of repository processes varies for different customers. Understanding customers’ project-specific requirements and their regulatory compliance needs, are essential to developing a Quality Management System (QMS) to meet these needs. Methods: Elective standards applicable to biorepository activities include International Organization for Standardization (ISO) standards 9001, 13485, 14971, and 15189. Guidelines (i.e., ICH) and Best Practices (i.e., ISBER and NCI) may also apply. Applicable US regulatory standards could include cGLP, cGMP, cGCP, cGTP and CLIA. Once customer requirements are known, an analysis of these requirements against the applicable parameters is performed. Results: Establishing targets based on customer requirements, and monitoring and trending performance to these targets, leads to a continuous improvement environment. Frequently used indicators include customer feedback, specimen condition, data error rates, turnaround time for specimen receipt, processing, evaluation and shipment, and measurement of first time quality for key tasks. Conclusions: An effective QMS ensures the flexibility and capability of an organization to meet customers’ specific needs and their distinct regulatory requirements. Whether specimens are stored for custodial purposes, or services such as processing, testing, aliquoting, storage and distribution of blood and tissue are provided, the application of specific quality management tools to maintain and control biorepository processes is essential.

QAC 02

Lost Product When Monitoring & Controls Worked Fine – What Went Wrong?

Kevin Bull¹
¹Veriteq Instruments, Inc., Richmond, British Columbia, Canada

Background: Monitoring and controlling temperature with independent systems is, in general, the best approach for maintaining the specifications of controlled environments. However, a closer look at the stability and accuracy of these systems may tell another story. Automated systems in particular provide real-time digital display of temperatures and send alarms when out of range. Why then do we still hear about losing thousands, or even millions of dollars in specimens, for example, despite everything seeming to be normal? It stems from a belief that temperature measurement accuracy equates to certainty, when it is no more than a probability. Methods: Understanding what measurement accuracy means and what it does not mean in terms of maintaining desired temperatures. Using simple statistics, we can show how the accuracy of a measuring device determines the degree of confidence that an environment will be within its acceptable range. Results: Systems that rely on the temperature accuracy of measuring devices alone can be shown to have varying degrees of probability that an environment will be within specification. Conclusions: This session provides an understanding of how to ensure that system display temperature and ‘real’ temperature read the same.

QAC 03

Three Strategies for Environmental Monitoring: Understanding the Differences

Kevin Bull¹
¹Veriteq Instruments, Inc., Richmond, British Columbia, Canada

Background: Today, protecting temperature-sensitive goods in controlled environments is accomplished using three strategies: distributed, centralized and hybrid systems. Each method solves a variety of problems, either by themselves or in conjunction with other resources. Methods: Understanding how each of these strategies align with the objectives of protecting valuable products and maintaining continuous records. Results: The pros and cons of temperature monitoring with different approaches for protecting product quality and maintaining records needed for meeting regulations. Conclusions: This session provides an understanding of the best-fit strategy for different types of monitored environments.

QAC 04

Quality Control for Large Archived Collections: Increasing The Value, Decreasing The Cost

Kathi Shea¹, Elizabeth Wagner², Carol Giffen³, Kevin Meagher³, Carla Chorley⁴, Kent Treichler¹, Vanessa Esteves¹, Jamie Fitzpatrick¹, Linda Brunson¹
¹SeraCare Life Sciences, Inc., Gaithersburg, MD, USA; ²National Heart, Lung, and Blood Institute, Bethesda, MD, USA; ³Information Management Services, Inc., Silver Spring, MD, USA; ⁴SeraCare Life Sciences, Inc, Frederick, MD, USA
Background: The National Heart, Lung, and Blood Institute (NHLBI) Repository contains 4.6M biospecimens from over 70 collections conducted by 46 research programs over 40 years. The NHLBI has focused on increasing the utility of this national resource by making collections information available via BioLINCC (https://biolincc.nhlbi.nih.gov/home/). Collections were compiled and managed by multiple groups with varying levels of quality control (QC) and many of the older collections have high discrepancy rates. A QC effort is underway to assess the accuracy of data and identify any visible quality indicators. Methods: A top-down approach to collections QC was used. Collections with the highest scientific value were targeted. A container-level reconciliation was performed to identify major gaps between the physical and the virtual inventories. A random sampling of the physical inventory was conducted and the criticality of observed discrepancies was analyzed. A determination of clinical data and informed consent availability that could allow broad research use was conducted. Results: Collections error rates have ranged from 0% to 100%, with varying levels of criticality. Collections with a high probability for future use are being further reconciled and collections with a low probability of future use will be discarded. Conclusions: This systematic approach to quality control allows for efficient review of large archived collections. This effort will ensure accuracy of data for the physical inventory, a reduction in custodial repository costs, and informed utilization of the collections. These efforts increase the overall value of the collections to the NHLBI and to the research community as a whole.

QAC 05

Effectively Addressing Quality Assurance Measures to Ensure Global Compliance of Biospecimen Samples and Associated Data

Jennifer Benner
1BioStorage Technologies, Inc., Indianapolis, IN, USA

Quality assurance (QA) procedures are fundamental to the successful operation of the biospecimen repository. It is necessary to have a fully integrated quality assurance system and comprehensive standard operating procedures to ensure the handling, processing, annotation, storage, and transportation of biospecimens occur at a consistently high level. The presenter will provide an illustrated overview of the GxP regulatory compliance requirements and expectations for computerized systems that produce, distribute and archive biospecimens. The presenter will also put emphasis on the management of electronic data and documents associated with biospecimen collection. Additional QA components that will be highlighted, include: •An overview of the regulatory framework for biorepositories •How to integrate quality assurance processes as an ongoing component of standard operating procedures •The role of quality assured and validated methods for specimen security and data confidentiality •Best practices for ensuring business continuity with data back up systems •How to establish a chain of custody for your samples to guarantee quality.

QAC 06

Pathologist-Verified Biospecimens Enable Identification of Renal Cell Carcinoma Protein Biomarkers in Human Blood

Dynelle Mackey1, Shannon Richey1, Sandra Schultz2, Ravi Amunugama2, Richard Jones2, Ruth VanBogelen2, Elizabeth Peters1
1Asterand, Inc., Detroit, MI, USA; 2NextGen Sciences, Inc., Ann Arbor, MI, USA

Background: Properly verified biospecimens are initial resources critical for identifying biomarkers in molecular-based biomedical research. Unfortunately, limited availability of adequately robust clinically annotated biospecimens as well as inconsistencies in clinical data that contradict pathology diagnosis can cause ambiguity in differentiating protein biomarkers in tumor and non-tumor tissues. In this study, candidate renal cell carcinoma protein biomarkers in blood were identified by determining what proteins are present and up-regulated only in tumor compared to normal human tissue and then determining which of these were also detected in blood plasma/serum samples. Methods: Quality-controlled and independent pathologist-verified fresh frozen moderately differentiated kidney adenocarcinoma tissue, adjacent normal kidney tissue, and plasma/serum from the same patient were analyzed by GeLC-MS/MS proteomics platform. Protein identification profiles were obtained with Scaffold algorithm using files generated by Mascot. To assess quantitation, Venn diagrams illustrated overlap and correlation coefficients were calculated for each of the sample types. Results: 3237 total proteins were detected in normal and/or tumor kidney tissue. 771 proteins (p < 0.05) were differentially expressed between normal and tumor. Of the 771 proteins, 120 proteins, 28 were ≥ 2-fold increased in tumor, 55 were ≥ 2-fold decreased and 37 had fold changes < 2-fold. Conclusions: Differentially expressed, up-regulated plasma/serum proteins (28) were identified and linked to glycolysis, rennin-angiotensin system, glutathione metabolism and Ras signaling pathways. Independently verified and quality controlled biospecimens enable integration of clinical and downstream proteomic pathway data for identification of biomarkers in human blood.
QAC 07

The Korea Biobank Project: Evaluation of the Impact of Pre-analytical Conditions on Blood Quality

Soon Young Jeon1
1National Institute of Health, KCDC, Seoul, South Korea

Following the rapid progression of genomic research in humans, the discovery of critical genes and pathways as well as the follow up analysis of their impact and significance will depend on the quality of biological specimens. For quality control of blood samples, National Biobank of Korea performed experiments to assess the effect on the delay of blood processing time on the quality of serum and plasma. Statistically significant variation of biochemical measurements was determined using the repeated-measures ANOVA. The significant change limit (SCL) was used to determine the clinically significant changes of the measured analytes. In spite of many conflicting previous reports, the levels of seven analytes (AST, GGT, LDH, CRP, BUN, Creatinine and Glucose) were different in the serum according to the time delay before or after separation. In addition, the repeated freeze/thaw cycles affected the levels of LDH and ALT both in serum and plasma, whereas the level of TG was varied in only the serum sample. These results showed that the level of some biochemical analytes depended on the pre-analytical conditions such as the delayed time or freeze-thaw cycles.

QAC 08

DNA Degradation under Different Storage Conditions: a Long-Term Study to Optimize DNA Preservation

Thomas Knebelsberger1, Florian Battke2, Birgit Gemeinholzer3, Hans-Peter Klenk4, Michael Raupach5, Isabella Stöger1, Johann-Wolfgang Wägele2, Holger Zetzsche5, Gerhard Haszprunar1
1Zoologische Staatssammlung München, Munich, Germany; 2Zentrum für molekulare Pathologie (ZMP), Munich, Germany; 3Botanischer Garten und Botanisches Museum Berlin-Dahlem, Berlin-Brandenburg, Germany; 4Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, Braunschweig, Germany; 5Zoologisches Forschungsmuseum Alexander König, Bonn, Germany

DNA degradation was measured by a quantitative real-time polymerase chain reaction (qPCR) method. Here we present the results of our experiments after 13 months of storage. Results and Conclusions: DNA preservation in water led to dramatic degradation after a few months of storage at the higher temperatures (RT and 4°C). With the other storage agents there was only a weak influence of the storage temperature on DNA quality. Sample dehydration had a positive effect on DNA quality, whereas the influence of trehalose was practically negligible. For large DNA fragments preservation was best in Qiagen DNA Tubes. Surprisingly, we found no influence of repeated freezing and thawing of the samples on DNA quality.

QAC 09

Unforeseen Consenting and Tissue Collecting Issues Arising During the Creation of a Tissue Repository Lab (TRL)

Dana Oliver1, Peter Williams1, Kimberly McCormick1
1Saint Louis University, Saint Louis, MO, USA

Background: The foundation of research is the availability and use of donated de-identified patient samples. This abstract reports a lack of awareness of proper transport of samples and appropriate use of consent forms. Methods: Retrospective review for quality assurance of tissue donations revealed problems obtaining appropriate consent and maintaining the integrity of specimens (through monitoring time intervals for transport from the OR to the frozen section lab then the TRL). Results: Patients(n=879) resulted in 3001 specimens for the TRL from 6/29/05-1/28/10. Concerns emerged: potential contamination from prior tissue processing; time span for transport of specimens to TRL (75% received<30 minutes); not notified specimens were available; not enough residual tissue after pathology’s processing (38 patients/4.3%); tissue released to TRL directly by the surgeon before diagnosis (2 patients,0.2%/3 aliquots(0.1%)). Consenting problems: not consented (5 patients,0.5%/72 aliquots(2.4%); 2 patients consented with non-TRL forms (0.2%)/3 aliquots(0.1%). Conclusion: In our institution, consenting problems represent approximately 3% of specimens; these specimens cannot be used for research. It’s disconcerting, if the diagnosis of these 94 (3%) specimens is rare. Tissue degradation due to prolonged time from surgery to TRL adds to this insufficiently investigated. Methods:As part of the DNA Bank Network Project (www.dbank-network.org) funded by the German Science Foundation (DFG) we investigated DNA degradation in sample storage at five temperatures (room temperature, +4°C, -20°C, -80°C, -196°C), and in three different agents (buffer, water, QiagenSafe DNA Tubes). The influence of sample dehydration, protective additives (trehalose) as well as of repeated freezing and thawing was also examined. DNA degradation was measured by a quantitative real-time polymerase chain reaction (qPCR) method. Here we present the results of our experiments after 13 months of storage.

Results and Conclusions: DNA preservation in water led to dramatic degradation after a few months of storage at the higher temperatures (RT and 4°C). With the other storage agents there was only a weak influence of the storage temperature on DNA quality. Sample dehydration had a positive effect on DNA quality, whereas the influence of trehalose was practically negligible. For large DNA fragments preservation was best in Qiagen DNA Tubes. Surprisingly, we found no influence of repeated freezing and thawing of the samples on DNA quality.
number. Specimens not properly consented are ‘quarantined for an undetermined time’. Non-consented specimens (typically discarded) which cannot be released to researchers could be used to validate new lab methods. Researchers are notified annually of protocol/consent renewal, that the TRL has a specific consent form; using it requires tissue be stored in the TRL.

QAC 10

Quality Controls on Animal Mesenchymal Stem Cells (MSCs) Banked in Istituto Zooprofilattico Sperimentale of Sicily-Italy

Patrizia Di Marco¹, Maura Ferrari², Lorenzo Sesso¹, Giuseppa Purpari¹, Laura Russotto¹, Santina Di Bella¹, Annalisa Guercio¹

Istituto Zooprofilattico Sperimentale della Sicilia, Palermo, Italy; ²Istituto Zooprofilattico Sperimentale Lombardia e Emilia Romagna, Brescia, Italy

Istituto Zooprofilattico Sperimentale is a research laboratory working for human and veterinary health according to a quality system regulated by UNI CEI EN ISO/IEC 17025:2005 norms. Among research activities there is cell isolation, amplification and banking. MSCs, primary and stabilized cells are banked. Equine and canine MSCs are collected from Bone Marrow (BM) and Adipose Tissue (AT). MSCs are used in order to study tissue remodelling both autologous and allogeneic implantation. Quality controls and safety testing methods are applied to assure cell biosafety. Biosafety controls are applied to donors, reagents, growth media, bone marrow and adipose tissue samples and MSCs. Microbiological controls are: bacteria and fungi detection: samples are inoculated into liquid and solid specific media; mycoplasma detection: culture in solid and liquid media, indirect DNA staining (Hoechst 33258), Polymerase Chain Reaction (PCR); viruses detection: a panel of tests to detect pathogens, endogenous and adventitious viruses (culture in permissive monolayer cultured cells, PCR, electronic microscopy, immunoenzymatic tests). MSCs characterization: colony forming unit, differentiation assays and molecular biology. Oncogenicity and tests: evaluation of capacity of the produced MSCs to induce tumor “in vitro” and “in vivo” in nu/nu mice. Stem cell banks have to assure the quality, traceability and MSCs safety. These aims are particularly important in the avoidance of transmissible diseases. A safety testing regime ensures the availability of MSCs for clinical and experimental use. Our certified quality system is also a guarantee for shared activities with other research groups.

QAC 11

The AIDS and Cancer Specimen Resource’s Audit Checklist Tool for Assuring Multisite Member Compliance with Best Practices for Biorepositories

Sylvia Silver¹, Leona Ayers¹, Debra Garcia¹, Michael McGrath¹

¹AIDS and Cancer Specimen Resource (ACSR), San Francisco, CA, USA

Background: The US National Cancer Institute (NCI)-supported AIDS and Cancer Specimen Resource (ACSR) is composed of three regional biorepositories. Such multisite operations are challenged by constraints of distance and different physical facilities, access to resources, personnel and organization. Quality performance of ACSR is facilitated by a Central Operations Data Coordinating Center (CODCC).

Methods: The ACSR CODCC developed an audit tool based on NCI/ISBER Best Practices for Biorepositories that includes evaluation of: administration, internal and external guidelines, safety, inventory, marketing and informatics. Yearly audit events include 1) self audit with remediation of deficiencies, 2) onsite audit by a CODCC/NCI team with exit discussion followed by an audit report and 3) remediation of any deficiencies with documentation and 4) discussion of audit results with the ACSR executive committee.

Results: Application of this auditing format in 2009 allowed the ACSR to identify areas affecting quality of biorepository samples, opportunities for process improvement, documentation of adherence to good practices as prescribed by approved SOPs and opportunities for continuing improvement. 2009 audit findings have been translated into improved audit tools for our 2010 audit, updating of SOPs and a better understanding of practice issues across the enterprise.

Conclusions: The repeated use over time of a universally applicable auditing tool for assessment of multisite biorepository enterprises provides a format for biorepository continuing quality improvement. This process is expected to assure a consistent or more predictable biorepository product and thereby provide better service to our research community.
QAC 12

The Mechanical Method Of Tissue Homogenization By Abrasive Materials And Cavitation For DNA and RNA Extraction

Chon Boon Eng¹, Yi Bing Aw¹, Shi Min Tan¹, Rajeev Singh¹, Wei Ling Tan¹
¹NUH-NUS Tissue Repository, Singapore

Sample preparation of solid tissue specimens is one of the key factors for effective extraction of DNA and RNA. The tissue needs to be broken down into fine particles for cell lysis and to maximize biomolecules yield. Effective homogenization is thus vital. Currently, there are various methods of tissue homogenization such as beads mills, rotor-stator, mortar/pestle, vortex and sonication. Our lab has evaluated a prototype unit developed for tissue homogenization through the use of abrasive materials in conjunction with cavitations. DNA and RNA yields as well as the quality of the biomolecules are evaluated. We analyzed the RNA quality by 18S/28S rRNA ratio and used PCR and gel electrophoresis for DNA quality assessment. Results showed that this method of tissue homogenization is comparable to rotor-stator which is routinely performed in our lab.

QAC 13

Biospecimen Reporting for Improved Study Quality (BRISQ)

Helen Moore¹, Jim Vaught¹, Lisa McShane³, Scott Jewell², Andrea Kelly³
¹National Cancer Institute, Bethesda, MD, USA; ²OSU Comprehensive Cancer Center, Columbus, OH, USA; ³Rose Li and Associates, Inc., Bethesda, MD, USA

Background: The amount of detail reported concerning biospecimen characteristics and handling varies widely in scientific publications. We addressed this by compiling reporting recommendations for biospecimens. Methods: A workshop was held at the 2009 Biospecimen Research Network Symposium to form biospecimen reporting recommendations. The resultant list was refined at monthly teleconferences by a committee of workshop attendees and other experts. Results: The committee composed a three-tiered list of biospecimen data that should be reported, if known and applicable, for all biospecimens or patients in the study. The first tier, items necessary to report, includes biospecimen type; relevant clinical characteristics; collection, stabilization, and preservation mechanism; type and composition of long-term preservative; storage temperature and duration; shipping temperature(s); and composition assessment and selection. Items advisable to report form the second tier: patient demographics; accrual scheme; time and temperature between acquisition and stabilization; type of collection container; time and temperature in preservation solution; aliquot volume; shipping duration(s); gross and microscopic review; proximity to relevant anatomical lesion; and details of enrichment for relevant component(s). Additional items to report, or third-tier items, include agonal state and cause of death for postmortem biospecimens; relevant exposures; reproductive status; nature of biobank; time from blood flow cessation to acquisition; specimen size; type of storage container/slide and shipping vessel; shipping conditions; number, time, and temperature of any freeze-thaw events; embedding medium; and quality assurance measures. Conclusions: If followed, these recommendations will provide readers with comparable method information to evaluate, interpret, compare, and reproduce the results of experiments that employ human specimens.

QAC 14

Quality Assurance and Annotation of Paraffin Block Registry

Han-Ik Bae¹, Jungtae Kim¹, Yujin Choi¹, Yun-Sik Kwak¹, Zi-Guang Xu¹
¹Kyungpook National University Hospital, DaeGu, South Korea

Every year, over one hundred thousand paraffin-embedded tissue blocks (PETs) are made for making final diagnosis in the departments of pathology in general hospitals. The PETs should be used for biological research experiments if genetic materials in the PETs are well preserved. We tested the quality of RNA and DNA when fixed in 10% buffered formalin (FF-PETs), methacarn (MF-PETs) or the fresh frozen tissue (FF-PETs) of endoscopically mucosal resected (EMR) or submucosal dissected (ESD) gastric adenocarcinomas. Three groups consisted of 20 patients. RNA and DNA integrities and stabilities are measured by Analytic Bioanalyzer (Agilent Ltd., USA) and performed GAPDH PCR. MF-PETs were satisfactory (70% success rate in GAPDH RT-PCR). Even though the FFT are the best method for preservation of genetic materials, MF-PETs of EMR or ESD tissue are necessary, because invasion depth of the cancer cells is important for diagnosis and treatment evaluation of EMR- or ESD-treated gastric adenocarcinomas. Because the genetic materials are fragile, the PETs should be stored at room temperature (-20 °C in the case of MF-PETs) and improvements of tissue fixation, processing and storage methods are necessary for long term storage of the tissue and genetic material. The standardization and quality control of RNA and DNA extraction methods with reliable verification are important. A registry integration program for multi-institutional quality assurance might be consist of annotation (especially, for banking of tissue microarray blocks), quality control, search and distribution portion of the proper resources.
QAC 15

Integrative Multi-level System to Monitor the Quality of Stored Biological Samples

Daniel Rivard1, Nancy Tremblay1, Céline Lefebvre1, Daniel Gaudet2, Steve Arsenault1, 1Genome Quebec and Chicoutimi Hospital/Ecogene-21 Biobank, Chicoutimi, Quebec, Canada; 2Chicoutimi Hospital / University of Montreal, Chicoutimi, Quebec, Canada

Background: Preserving and monitoring the quality, integrity and security of stored biological samples is a huge biobanking challenge. At each step, the way a procedure is applied has an effect on the status of the sample. An integrated, systematic and comprehensive quality system is required to assure the security, prevent the deterioration and estimate the duration and quality of life (DAQOL) of each biospecimen. Methods: The Genome Québec and Chicoutimi hospital/Ecogene-21 Biobank (GQ Biobank) has developed and implemented a robust multi-level quality system to monitor the integrity, DAQOL and security of stored biological samples. This system is inspired from the pharmaceutical industry standards and includes an operating and a documentation structure established to prevent and anticipate problematic situations. Central monitoring allows the supervision of samples processing and storage, physical access, technical aspects and to trigger alarms when required. DAQOL control system evaluates the effect of time, storage conditions and sample handling on selected biomarkers such as proteins, hormones, lipids or electrolytes. A set of quality control (QC) indicators facilitates the longitudinal follow-up of the samples, technologies and methods, from sample collection to downstream analyses. Results: The system, along with its standard operating procedures, access policies and monitoring tools, has been tested in clinical trails and in community and population genomic projects. This allowed to improve the QC tools and algorithms. Conclusions: Reliable QC systems are absolutely required to monitor the quality of stored biological samples. The needs are huge and evolve over time. The GQ Biobank is committed to cover the unmet needs.

QAC 16

High-Throughput DNA Quality Control: Allelic Discrimination Panel for Determining Sample Contamination, Gender and Ethnicity in a Biorepository Setting

Michael DiCola1, Paul Van Hummelen2, Qi Wang2, Amrik Šahota1, David Toke1, Jay Tischfield1, Andrew Brooks1

1Rutgers University, Piscataway, NJ, USA; 2University of Medicine and Dentistry of New Jersey, Piscataway, NJ, USA

The quality of genomic DNA is a core component for most biorepository programs. To date many different approaches have been used for both the quantitative and qualitative appraisal of gDNA, however, there is no standardization for the functional assessment of DNA quality for downstream applications. Currently, most gDNA quality measurements use non-specific assays which demonstrate the global quality of nucleic acid but provide little or no information on gender mismatches, potential sample contamination or ethnicity which are important metrics for any lab reposing or managing samples in a repository setting. We have developed a rapid, cost effective means for assessing the quality of gDNA while capturing critical information on each sample tested. A panel of 96 SNPs (Single Nucleotide Polymorphisms) has been developed and validated using the Fluidigm 96.96 dynamic array for the efficient and cost effective processing of samples using this panel. This study describes a panel of SNPs that have been validated to determine sample contamination, decipher reported gender mismatches for genotyping studies, as well as determine ethnicity information for each gDNA. The correlation of our approach to standard QPCR validation of all assays utilized is 100%. The correlation to SNP data from DNA microarray and capillary electrophoresis analysis is 100%. This approach allows the repository to easily quality control over 10,000 samples per month while reducing operating costs and generating essential information that is used for accurate sample and study management.

QAC 17

Multi-laboratory Assessment of Variations in Spectrophotometry-based DNA Quantity and Purity Indexes

Sung Mi Shim1, Ji Hyun Kim1, Seung Eun Jung1, Dong Joon Kim1, Ji Hee Oh1, Hae Young Nam1, Jae Eun Lee1, Eun Jung Hong1, Jun Woo Kim1, Bok Ghee Han1, Jae Pil Jeon1

1Center for Genome Science, Korea National Institute of Health, Seoul, South Korea

Human genetic studies have used an increasing number of biobanked DNA samples which requires the consistency of DNA quantity and purity between multi-centers or multi-laboratories. In an attempt to standardize DNA quantitation protocols, we performed the DNA quantitation project in which 16 technicians from 11 laboratories participated in measuring optical density (A260, A280, A230) of multiple DNA samples (n=35) of known concentrations in order to analyze variations of DNA quantity and purity indexes. The mean inter-individual coefficients of variation were 21.9%, 7.4% and 24.7% for A260, A260/A280 and
A260/A230 ratios, respectively. The mean intra-individual coefficients of variation were 9.9, 1.7 and 8.3 for A260, A260/A280 and A260/A230 ratios, respectively. We identified that more than 100ng/ul DNA concentration reduced the variability of DNA quantity (A260) and purity (A260/A280 and A260/A230 ratios) indexes. This work would help standardize DNA quantitation protocols of obtaining multi-center collaborated biobanked DNA samples.

QAC 18
Assessment of Human Tissue Quality by Cytology Smear Estimate of Necrosis Correlates with DNA Quantity But Not Quality
Cathy Martinez1, Marlena Martinez2, Sudha Menon2, Joseph Glass2, I-Ming Chen2, Therese Bocklage1
1University of New Mexico School of Medicine, Albuquerque, NM, USA; 2UNM SOM Dept. of Pathology, Albuquerque, NM, USA

Background: Cytology smears assessed at the time of tumor collection can provide information on cell intactness (percent complete cells versus nuclei stripped of cytoplasm) and percent necrosis. This study evaluated whether cytology morphologic parameters predict DNA quality and quantity. Methods: Thirty cases of five tumor types (sarcomas, gynecologic epithelial carcinomas, renal cell carcinomas, thyroid carcinomas and miscellaneous other) were evaluated by DNA concentration and A260 to A280 ratio. Histology assessment of paired formalin-fixed paraffin embedded tissues were compared with cytology findings and DNA quality/quantity data. Cytology parameters included percent intact cells, percent stripped nuclei, and percent necrosis (semiquantitative assessment by one cytopathologist). The same pathologist reviewed H&E sections for percent tumor volume and percent tumor necrosis (cellular intactness could only be assessed on the smears). DNA concentration and ratios were obtained using standard methodology. Results and Comparisons: In general, cytology smear assessment of necrosis versus non-necrosis matched the H&E stained sections of tumor sampled adjacent to tumor taken for frozen storage. Five specimens with >90% cellular necrosis exhibited low DNA concentrations relative to specimens with stripped nuclei or entirely intact cells. DNA quantity and quality data showed no relationship to the estimated percent of cells with stripped nuclei. Gynecologic epithelial tumors averaged the highest concentrations of DNA (mg/ml). Conclusions: In this pilot study, cytology estimates of necrosis predicted DNA concentration but not quality. Immediate smears may be useful in selecting tumor samples most likely to yield significant amounts of DNA.

QAC 19
How Implementing Proven Business Methodologies to Biorepository Processes can lead to Streamlined, Efficient Operations
Lori Ball1, James Grace2
1BioStorage Technologies, Indianapolis, IN, USA; 2Eli Lilly Company, Indianapolis, IN, USA

This session will review the structure and strategic benefits of implementing proven process improvement methodologies (i.e. Six Sigma) to combat rising development cost, cycle times and quality concerns. Although the information will be applicable for many operations, the presenters will focus on the role these strategies play in sample management for the pharmaceutical and biotech industries. Co-presented by two Six Sigma certified professionals, who have collectively spent 35 years in the industry, the presentations will highlight how these strategic management processes can lead to a 30 percent increase in operational efficiency. It is well documented that time is critical in pharmaceutical development, as one day lost in R&D could cost a company millions of dollars. Conversely, if a drug developer abandons a product after Phase II testing, it could have a great financial impact on the organization. Therefore, it is crucial that organizations understand the linkage between systematic, comprehensive processes and the positive effects these processes have on operational effectiveness. As such, the presenters will examine these challenges, provide practical design guidelines and use real-world case studies that help improve the success of this approach, while looking at sample management from an operational planning perspective. Topics covered, include: - How end-to-end process improvements help streamline operational activity, such as sample preparation, storage and transportation - How to use metrics as the basis for a comprehensive sample management plan - Process improvement methodologies that can add additional quality control measures to day-to-day systems and processes for managing samples and associated data.

RAT 01
Using Automation to Improve Storage and Handling of Biospecimens in Legacy Collections
Karen Pitt1, Mark Cosentino2, Kathleen Groover3, Tim Sheehy3, Judith Franke4, Donna Pike5, Marianne Henderson1
1National Cancer Institute, Bethesda, MD, USA; 2SAIC-Frederick, Inc., Frederick, MD, USA; 3Fisher Bioservices, Frederick, MD, USA
Background: The Division of Cancer Epidemiology and Genetics (DCEG) within the U.S. National Cancer Institute (NCI) has collected approximately 12 million specimens in support of 500 studies aimed at understanding the etiology of cancer. Most specimens (68%) are stored at -80°C and many were collected prior to the routine use of printed labels and barcodes. Several other challenges exist with the storage and handling of specimens such as the use of inconsistent containers, inefficient use of containers due to partial withdrawal of biospecimens, and storage of specimens that have lost volume due to evaporation as well as other challenges all leading to higher labor costs for specimen handling, storage and retrieval. Methods: To address these challenges, we are using automation to re-format, re-label, and re-organize material types to the extent possible without compromising specimen integrity. DNA specimens from the same subject are being combined and transferred into automation-friendly, space-efficient containers bearing 2-D barcodes. Other material types are being re-labeled (as needed) and re-grouped so that they can be stored densely in a manner that allows for more cost-efficient storage and labor saving retrieval practices. Results and Conclusions: Initial efforts to automate the handling of DNA specimens have led to significant decreases in specimen processing time and storage space requirements. Pilot efforts to reorganize all specimens indicate that automation has the potential to lead to greater efficiencies in storage and handling and consequently will result in significantly lower overall costs for program management.

RAT 02

Automated Versus Manual Buffy Coat Recovery

Kristian Spreckley¹, Melvyn Whiteside¹
¹RTS Life Science, Manchester, Lancashire, UK

Background: In 2006 RTS worked with UK Biobank to produce a fully automated system capable of processing their blood samples. A strong market requirement has now led to the production of a smaller, cheaper and more versatile system to suit the needs of smaller sample processing laboratories. The new Automated Blood Fractionation system now employs a modified buffy coat recovery process that enhances yield to approach the very best manual recoveries. Methods: Manual buffy coat extraction was compared to automated buffy coat extraction using the new RTS buffy coat recovery protocol. Buffy coat volume was measured in primary tubes and then, following aliquoting, in secondary tubes. DNA extraction was performed on harvested buffy coat and also from post fractionation remnants, i.e. remaining red blood cells, and compared for manual versus automated processing. Results: Analysis of buffy coat volumes show that we are recovering up to 90% of the volume measured in the primary tube, with recovery being matched between manual and automated processing. However, following DNA extraction on these samples, DNA yield was found to be 80% of that achieved from manually extracted samples. Conclusions: DNA extraction results indicate we are currently achieving 80% of the DNA yield accomplished from manually processed buffy coat samples. Manual processing allows constant alteration of movements and analysis of buffy coat recovery, which is impossible to achieve during automated recovery. However, the reproducibility of automated recovery means that we can guarantee this yield on a consistent basis and will not be subject to the variability inherent in manual processing.

RAT 03

Biobank Laboratory Automation for Sample Processing at the Brazilian National Tumor and DNA Bank (BNT)

Cláudio Gustavo Stefanoff¹, Leticia Rocha¹, Luciana Castro¹, Jose Claudio Casali-da-Rocha¹
¹Brazilian National Cancer Institute, Rio de Janeiro, Brazil

Background: The sample processing is the most technically demanding part of a biobank service, especially because of the large number of samples and protocols, which requires special attention to avoid operational mistakes. Due to the crescent number of sample collection and processing needs, in 2008 we started the implementation of automation of the BNT Laboratory. Methods: To automate fluid aliquoting, we used MAPI System (CryoBio System, CBSTM) platform to process primary samples (plasma, serum) into multiple aliquots. Steps included the filling, sealing and bar-code identification of straws of 0.3 or 0.5mL. We introduced the automatic platform MagNA Pure LC 2.0 (Roche Diagnostics) for both automated nucleic acid isolation and PCR set-up. Using the magnetic bead technology, the instrument processes blood and tissues samples. Steps included sample uptake, lysis, binding to magnetic beads, washing and elution. Results: The MAPI system has been successfully set up at BNT for the preparation of fluids. To date, 1,300 blood samples from 550 donors were processed using MAPI. MagNA Pure proved to be very efficient for mid scale capacity of extracting a hundred samples per day. Also, 450 blood and 250 tissue samples were processed into DNA and/or RNA with MagNA Pure. Conclusions: Both MAPI system and MagNA Pure platforms proved to be flexible and efficient tools. The automation of specimen processing in our biobank laboratory represented clear advantages: it increased sample processing productivity, optimized lab spaces, and reduced costs. Additionally, MAPI increased the capacity of freezer storage.
RAT 04

Introducing Automation to Improve Throughput in DNA Extraction and Sample Aliquoting for Human Biofluids

Marianne Henderson¹, Timothy Sheehy², L. Mark Cosentino², Karen Pitt¹
¹National Cancer Institute, NIH, DHHS, Bethesda, MD, USA; ²SAIC-Frederick, Frederick, MD, USA

Background: The US National Cancer Institute’s Division of Cancer Epidemiology and Genetics (DCEG) conducts population-based and interdisciplinary research to discover the genetic and environmental determinants of cancer. DCEG has over 500 studies representing approximately 12 million collected specimens. These specimens have been or will be processed for DNA extraction, quantitation and aliquoted in an automation friendly manner for genomic testing. In close collaboration with SAIC-Frederick, DCEG initiated an aggressive plan to address the growing utilization of its DNA collection by implementing lean manufacturing and TQM practices into its specimen processing. The challenges in handling legacy specimens were identified; lack of barcodes, evolving labeling algorithms, multiple container sizes/types and inconsistent aliquoting schemes. The goal became to successfully overcome these challenges while increasing throughput at a lower cost per sample. Methods: Addressing these challenges, DCEG began integrating automation to create pre-qualified, extracted DNA from biofluids for downstream applications. Pre-qualified samples are arrayed and tracked to allow for automated requesting, retrieval and production of run-ready plates for high throughput genomic testing. The automation allows for continuity of operations and short-term storage that is integrated within the robotic processing line. Results: Initial efforts to automate the processing and handling of DNA specimens has led to the promise of significantly reduced costs, processing time and storage space requirements for the pre-qualified DNA. Additional components to the assembly line are being considered to expand the utility and throughput of the laboratory. The initial results indicate that greater efficiencies in biospecimen program management are attainable with automation.

RAT 05

A Distributed Approach to Biobanking

Matthew Hamilton¹, Martin Frey²
¹Hamilton Storage Technologies, Hopkinton, MA, USA; ²Hamilton AG, Bonaduz, Graubunden, Switzerland

Background: This project shows the advantages of distributed small scale biobanks that are shared between a common IT network to build a secure, cost effective, flexible, and reliable approach to large scale biobanking. Methods: The approach will be addressed by using multiple compact, localized ambient to -80 °C automated sample management systems. Each automated system will have access to a secure and compliant web service interface that will be integrated into a common Bio laboratory information management system. Results: It is expected that allowing satellite laboratories to store and maintain their own samples locally helps facilitate a common process and approach to flexible biobanking but also increases the quality of biological research programs. Conclusion: By introducing a unique and simple approach to satellite biobanking laboratories and combining a common top level interface that is integrated into a Bio LIMS results in a comprehensive, secure, efficient, and flexible solution for distributed biobanks.

RAT 06

Automated Annotation of Histopathology Data from Final Pathology Reports to Biorepository Samples

Azita Sharif¹, Stefano Santoro¹, Sarah Dry²
¹Daedalus Software, Inc., Cambridge, MA, USA; ²UCLA, Cambridge, MA, USA

Rich histopathologic annotation enhances the value of tissue biorepository samples. Currently, no automated, accurate annotation processes exist. Manual data entry underlies most current approaches. To solve this deficiency, we developed a novel automated process to extract standardized histopathology data from sections of the finalized pathology report (PowerPath) to download the information to our biorepository database (BTM) for accurate sample annotation. Customized synoptic reports (SynR), based on College of American Pathologists recommendations, were developed for each gastrointestinal (GI) system organ. SynR are imported into the microscopic description section. Standardized language includes tumor types, grades and staging information. Non-productive text is deleted. Free text is limited to one field. The microscopic section text is imported from PowerPath into BTM. Then, synoptic report text is extracted, parsed and converted into annotations. These are entered into the Lucene text search engine as indices pointing to the surgical pathology case number. Each of these annotations can be used to search for samples from the relevant surgical pathology case. GI SynRs, introduced in 2007, are used routinely by all UCLA GI pathologists. We permit personalized language in the final diagnosis section as SynR in the microscopic description section ensure standardized language. Using pancreas as the test case, histopathologic data was imported successfully from the final PowerPath report into BTM and correctly associated with tissue samples. Samples with detailed histopathologic criteria are retrieved easily, for example, mixed acinar-endocrine + uncinate process + pT2. Complex searches using both SynR and other
data fields elsewhere in BTM (i.e., demographics) are possible.

RAT 07

Automated Processing of Biological Samples- The Experience of the InterInstitutional Multidisciplinary Biobank (BioBIM)

Fiorella Guadagni1, Antonella Spila1, Umberto Nanni2, Paolo Somma1, Vincenzino Perrone1, Francesco De Angelis1, Raffaele Palmirotta1, Patrizia Ferroni1
1IRCCS San Raffaele Pisana, Rome, Italy; 2Sapienza University of Rome, Rome, Italy

Traditional and innovative laboratory procedures are used for biomarker discovery studies and for the appraisal of biomolecular markers correlated to possible determinants of clinical outcome. This objective is easily achievable in our Institution thanks to the availability of a Multidisciplinary InterInstitutional BioBank (BioBIM) fully equipped for the automation of sampling, processing, storage and tracking of biological samples and completely integrated with the diagnostic section through an informatics platform connecting the laboratory informatics with a pre-analytical robotic system. Biological samples and tube racks are identified by a linear bar code and then the tube rack is scanned on a 2D reader, since each tube is assigned a unique 2D identifier. After this procedure, the aliquoting is carried out on a robotic platform by using the previously identified tubes. Finally the tube racks are stored at –80°C. A Sample Tracking Software is utilized to track all the sample identification and physical storage information. A tracking of plates and boxes handling is performed by means of RFID technology. All samples are automatically recorded in databases with encoded identification. Decoding can only be done by the biobank responsible, investigator or other authorized members of the research team. The entire process from bleeding to sample storage is controlled by an IT integrated platform. All personnel is using Standard Operating Procedures defined by international guidelines when available or internal validated and implemented protocols and procedures to accurately dispense small blood aliquots to 384-wells GenPlates using liquid handlers equipped with 1mL disposable tips. Procedures were optimized for various sample types. GenPlates stored in the GenVault dynamic archive can be further processed to obtain high-quality DNA. Protocols were developed to extract DNA from GenPlate elements using an automated workstation mounted with a thermoshaker and specialized labwares. Extracted DNA is further purified with a magnetic bead-based technology and quantified by fluorescence on the same robotic platform equipped with a gripper arm, a 96-well magnet and a plate reader. Workflow among robotic workstations is ensured by normalized manual procedures. Results: Automated workshops along with manual steps can be configured to accurately dispense small blood aliquots to 384-wells GenPlates. Highly-complex, thoroughly-tested protocols ensure no contamination and sample homogeneity with a throughput of hundreds GenPlates per day. Downstream extraction, purification and quantification of 96 high-quality samples can be achieved in 3 hours using this integrated system. Conclusions: We developed, validated and implemented protocols and procedures to maximize off-the-shelf technologies’ versatility which we combined with accurate manual steps to achieve outstanding simplicity, quality and efficacy in DNA sample management.

RAT 09

Development and Testing of a Robotic Frozen Sample Aliquoter System

Dale Larson1
1The Charles Stark Draper Laboratory, Inc, Cambridge, MA, USA

Background: Traditionally, biological samples are frozen to protect their biochemical composition, preserve proteins and prolong cell life. All current methods of processing frozen samples require thawing before aliquots are prepared. However, repeated freeze-thaw cycling can damage samples in unpredictable ways and is labor intensive. Thus, biorepositories face a dilemma when building biospecimen inventories: freeze samples in multiple small volumes, consuming significant freezer storage space and increasing costs; or freeze in fewer large volumes, reducing initial processing time and storage
space at the expense of freeze-thaw cycling later. Methods: We developed a high-throughput robot capable of retrieving multiple frozen aliquots from a frozen biospecimen. The prototype extracts multiple frozen 0.10ml aliquots from a single 1.8ml cryovial of serum or plasma and deposits them into a separate cryovial for downstream analysis. The Rhode Island BioBank at Brown University independently evaluated the robot for reproducibility, variability and homogeneity using human plasma. Samples were analyzed for cholesterol, triglyceride, IgG and glucose at Children’s Hospital Boston. Results: The robot demonstrated it can extract multiple frozen, uniformly-sized and homogeneous portions of plasma which, when analyzed for 4 common analytes, give reproducible results with very low variability. The system maintains samples at -40 °C before, during and after coring. Conclusions: The high-throughput robot supports the needs of modern biobanking. It provides a tool to distribute serum and plasma samples without exposing them to freeze-thaw cycling; protecting sample integrity and delivering critical space, time and labor savings. Uses might include serum, plasma, cells, small molecule compounds in DMSO and frozen tissues.

RIF 01

Health Data Integration: Linking Clinical and Research Databases

Melissa Barber¹, John O'Dwyer², Marilla O'Dwyer², Garry Jennings¹, Anthony Dart³
¹Baker IDI Heart and Diabetes Institute, Melbourne, Victoria, Australia; ²CSIRO, Herston, Queensland, Australia; ³The Heart Centre, Melbourne, Victoria, Australia

Background: The Alfred Hospital Heart Centre and Baker IDI Heart and Diabetes Institute maintain several large databases containing detailed cardiovascular records, however without linkage searching across databases was difficult and time consuming. This projects aim was to introduce a "platform" to link these records; and to access the de-identified data in a secure manner to facilitate research. Methods: An experienced database administrator conducted an audit of the data sources and linking interfaces available. Adherence to current privacy laws and ethics was considered in choosing the platform to utilize. Results: The Health Data Integration (HDI) system, developed by the Australian e-Health Research Centre, was selected and a ‘virtual data repository’ was created linking > 41,000 Cardiac Catheter Laboratory, >11,500 Echocardiography Laboratory, >1,300 Heart Failure Clinic, >13,500 Healthy Hearts Clinic and >5,900 Biobank records. Inclusion of the Baker IDI Biobank database provides scientists with access to additional detailed clinical data relating to Biobank samples which are also available for approved research. The system has successfully assisted two research projects; (1) linking the Echocardiography and Biobank databases to identify specific valve disease patients with Biobank samples for genotyping, and (2) linking the Heart Failure and Echocardiography databases for a retrospective study of valve disease and renal dysfunction in heart failure patients. Conclusion: We have established a centralized access point for our clinical and research databases. This will enable clinicians and researchers to retrieve a broad range of de-identified patient information using a secure and user-friendly interface.

RIF 02

A Three-Tiered Approach to the Collection and Protection of Biospecimen Data: A Triple Threat

Zachery von Menchhofen¹, Diane McGarvey¹, Virginia LiVolsi¹
¹University of Pennsylvania/CHTN-Eastern Division, Philadelphia, PA, USA

Background: The internet allows for sharing of data, speeding the exchange and transfer of data. Within healthcare/scientific research environments, protection of patient information is crucial. The needs for swift information access versus protection of patient information are not necessarily opposite dictums and can be synched in order to advance scientific research. Method: The Cooperative Human Tissue Network Eastern Division (CHTN-ED), an NCI sponsored biorepository that prospectively procures human biosamples, has developed a three-tiered informatics approach to tracking and disseminating human biospecimens data while simultaneously ensuring HIPPA level compliance and patient anonymity. This schema employs a three-tiered approach utilizing: 1) database technology on multiple secure data-servers with functional record level encryption and unique identification numbering for data position tracking reference and de-encryption. 2) Programmatic Regular Expression Matching of patient clinical and pathological documentation prior to storage and dissemination. 3) Network layer using multiple computer industry protocols. While the structure of database, application and network has been used historically, CHTN-ED’s synergy of these constituent factors along with cross-platform internet controls speeds intellectual exchange while still ensuring clinical anonymity. Results: The CHTN-ED has developed and implemented this structure. This demonstrates a proven record of success in providing real-time access to biosamples and the analogous, comprehensive and sensitive data, while protecting all patient clinical information. Conclusion: Using the integration and interaction of the programmatic informatics components in a novel approach allows the distribution of biomaterials and corresponding data across the internet to advance the interests of scientific community.
Practical Experience with Integration of IT Systems used to Collect Biospecimen and Patient Data

Rainer Warth¹, Daniel Simeon-Dubach¹
¹Foundation BioBank-Suisse, Bern, Switzerland

Biobank-suisse (BBS) is a collaborative network of Swiss biobanks running a web-based database combining information about biospecimens and patient data from participating biobanks. One major issue is interoperability which would ensure that the maximum amount of data from different sources could be collected into a single patient record to be used for research. BBS investigated the situation in Switzerland to propose a concept to ensure better use of resources and increase patient privacy. We set-up a server to test the integration of applications such as CAISIS, TMAj, and SINATRAS. We analyzed the IT infrastructures in place at 6 different hospitals, where biospecimens are collected. We determined the functionality of the applications mentioned above and compared the underlying data structures. This allowed us to propose practical solutions for the collection and use of biospecimens in research. At the 6th hospital we found that the collection for biomedical research is little automated. Most data is collected manually. Automated data transfer from medical IT systems to IT systems used in research does not exist. The hospitals use different IT systems in their biobanks. None of the local biobanks exchange data with the local cancer register. We compiled a list with all IT systems in use and defined interfaces to better integrate with medical IT systems, other biobanks, and IT systems used in research. In the federated Swiss health care system, optimizing the interoperability of the IT systems could save money that is better spent for specific research projects.

Tissue Micro Arrays in Oncology Drug Development: Statistical Powering of Miniature Repositories to Enable Meaningful Results

Martin Jenkins¹, Christopher Womack¹
¹AstraZeneca, Macclesfield, UK

Background: Demonstration of spatial molecular expression in human tissue micro arrays (TMA) by immunohistochemistry (IHC) and in situ (ISH) hybridization is a key part of oncology drug development (R&D). TMAs are miniature biorepositories of formalin fixed paraffin embedded tissue. Their composition should be determined statistically in advance to ensure meaningful research results. Methods: To test expression of molecular targets in a range of human cancer samples, we have established a tiered cascade of TMAs. These enable IHC and ISH screening of multiple tissue cores across multiple cancer sub types. We used statistical methods to ensure that the composition of individual TMAs would enable the research question to be confidently answered. Different methods are appropriate depending upon whether the aim is to determine frequency of expression, differentiate clinical cohorts or compare follow-up amongst IHC-defined groups. Results: The three tiers of the TMA cascade each required different compositions for statistical powering. For example, in a general cancer multitumour TMA, cores from 22 donors delivers a 90% chance of detecting a positive result if the frequency in the population is greater than 10%. Cancer specific TMAs in tier two and three require 30-40 donors per group to recognize statistical differences between cancer subtypes, while comparison of clinical follow-up can require several hundred individuals. Conclusions: Establishing what is effectively a high throughput cascade of TMAs to investigate potential target expression in oncology requires considerable resource. It is important that the composition of the TMAs are at the outset appropriate to answer specific research questions.

Development of an Electronic Management System and Agenda for Controlling Sample Processing & Retrieving in the Biobank Laboratory

Jose Claudio Casali-da-Rocha¹, Eduardo Vichi¹, Paulo Camanho¹, Claudio Gustavo Stefanoff¹, Marcio Costa¹, Ivan Valadares¹
¹Brazilian National Cancer Institute, Rio de Janeiro, Brazil

Background: To date (Jan 29th, 2010), the Brazilian National Tumor and DNA (BNT) has stored 14,312 samples, from 3720 donors. Samples collected at the Brazilian National Cancer Institute are included in SISBNT after double de-identification, integrated with clinical, pathological, laboratory, and epidemiological data. Tissue aliquots can be either stored in -80 °C freezers or processed into DNA, RNA, protein, micro-dissected tissues, and other derivatives. Fluids, including blood, pleural and ascite, are immediately processed into liquid phases (plasma, serum, other), cell phase, DNA, among others. Methods: Due to the crescent demand of our biobank laboratory in order to attend research projects, we needed to develop an IT solution to control a number of derivates that should be linked in the processing chain, from the electronic informed consent, samples collected at different times, and their multiple primary and secondary derivates. Results: We developed a user-friendly tool for the SISBNT Oracle platform with a processing screen to select a particular aliquot and to registry their derivates identified by 2D barcodes. Additionally, an electronic
agenda was created to optimize human resources and equipment for activities related to a specific distribution project in the biobanking laboratory. Interestingly, the system checks resources and equipment available in the requested period, avoiding overlap. Conclusions: This tool facilitated the routine workflow, which allowed us to organize shipping times, and the online derivate request traced by the customer. With the implementation of this new feature, it was possible to increase the efficiency of our service, organize internal processes and improve customer service.

RIF 06

Integration of Cylindrical Storage Mapping Software with a Grid/box-like Storage Database: from StrawIt™ to caTissue

Tyron Hoover¹
World BioBank, Memphis, TN, USA

Background: Automated assignment of storage locations for biospecimens promotes efficiencies in accuracy and time management. We present a novel integration of two software platforms, both designed specifically for the management of biospecimens, to achieve this goal: (1) StrawIt™, the platform storage location program utilized with the MAPI storage system (both by Cryo Bio System, Groupe I.M.V. Technologies, France), and (2) caTissue Suite, the NCI’s biostorage program. StrawIt™ nicely manages a cylindrical storage system (a liquid nitrogen [LN2] tank). CaTissue manages grid/box-like storage configurations (such as mechanical freezers). We have successfully integrated the two systems in a semi-automated fashion. Methods: Properly managing the output data files from the StrawIt™ system, containing assigned locations of cryostraws in our LN2 tank, allows us to routinely map locations to correct data fields in caTissue. Output files from StrawIt™ are CSV files. CSV files are automatically and routinely imported into correct Storage Position data fields in caTissue. Results: Unique storage locations for our cylindrical LN2 tank (e.g., T01.Q1.C.03.L2) are mapped automatically to appropriate caTissue storage fields. Conclusions: StrawIt™ can successfully integrate with caTissue to automatically populate storage locations assigned by StrawIt™ into caTissue. Management of output storage files allows the apparent limitation of caTissue to grid/box-like containers to be overcome. It also saves time and reduces error.

RIF 07

Business Management Tools Help Biobank Data Become Best Practice Indicators

Rita Lawlor¹, Eugenio Schiarante², Nicola Sperandio¹, Paola Perantoni¹, Aldo Scarpa¹
¹University Hospital of Verona, Verona, Italy; ²Network Solutions For Business (NSB srl), Altavilla Vicentina, Vicenza, Italy

Background: Biobanking best practices suggest methods to improve quality of biological materials collected. Current information systems registering biorepository data are static. While they hold varying amount of data and provide varying degrees of search criteria, they do not make use of the data themselves. These systems could be used to provide quality monitoring and evidence based data analysis thus improving best practice methods. Methods: A relational database infrastructure was created based on the analysis of biobank specimen annotation data-sets in cancer research projects. Collection and conservation protocols also provided data-set information. Specimens considered were tissue, blood and blood derivatives, DNA, RNA and cell lines. Quality test data were then added as additional related tables. This infrastructure was then developed on a management control software platform. Key performance indexes were identified based on quantitative and qualitative analysis of sample and data. Results: We have developed a specimen data management system that provides quantitative and qualitative analysis for sample selection. This allows only completely homogeneous samples to be selected. The comparative key performance indexes act as a quality control marker when applied to certain collection parameters. As such, it provides an indication on where to improve collection times to improve quality. Conclusions: The information stored in a biobank is crucial to add value to biological specimens. However it also provides a data source to improve best practice methods. The application of business performance index tools to biobanking specimen registration software provides a means of improving biobanking using evidence-based analysis on data collected.

RIF 08

Laboratory Information Management System (LIMS) for a Biobank - SamWise

Minttu Jussila¹, Päivi Laiho¹, Outi Törmäwall¹, Markku Laukkanen¹, Markus Perola¹, Leena Palotie¹
¹National Institute for Health and Welfare, Helsinki, Finland

Background: National Institute for Health and Welfare, Public Health Genomics Unit administers an extensive number of biological samples collected in various
epidemiological and population based cohorts in Finland. Currently the biobank houses over 700 000 blood, DNA or RNA samples from more than 200 000 individuals. The biobank is focused on centralized DNA-extraction, quality control, storage and sample logistics. It is managed by a tailor-made laboratory information management system, SamWise. Over the past years, three different database systems have been in service in the biobank, but the need for more sophisticated and flexible LIMS has gradually emerged. Functionalities for sample management and DNA-extraction in SamWise started to operate in 2008 after one year of development. Since then the system has been built towards a more comprehensive, easily modifiable and user-friendly LIMS. Laboratory Information Management System, SamWise is designed to govern all steps of the sample flow within the biobank; data entry, recording of the samples, DNA-extraction results, quality and quantity measures, aliquoting data, sample locations and distribution of the samples. Data management is handled by versatile queries. Inventory elements, sample flow and logistics rely heavily on unique barcodes. SamWise is an in-house developed system combining database functions and LIMS. It is implemented using ASP NET and C++. It is currently using Microsoft SQL server database as a data warehouse. SamWise can be operated by several parallel users using any AJAX enabled Web-browser. Strict data confidentiality rules are followed in parallel users using any AJAX enabled Web-browser. Strict data confidentiality rules are followed in processes and all operations in the database are recorded into a transaction log.

RIF 09

**NHLBI BioLINCC: Methods for Study, Data Preparation and Biospecimen Linkage for a Shared Resource**

Carol Giffen¹, Sean Coady², Elizabeth Wagner³, Kathi Shea⁴, Kevin Meagher¹, Leslie Carroll¹, John Adams¹

¹IMS, Inc., Silver Spring, MD, USA; ²National Heart, Lung, and Blood Institute, Bethesda, MD, USA; ³National Heart, Lung, and Blood Institute, Bethesda, MD, USA; ⁴SeraCare Life Sciences, Inc., Gaithersburg, MD, USA

Background: BioLINCC is an NHLBI research resource which provides a single point-of-access to an aggregate of clinical data from more than 70 historical research studies and more than 4.6 million banked biospecimens dating from more than 30 years ago to the present. To establish and maintain this centralized shared resource, data must be prepared for sharing with qualified researchers and the linkage between data and biospecimens must be determined. Methods: Standard approaches are utilized to prepare the submitted clinical data for sharing. Variables and accompanying documentation are reviewed for data sharing suitability. Personally identifiable information is removed and frequencies of data variables are compared with the study’s published findings to confirm data accuracy. Data dictionaries prepared from submitted data are created. Variables regarding patient informed consent are analyzed and compared with the study’s associated informed consent template documents. Biorepository inventory data are compared to submitted study data to link the two research resources. Unlinked specimens, specimens for subjects with insufficient consent, and questionable data values are investigated and corrections are made to the database upon confirmation from the original study coordinating center or study researchers. Results: Since BioLINCC program inception in September 2008, over 70 research studies including 38 with a stored biospecimen component have been reviewed and posted to the BioLINCC website. 4.2 million biospecimens, representing more than 1.1 million study participants have been successfully linked to their research data. Conclusions: The creation of a shared data and biospecimen research resource is feasible when standard operating processes are established and consistently applied.

**RIF 10**

**BIOMAP: A Flexible, Integrative Sample Research Management System for Biobanking**

Steven Day¹, Patrick Pirrotte¹, Phani Tangirala¹, Pierre Plumer¹, Edward Suh¹

¹Translational Genomics Research Institute TGen, Phoenix, AZ, USA

Background: As biospecimen science and sample processing technologies are evolving, software solutions do not provide sufficient flexibility to handle the variations in protocols that occur across projects. The Biospecimen Material Accessioning and Processing (BIOMAP) system was developed to support the Integrated Biobank of Luxembourg (IBBL) and address the data management challenges in the fledging biobanking space with the intent of increasing operational efficiencies, storing complete biospecimen data and ultimately promoting scientific discovery. Methods: BIOMAP addresses two shortfalls associated with software solutions in the biobanking space. Firstly, both biospecimen and sample/clinical data tracking are managed in a single system. The system is workflow driven and allows annotations to be compiled throughout the sample lifecycle providing a single access point to view their complete profiles. Secondly, the system is designed with the ability of all sample collection activities to be project driven. That is, the types of samples expected to be collected, the sites involved, and the data collection forms for the project are governed by user defined templates. Results: BIOMAP has been configured and deployed for a number of different projects with varying sample and data collection requirements. Users have lauded the system for its ability to manage donor and sample identifiers, extensive data collection opportunities, standardized clinical vocabularies for online data
collection, in-depth reporting and user friendly experience. Conclusion: BIOMAP's adaptability and features have demonstrated that it can accommodate a variety of biobanking projects by providing a single data management portal and serves as a robust, stable foundation for eventual research and discovery pursuits.

**RIF 11**

**Continuous Development of a Tumor Bank Database: 12 Years of Experience of the A C Camargo Hospital (Sao Paulo, Brazil)**

Antonio Campos¹, Diogo Patrao¹, Luiz Camargo¹, Mario Dourado¹, Andre Silva¹, Louise Mota¹, Eloisa Olivieri¹, Dirce Carraro¹, Helena Brentani¹, Fernando Soares¹

¹A C Camargo Hospital, Sao Paulo, Brazil

Background: The A C Camargo Hospital Tumor Bank (ACCHTB) was established in 1997 to provide human tissue samples for the Human Cancer Genome Project, an initiative by the Sao Paulo Research Foundation and the Ludwig Institute for Cancer Research. To ensure the proper management of information associated with the collection of tissue, a database has been continuously developed by the Laboratory of Biotechnology (LBHC), with the help of members of the ACCHTB. Methods: Since the establishment of the ACCHTB, regular meetings between members of the LBHC and the AACHTB have led to the refinement of the database, which has been implemented in new versions of the ACCHTB management system. Results: The management system has evolved from a first version with basic solutions to the version currently in use, which has an interface for the management of the samples collected (e.g., fresh frozen or FFPE tissue, blood), the molecules extracted (e.g., DNA and RNA), the associated clinicopathological information and also of the research projects requiring access to samples stored by ACCHTB. Conclusions: The experience gained has been used for the development of new solutions useful in tumor banking and cancer research. All software developed is freely available and is currently being translated into English and Spanish.

**RIF 12**

**caTissue Suite: An Open-Access, Feature-Rich Tool for Biospecimen Annotation and Data Sharing**

Dave Mulvihill¹, Amy Brink¹

¹Washington University School of Medicine, Saint Louis, MO, USA

Background: Advances in molecular technologies and clinical trial design have mandated new requirements for the operation of biorepositories. caTissue Suite is a caBIG™ application designed to manage the associated complexities of biospecimen annotation data. Methods: caTissue Suite is a software application developed with requirements gathering and acceptability testing by multiple institutions. The application uses a web browser to store and retrieve data from a relational database. Its open program interface (API) permits customized access to all of the application's features, and data integration or migration from other data systems. Using caGrid, multiple installations of caTissue Suite can connect to facilitate data and biospecimen sharing across institutions. The application supports role-based access to administrative functions (container and protocol management), biospecimen accessioning, and investigator queries. An interface allows for import and coding of textual pathology reports. Discrete pathology and clinical data entry is also supported through customized data form creation. Results: caTissue Suite is sufficiently scalable and configurable for broad deployment across biorepositories of varying size and function. Numerous institutions have adopted the application and are using it in their daily operations. A caBIG™ supported, web-based "Knowledge Center" (https://cabig-nci.nih.gov/Biospecimen/KC) provides on-going application support via discussion forums, technical and user guides, training tools, and webinars. Conclusions: caTissue Suite is a freely available, fully supported, open-access software application for biospecimen data management. Use of caTissue Suite by several NCI Cancer Centers and other biospecimen resource groups is providing a rapid and facilitated path toward standardizing biospecimen informatics and promoting biospecimen data sharing both nationally and globally.

**RIF 13**

**BioBanking for Exploratory Research – A Collaborative Approach to Enhance Research Efforts**

Inge Tarnow¹, Anette Martinsen¹, Britta Krath¹, Lars Dragsted¹

¹University of Copenhagen, Frederiksberg, Copenhagen, Denmark

Background: Copenhagen University Biobank for Exploratory research (CUBE) stores biological specimens (human and animal) from experimental research projects associated with the University of Copenhagen. Experimental research materials could potentially generate more research output than initially planned. With novel information technologies, organizations can further utilize the collected samples to spur future explorative research and boost breakthrough research results. CUBE sought out for a biobanking informatics software which provides centralized data management, security, and control, in an effort to maximize data visibility, reduce manual efforts, and ensure regulatory compliance. Methods: CUBE identified comprehensive requirements to
establish its informatics backbone. The software needed to allow easy data entry on information associated with researcher, freezer, sample type, project, on any unique sample. Role-based access control was needed to provide complete data security. Moreover, extensive data accessibility was a critical requirement to take the collaborative efforts to the next level. Results: By leveraging the informatics software, information on projects, plans, and operational procedures can be stored with associated individual samples or sample batches. Sample identities can be generated in batch with printed barcode labels and assigned to the designated researcher prior to receipt of actual samples. In the later phase of the implementation project, real-time information will be shared via web-browser among multiple researchers, both internal & external. Conclusion: Consolidating user requirements on critical operation areas to select the best-suited informatics solution and establishing a solid implementation methodology are key to ensure success of a biobank’s IT project, enabling a collaborative approach to enhance research efforts.

RIF 14

Integrating Patient Specimen Biorepositories with Clinical Laboratory Information Systems to Advance and Support Personalized Medicine: The Massachusetts General Hospital Model

John Gilbertson1, Suzanne Raposo2, Patrick Sluss1
1Massachusetts General Hospital, Boston, MA, USA; 2Massachusetts General Pathology, Boston, MA, USA

Background: MGH is one of the largest academic hospitals in the world, with over $500 million in sponsored clinical and translational research per annum. Last year, MGH Pathology built a combined clinical research testing/tissue banking facility known as “the CLR” to support this research community. Rather than using a LIMS or a banking specific IT system, the CLR was built on the department’s existing, clinical laboratory information system (LIS). Reasons for the decision included the need to support a large research clinical testing flow, the ability to leverage existing infrastructure and personnel and the system’s proven ability to manage the hospital’s clinical specimen flow. Methods: MGH runs a Sunquest LIS with the Shared Application Module (SAM) (Sunquest Information Systems, Tuscon AZ USA). The CLR was created as a new laboratory in SAM with controlled dictionary, data and specimen sharing with main clinical lab including access to enterprise interfaces. Tissue banking was implemented as a set of tests under the LIS test menu that drove specimen and data collection, custom requisitions, automated processing, aliquoting and archiving under nitrogen. Results: The CLR went live in December 2009 as a consented repository. It has clean operational and financial separation from the main clinical lab with complete, controlled access to hospital billing, ADT, results, specimen routing and patient safety systems. Conclusions: The use of the LIS allowed rapid deployment of the CLR and should make it stable and scalable. The system is tested to support millions of specimens each year.

RIF 15

The Impact of Data and Knowledge Integration on Biobanking and Collaborative Discovery

Chris Asakiewicz1
1IT Strategy and Management Consulting, LLC, Chatham, NJ, USA

Personalized approaches to drug discovery, drug development and clinical care promise a new generation of preventive and preemptive health care. But countless data and knowledge ‘disconnects’ continue to result in delays, dysfunction, and poor clinical outcomes. To address these challenges organizations are beginning to look to interoperable software tools, standards, databases, and computing infrastructure to accelerate the shift to a personalized medicine paradigm. But what are the risks involved in integrating these interoperable components across processes in discovery research, biobanking, imaging, and clinical research – and how might these risks be mitigated? This paper discusses the efforts involved in identifying and addressing these risks in the establishment of a biobank and collaborative discovery environment to facilitate research in a rare disease – Neurofibromatosis (NF). Specific attention is given to outlining the “key” components of an integrated collaborative research process and how the components are used for collecting and leveraging results and findings within and across the NF research community. The paper discusses the risks associated with data and knowledge integration and how best to manage these risks to facilitate interoperability and collaboration. Finally, the paper discusses how adhering to “best practice” in data and knowledge integration can facilitate the collection and leveraging of research results and findings across a scientific community; allowing new hypotheses to be surfaced, discussed, and tested, data and biospecimens to be more effectively leveraged, and most importantly, research results and findings to be surfaced and reviewed in a more timely manner.
RIF 16

Advances in Sharing Biorepository Information through the Common Biorepository Model (CBM)

Andrew Breychak¹, Ian Fore², Anna Fernandez³, Elizabeth Prince¹, Carolyn Compton², Jim Vaught²
¹Sapient Government Services, Rockville, MD, USA; ²National Cancer Institute, Rockville, MD, USA; ³Booz Allen Hamilton, Rockville, MD, USA

Background: Last year, we introduced the National Cancer Institute’s initiative to create a Common Biorepository Model for biobanks and biorepository management systems vendors to use to broadcast searchable summary-level data about the available specimen collections that researchers could gain access to.

Methods: We report from an informatics perspective on the advances over the last year to augment the number of Biorepository management system vendors and the Biorepository communities interested in joining in the ‘CBM Challenge’ to share non-cancer and cancer-related specimen data.

Results: We have collaboratively assembled vocabulary lists from the Specimen Resource Community across additional NIH institutes that have biorepositories, as well as reached to key biorepository management software vendors to participate in testing early Model, database, and associated caBIG(r) (Cancer Bioinformatics Grid) caGrid service to connect repositories together to publish searchable summary level de-identified information about their biobank specimen inventory. We will demonstrate the progress-to-date of the early CBM Grid service and how we are able to obtain specimen data from several test data sites.

Conclusions: The CBM initiative has drawn participation across fourteen biorepository software vendors and steps are in progress to share summary-level biorepository data across the participants using semantically integrated and syntactically interoperable methods developed for the NCI caBIG(r) program. Through use of the caBIG(r) infrastructure and the NCI Specimen Resource Locator (SRL) initiative, there is a plan to make specimen information available to researchers and institutes looking to quickly identify locations of specimens and availability to advance their research.

RIF 17

Integrating Biospecimen Management with the Rest of Research and Healthcare using caBIG® and caTissue Suite

Ian Fore¹, Michelle Lee², Anna Fernandez³, David Mulvihiill⁴
¹National Cancer Institute, Rockville, MD, USA; ²SAIC Frederick, Gaithersburg, MD, USA; ³Booz Allen Hamilton, Rockville, MD, USA; ⁴Washington University School of Medicine, Saint Louis, MO, USA

Background: As advances in biotechnology have increased and the role of biospecimens in clinical discovery, it becomes essential that bioinformatics tools support the reporting and exchange of biospecimen information.

Methods: Through the caBIG® (cancer Bioinformatics Grid) program, the US National Cancer Institute focuses on developing common vocabulary, data standards, and technology grid interfaces to enable interoperable solutions across tools required for biomedical research (clinical trials, biobanks, imaging, etc). caBIG® caTissue Suite is an open-source example that employs these standards and continually evolves to meet the biorepositories’ and researchers’ needs.

Results: caTissue Suite is a caBIG® biorepository management tool designed for biospecimen inventory, tracking, and annotation. The software capabilities include data migration, pathology and clinical data entry, and customization through an application programmers interface (API). caTissue is in full production or pilot testing at several institutes inside the US and abroad, including Canada, UK, the Netherlands, and Australia. Using caGrid, multiple caTissue instances can connect to facilitate data and biospecimen sharing.

Conclusions: The growing caTissue Suite community and their requests for connecting to tools within their institutes support the move towards a service-oriented architecture. NCI will define and use the Service Aware Enterprise Architecture Framework (SAEAF) to provide secure and updated enterprise-access to clinical trial data, pathology images, and molecular analyses associated with the specimen. Other tools (including non-caBIG®) could also access the information through the service specifications and caGrid. The interoperability and reuse of data through services can save scientists’ research time; improve their efficiency, and reduce institution and government costs.
Special Events

Special Pre-meeting Session: Has the Time Come to Form a European Chapter of ISBER?

Tuesday, May 11th
12:30pm - 1:30pm
Willem Burger Zaal (3rd Floor)
Chairs: Robert Hewitt and Pasquale De Blasio

Overview: The objective of this session will be to find out the level of interest in forming a European chapter of ISBER. The alternative possibility of a European-African chapter will also be discussed. The session will begin with a short presentation describing the services and opportunities that the proposed chapter might offer. Active discussion will then be invited from meeting participants, to find out their opinions, wishes and expectations. Finally, a survey form will be distributed to gather additional feedback.

“Get to Know ISBER” Breakfast:

Wednesday, May 12th
7:30am - 8:20am
Van Beuningen Zaal (3rd Floor)

Meet members of the ISBER Council and find out more about ISBER. This breakfast is open to all interested parties, especially new members, first time meeting attendees, and registrants who are interested in becoming a member in the future.

Working Group Breakfast Schedule
(Please see page 99 for Working Group descriptions)

Thursday, May 13th
7:30am - 8:20am

Biospecimen Science
(Current WG Members Only)
Schadee Zaal (3rd Floor)
Leader: Fay Betsou

Informatics
Mees Zaal (4th Floor)
Leader: Cheryl Michels

Informed Consent Procedures
Ruys Zaal (4th Floor)
Leader: Scott Jewell

Enviro-Bio Specimens
Hudic Zaal (3rd Floor)
Leaders: Paul Bartels & Yeonhee Lee

Pharma-Academia
Van Beuningen Zaal (3rd Floor)
Leader: Joseph Kessler

Friday, May 14th
7:30am - 8:20am

Automated Repositories
Hudic Zaal (3rd Floor)
Leader: Andy Zaayenga

Biorepository Funding & Promotion
Van Beuningen Zaal (3rd Floor)
Leaders: Sara Loud & Hollie Schmidt

Biospecimen Science
(Open meeting; all meeting attendees are welcome)
Schadee Zaal (3rd Floor)
Leader: Fay Betsou

Rights to & Control of Human Tissue
Mees Zaal (4th Floor)
Leaders: Ty Hoover & Rajiv Dhir
ISBER Awards Presentation and Business Meeting:

Thursday, May 13th
11:30am - 12:30pm
Willem Burger Zaal (3rd Floor)

All meeting attendees are encouraged to attend the Awards Presentation and Business Meeting. You must attend to receive a Poster Award or a Door Prize!

- Outgoing President’s Message
- Presentation of 2010 ISBER Awards
  - Special Service Awards
  - Distinguished Leadership & Service Award
  - Award for Outstanding Achievement in Biobanking
- Strategic Plan
- Introduction of the 2010-2011 ISBER Council
- Presentation of the Presidential Gavel
- Plans for the 2011 Annual Meeting
- ISBER Committee Reports
- Update on Biopreservation and Biobanking (official Journal of ISBER)
- Presentation of the 2010 Poster Awards
  - The Asterand-ISBER Biospecimen Science Poster Awards
  - ISBER Biobanking Poster Awards
- Presentation of ISBER Exhibit Door Prizes

RoundTable Lunch Discussions: RoundTable discussions on Wednesday run concurrently with the Corporate Workshop

Join your colleagues in an interesting discussion on a special topic area during lunch! For further details and RoundTable Lunch Discussion topics, see page 97.

Wednesday, May 12th
12:30pm - 2:00pm
See Program for Topic/Room Assignments

AND

Thursday, May 13th
12:30pm - 2:00pm
See Program for Topic/Room Assignments

*Sign-ups for the RoundTable Discussions are available by the Registration Desk (Ground Floor).
Corporate Workshop:

**Ambient Temperature Technology for Sustainable Biobanking of DNA, RNA and Blood**  
Sponsored by GenVault Corporation

**Wednesday, May 12th**  
12:30pm - 2:00pm *(This workshop runs concurrently with RoundTable discussions)*  
*Mees Zall (4th Floor)*

**Speakers:**  
Steve Arsenault, Génome Québec-Centre hospitalier affilié universitaire régional Biobank, Chicoutimi, Québec, Canada, Michael Barnes, PhD, Cincinnati Children's Hospital, Cincinnati, OH, USA, Pasquale De Blasio, BioRep, Milan, Italy, Vinzenz Lange, DKMS Life Science Lab GmbH, Dresden, Germany

**Workshop Overview:**  
Attendees will learn about the use of dry-state, ambient temperature technology for collection, transport and storage of purified DNA, RNA and crude biosamples in a cost-effective, energy-efficient manner. Speakers will describe the use of GenVault products in their sample management, including GenPlates for crude biosample storage and transport; and GenTegra™ for storage and transport of purified DNA and RNA. Steve Arsenault, of Génome Québec, will discuss the use of GenPlates for automated, high-density, ambient temperature biobanking of blood samples. Dr. Michael Barnes, of Cincinnati Children's Hospital, will share data from a study of RNA stabilized at ambient temperature in GenTegra™ for Affymetrix expression profiling. Pasquale De Blasio of BioRep, will discuss the use of GenPlates for collection and transport of blood samples from Somalia, simplifying field collection and storage and enabling shipping without ice. Dr. Vinzenz Lange, of DKMS Life Science, will describe the use of GenPlates for storage of samples for their bone marrow donor registry.

**ISBER Workshops:**  
Sponsored by the ISBER Education & Training Committee

**Practical Approaches to the Daily Workflow Processes of a Tissue Bank**

**Wednesday, May 12th**  
4:30pm - 6:30pm  
*Willem Burger Zaal (3rd Floor)*

**Workshop Overview:**  
This workshop will present the workflow processes developed over time in a human tissue repository that operates multi-tissue collection initiatives. It will highlight the challenges faced over the years in the operation of these different initiatives and the solutions developed. Additionally, the perspective from an environmental specimen bank will be shared with participants. Presenters will share QA/QC processes and the templates of forms utilized in the different processes. Presenters will also provide the opportunity for participants to share their unique experiences and how they developed solutions to these situations. The overall goal of the workshop is to provide a forum for the exchange of ideas, the sharing of resources and the development of a network of individuals who can continue to work together in the future to improve their tissue banking activities.
Workshop Facilitators:
Stella Somiari, PhD, Windber Research Institute’s (WRI) Tissue Bank, USA, Katherine Sexton, MBA, University of Alabama at Birmingham (UAB), USA, and Rebecca Pugh, MS, National Institute of Standards and Technology (NIST), USA

Who should attend?
The workshop is for Researchers, Technicians or other repository personnel who collect human or environmental specimens and may be:
- In the process of setting up a repository
- Interested in sharing ideas and gaining new insights
- Interested in learning from the experience of others about general or specific repository workflow issues.

Benefits of the workshop:
- Lessons learned will help individuals to identify solutions to their ongoing challenges.
- Individuals planning a tissue bank will gain information to jump start the process and identify appropriate contacts.
- Attendees will develop a network of repository personnel with whom they can communicate and share ideas after the workshop/ISBER meeting (build new collaborations).

Digital Microscopy as a Tool in Tissue Banking

Wednesday, May 12th
4:30pm - 6:30pm
Fortis Bank Zaal (4th Floor)

Workshop Overview:
Whole slide imaging is a cutting edge technology that is revolutionizing image sharing, fostering collaborations, and enhancing the importance of banked tissues. The tool allows the sharing of digital images among international biorepositories - promoting a better integration of the global biobanking community. The workshop will focus on the importance of digital microscopy and its scope for biorepositories. The whole slide imaging system is of tremendous importance because it will allow biobanks to create a digital archive of morphological features, allow easy access for pathologist slide review, allow researchers to ascertain the quality and quantity of the requested tissues, and reduce duplicate reviews and quality control. The workshop will focus on different aspects from scanning, storing, and sharing of digital slides, to the financial aspects of using digital microscopy, including possible ways for acquiring the required funding.

Workshop Facilitators:
Charles Handorf, MD, PhD, University of Tennessee Health Science Center, USA, and Anand Kulkarni, MD, University of Tennessee Health Science Center, USA

Who Should Attend?
Anyone interested in learning how to digitize histology tissue slides and use the images for image evaluation, quality control, or for analysis with different algorithms.

How you will Benefit from this Workshop:
- You will learn the importance of Whole Slide Imaging in Tissue Banking
- You will learn how to scan slides and archive them in a searchable database
- You will learn how Virtual Microscopy can help as service and support of Tissue Biobanks
- Discussions will address instrument procurement and operational cost
- The workshop will address digital “Imaging Integration for Multisite Biobanks” and “Importance of Digitizing for Quality Control”
- You will learn digital quantification on tissue microarrays

**Potentials and Pitfalls in Establishing a Global Network to Identify Bio-Specimens for Research**

*Friday, May 14th*
*8:30am - 10:30am*
*Willem Burger Zaal (3rd Floor)*

**Workshop Overview:**
This workshop will discuss the basic concepts, current use and future use of a global network aimed at identifying biospecimens for research. This workshop will strongly reflect the urgent need for international collaboration that is needed to alleviate some of the difficulties and challenges in obtaining rare disease specimens. It will stress the need for a central source of information for basic and clinical researchers who search for rare disease biorepositories and/or biospecimens.

The following areas will be discussed specifically:

- **The Specimen Resource Locator** – Jim Vaught will provide an update and future direction for the model presented at the 2009 ISBER Annual Meeting, and an assessment of the Specimen Resource Locator’s role in advancing global biobanking initiatives.
- **Rare Disease Biospecimens** – Yaffa Rubinstein will present the challenges and obstacles in acquisition of rare disease biospecimens, and will discuss the establishment of the RD-HUB, a central portal to link all rare disease bio-repositories (ORDR database of bio-repositories and bio-specimens). She will also present the challenges and difficulties encountered by the rare disease community around the world in obtaining sufficient amounts of biosepcimens for basic and clinical research, the need for collaborative and novel approaches, the use of patient registries to increase procurements of rare disease biospecimens, the urgent need for linking every patient registry with a biorepository, and the need for global rare disease network to facilitate sharing and collaboration among all stakeholders.
- **International Sample Exchange** - Peter Riegman will present the EuroBoNeT Biobanks project and show how in collaboration with other European projects, BBMRI and OECI-TuBaFrost, it represents a new way of thinking in setting up international sample exchange platforms for medical research.
- **Potentials and Pitfalls in Establishing a Global Network** – Rivka Ravid will provide an overview of the potentials and pitfalls in establishing a global network to identify rare/unique biospecimens. This discussion will deal with the following issues concerning bio/tissue banking of rare diseases:
  o Harmonization of standard operating procedures (SOP’s)
  o Establishing the ethical and legal regulations and the ethical Code of Conduct
  o Stimulating the search for biomarkers of these diseases
  o Setting up consensus on global regulations for biobanking of these specimens
  o Setting up a global infrastructure for a digital inventory/database of available specimens that are accessible to all
  o Formulation of strategies to increase collaboration/exchange of these specimens and their accompanying data for biomedical research.
Workshop Facilitators:
Jim Vaught, PhD., Office of Biorepositories and Biospecimen Research, National Cancer Institute, USA, Yaffa Rubinstein, PhD., Office of Rare Diseases Research, NIH-OD/ODP/ORDR, USA, Peter H.J. Riegman, PhD, Erasmus MC Tissue Bank, The Netherlands, and Rivka Ravid, PhD., Director, Brain Bank Consultant, The Netherlands

Who should attend?
• Anyone planning or starting a new biorepository
• Researchers
• Biobank/tissue bank managers and/or technicians
• Clinicians
• Pathologists
• Geneticists
• International Biotech companies
• Lawyers /ethics experts

We hope to draw the attention of medico-legal and ethics experts, as the regulations for handling specimens and the genetic testing in rare diseases are not yet rounded in an ethical code of conduct on an international level.

How you will benefit from this workshop:
• You will learn the basic potential and pitfalls in establishing an international network of biorepositories collecting specimens of rare diseases.
• You will learn what to avoid and how to be successful in setting up this special collection.
• You will learn about the legal/ethical requirements of such an international network.
• You will be able to contribute your input and experience during the Q&A and the discussion on rare diseases biobanking and setting up this global collaboration.

Expanding the Role of the Consumer in Biobanking

Friday, May 14th
8:30am - 9:30am
Fortis Bank Zaal (4th Floor)

Workshop Overview:
This workshop will discuss the expanded role of the consumer in biobanking, through disease advocacy organizations and as individual accelerators of research. Solutions for disease advocacy organizations to develop biobanks will be discussed as well as privacy solutions for the consumer. A novel bi-directional clinical trial matching solution that allows consumers to assign their own privacy directives and share information to trusted entities will be demonstrated. A case study will be presented for PXE International, a disease advocacy organization that is shaping research through consumer engagement. This interactive session will inform participants about privacy tools and novel consumer engagement practices that involve the consumer as an active, informed participant in research.

Workshop Facilitator:
Liz Horn, PhD, MBI, Genetic Alliance BioBank

Who Should Attend?
Anyone interested in engaging consumers in biobanking efforts, including working with disease advocacy organizations or individuals for sample procurement and cohort development.
How you will Benefit from this Workshop:
- You will learn about advocacy-initiated biobanks, organizational influences and motivations, and how to engage with this population.
- You will learn about new tools that allow individuals to make informed choices about their health information through privacy directives.
- You will see how PXE International is using the described infrastructure and tools to facilitate research.
- Discussions will address emerging roles for consumers in biobanks and opportunities for community and individual engagement.

**New Tissue Preservation Technologies Improving Commercialization of Human Biospecimens**

*Friday, May 14th*
*9:30am - 10:30am*
*Fortis Bank Zaal (4th Floor)*

**Workshop Overview:**
Standard methods for preservation of tissue specimens for molecular analyses, including freezing and embedding in paraffin, have not undergone significant improvements for many years, are not energy efficient, and require long-term investments in complex and expensive infrastructure. Cureline is an experienced player in the international biobanking arena, and we collaborate with various institutions on development of tissue procurement technologies that may improve commercialization of human biospecimens. An overview of existing cutting edge methods and new trends for tissue preservation will be given. A special emphasis will be on methods developed recently for preservation of solid tissue specimens. An access to these powerful technologies can bring any biobanking organization to a new level of servicing academic investigators and biopharmaceutical industry. The presentation will be supported with real examples/speakers and discussion of new trends in tissue preservation and commercialization.

**Workshop Facilitators:**
Olga Potapova, PhD, Cureline, Inc. and Irina Zaytseva, MBA, Cureline, Inc.

**Who Should Attend?**
This workshop would benefit Scientists working with human tissues, and biobanking managers determining the tissue procurement procedures.

**How you will benefit from this Workshop:**
- You will learn what the most advanced tissue procurement methods and technologies are in the biobanking science.
- You will learn how the presented technologies can improve the commercialization of human biospecimens.
- You will be able to interact with leading specialists on the subject.
- You will be able to participate in an open discussion with end users of presented technologies and learn from their experience.
**Vendor Meeting for Exhibitors:**

**Thursday, May 13th**  
5:30pm – 6:30pm  
*Van Beuningen Zaal (3rd Floor)*

Exhibitors are encouraged to attend this meeting to provide feedback to ISBER.

**Plan your Schedule/Itinerary at the Meeting...**

**Working Group Breakfasts**

**Thursday, May 13th**  
7:30am – 8:20am  
Session Name: ________________________________  
Session Location: ________________________________

**Friday, May 14th**  
7:30am – 8:20am  
Session Name: ________________________________  
Session Location: ________________________________

**Education & Training Workshops**

**Wednesday, May 12th**  
4:30pm – 6:30pm  
Session Name: ________________________________  
Session Location: ________________________________

**Friday, May 14th**  
8:30am – 10:30am  
Session Name: ________________________________  
Session Location: ________________________________

**Lunch Sessions (RoundTables/Corporate Workshop)**

**Wednesday, May 12th**  
12:30pm – 2:00pm  
Session Name: ________________________________  
Session Location: ________________________________

**Thursday, May 13th**  
12:30pm – 2:00pm  
Session Name: ________________________________  
Session Location: ________________________________
ISBER 2010 RoundTable Schedule

**Wednesday, May 12**

**Biobank Accreditation**

**Hudic Zaal (3rd Floor)**

Moderator: Rebecca Barnes  
Supported by: Genologics

- Discussion of existing accreditation schemes
- Proposed blueprint for the biobank accreditation process
- What requirements/components should be evaluated by the biobank accreditation program, and what educational resources map to these?

**Repository Automation: Challenges & Benefits**

**Van Beuningen Zaal (3rd Floor)**

Moderators: Andy Zaayenga and Ira Hoffman  
Supported by: Fisher Bioservices

- Automation Drivers
- Implementation Strategies
- Justification

**Wednesday, May 12, 2010**

**Pediatric Biobanking**

**Schadee Zaal (3rd Floor)**

Moderators: Michael Barnes and Mariaelena Salvaterra  
Supported by: Dataworks Development, Inc.

- Discuss operational opportunities and challenges specific to pediatric biobanking.
- Discuss IRB considerations specific to pediatric biobanking.
- Network with other pediatric biobankers.

**Biospecimen Research**

**Ruys Zaal (4th Floor)**

Moderators: Helen Moore and Kurt Zatoukal  
Supported by: Biostorage Technologies Inc.

- Relevance of Biospecimen Research to Biobanking and Research and Development
- International Priorities for Biospecimen Research
- International Funding for Biospecimen Research

**Enviro-Bio WG: Extending the Network**

**Plate Zaal/Van Der Vorm Zaal (4th Floor)**

Moderators: Paul Bartels and Yeonhee Lee  
Supported by: MVE-Chart

- How to increase the member in non-human field
- Develop the best way to communicate among members
- Develop road map for international network for non-human field
- Develop education and workshop for non-human field
Thursday, May 13th

Biobank Education and Training
_Hudic Zaal (3rd Floor)_
Moderator: Rebecca Barnes
Supported by: REMP
- How are biobanks currently accomplishing education/training of personnel?
- What resources and programs are available?
- What would be the required modules for a comprehensive training program?

Closing the Loop: Should Repositories Ask Researchers to Return their Experimental Results?
_Van Beuningen Zaal (3rd Floor)_
Moderators: Hollie Schmidt and Sara Loud
Supported by: LabWare, Inc.
- Reasons why a repository might want access to experimental results from scientists analyzing its samples
- Types of data return policies repositories are adopting (request vs. require, abstracts/papers vs. complete data sets)
- Experiences from repositories that have adopted data return policies

Evaluation of an Instrument to Aid IRB Protocol Review to Promote Best Practice and Evidence Based Banking Practice
_Ruys Zaal (4th Floor)_
Moderator: Lisa B. Miranda
Supported by: Phase Forward

DNA Normalization: Methods and Best Practices
_Schadee Zaal (3rd Floor)_
Moderator: Yufang Tang
Supported by: Genologics
- Methods for DNA normalization
- Manual vs. automation
- Is DNA normalization necessary in biorepository?

Challenges of Establishing and Running a Tissue Bank in Academic Institutions
_Mees Zaal (4th Floor)_
Moderators: Patrick Adegbuyega and Stella Somiari
Supported by: GenVault
How to deal with tissue repository challenges in the following areas:
- Donor Recruitment and getting informed consent.
- Competing interests between Surgeons, Pathologists and Basic Scientists.
- Specimen collection, quality control and validation.

Addressing SOP's for Categorizing Tissue-Types and Sample Collection
_Plate Zaal/Van Der Vorm Zaal (4th Floor)_
Moderators: Paul Bartels and Yeonhee Lee
Supported by: Asterand
- The best way to collect samples from animal and plants for future research.
  - What should be collected from one sample (organ, saliva, skin, intestinal contents, etc.):
    - category of resources
  - The best practice to collect samples in situ and in the lab.
  - The best practice to store and distribute
- What kinds of common guidelines or SOP do we need?
  - Which guidelines do we have in each country?
  - How can we share?
  - International cooperation to develop new ones
- International rule to share the information and samples among countries for basic research
  - Is there a general international law or guidelines to share or transport samples crossing borders: how can we solve these problems?
ISBER Working Group Information

The ISBER Working Groups are an ongoing initiative, organized around timely, challenging issues related to biobanking and are composed of individuals with expertise and experience in the subject area who are committed to advancing a dialogue and producing outcomes that will make a difference to the discipline of biobanking. The goal of these Working Groups is to identify and tackle important, unresolved issues related to specimen banking that could benefit from broader discussion, with the ultimate goal of creating white papers or other publications that would discuss the issues and propose strategies for addressing them. Working Groups meet by teleconference and email discussions throughout the year.

For More information, visit: [www.isber.org/wg/workinggroups.html](http://www.isber.org/wg/workinggroups.html)

Automated Repositories
Organizer: Andy Zaayenga

The quantity of environmental and biological specimens and derivatives is rising and will continue to do so. Automation of the processes to collect, prepare, distribute, and archive the materials and the data associated with those materials becomes compelling as laboratory operations increase. Interoperability and facile exchange of specimens and data between collections is critical. Automated repositories present challenging issues with regards to design, sample process, data process and labware. The repository management industry is at a juncture where establishment of automation guidelines will greatly accelerate future development.

Biorepository Funding & Promotion
Organizer: Sara Loud and Hollie Schmidt

As the establishers of a research biorepository, we understand why our resource and others like it are so important. For example, biorepositories provide samples to scientists without access to a large clinical base and by supporting multiple research teams, they enable economies of scale to be realized, thus making efficient use of limited funding resources. However, we have faced difficulties when applying for grants from funding agencies to support our repository. One difficulty is that grant processes at funding organizations are often geared toward investigator-initiated, hypothesis-driven research projects rather than research resources. Another difficulty we have encountered is an apparent lack of appreciation within funding organizations for the benefits we provide to the scientific community. If other repositories have faced the same or similar difficulties in generating support for their efforts, perhaps by working together we can better understand and overcome them.

Biospecimen Science
Organizer: Fay Betsou

Biospecimens stored in biorepositories are intended to be used for biomarker identification and validation. The performance of such biomarkers greatly depends on the pre-analytical variations of the samples having been used for its initial identification. Quality Assurance on this issue is therefore of the outmost importance and allows us to establish the right correspondence between processing methods and end-use biomarkers. Interaction with OBBR and related FP7 initiatives should be ensured, in order to avoid duplication of efforts and for the sake of consistency.

Enviro-Bio Specimens
Organizers: Paul Bartels and Yeonhee Lee

The focus of this Working Group will be international collaboration on all non-human tissue and environmental samples, such as microbes, plants and animals, including wildlife, domestic livestock, pets, insects etc (Biodiversity) and abiotic / chemical samples of relevance to biodiversity and human health. The Working Group will focus on preservation methods; best-use/multiple-use of samples; limitations of use / ethics & best-practices; ISBER guideline for Field collection; and Intellectual Property Rights with private collections / commercial enterprises. Goals for the group will also include the development of tactics for sample exchange for basic research and work towards development of a common database.
Informatics

Organizer: Cheryl Michels

Membership:
The ISBER Informatics Working Group will include representatives from ISBER member vendors who provide custom built and COTS systems. The Group will also include ISBER members who are involved in informatics within a repository.

Commitment:
Members of the Working Group must be ISBER members in good standing. The expectation is that we will have a one hour conference call each month. Most of the work of the group will be conducted individually and off line. A time commitment of no more than 5 hours per month is anticipated.

Issues:
1. Development of Best Practices for Information Management Systems to support Biobanking including:

   - Decision making tools for selection of homegrown, custom built, or off the shelf (COTS) system
   - Appropriate use of an information management system in the biobank
   - Sample labeling
   - Federal guidelines as they pertain to information management systems in the biobank

2. Development of Self-Evaluation Tools for Providers of Information Management Systems that support Biobanking

Informed Consent Procedures for the Collection of Biospecimens

Organizer: Scott Jewell

There is a wave of interest throughout the research medical centers around the world to develop biospecimen banks to represent all patients that enter a hospital system. There is clear direction that most governments require patients to be consented or at least attempts to consent are conducted to fulfill this endeavor. Because biospecimen bank personnel are integrally involved in the understanding and possibly the process to consent patients for the donation of biospecimens to research, it would be helpful to establish the most commonly used methods and the respective justifications for the processes. Some example questions include; when is it most appropriate to consent patients for the gifting/donation of biospecimens to research? For tissues should this happen during a clinic visit (first, second), pre-surgery, or post-surgery. What methods of educating and informing the patient are commonly used? What are the ethical issues surrounding the choices and justifications? Many approaches to informed consent are being used and if multiple methods could be used to maximize the process of consenting all patients a greater success rate would result. ISBER is a broad body of specialists who could help further define and harmonize these procedures.

Pharma-Academia

Organizer: Joseph Kessler

The purpose of the ISBER Pharma & Academics Working Group is to establish a forum to support the free exchange of information for the advancement of clinical sample biorepositories across the Bio-Pharma industry as well as the academic community. This allows for consistency and standardization of best practices between members, while providing the highest sample integrity and ensuring the quality development of clinical products through translational science and the betterment of mankind.

Goals include 1) establishing a database linking sample type, storage/stability conditions with analyte testing, 2) offering repository facilities for member visits, 3) evaluating repository achievement levels, and 4) information sharing and evaluation of optimum cold storage equipment.
Rights to & Control of Human Tissue Samples
Organizers: Ty Hoover and Rajiv Dhir

As human tissue samples become increasingly valued for research, in both academia and industry, the question of who has the right(s) to control the use of that tissue becomes increasingly important. Most would agree that specimens should be used to create the most value. However, there may be disagreements about what the best value or use of specimens may be. When there is conflict regarding use, at any point in the life cycle of a human tissue sample, how is that conflict best resolved? There is little guidance or precedent to look to. Presently, as with many aspects of biorepositories and biospecimen resources, the landscape regarding oversight of use, or non-use, of specimens is at best fragmented. The issues become even more acute when considering the use of scarce resources such as “rare” tumor samples. And, while it may well be the case that there is no one-size-fits-all solution, there may be value in thoughtfully considering if the time is right to consider developing specific recommendations regarding rights to and control of “donated” human tissue, and if so, what are the necessary next steps toward that end. Fundamental to developing such working recommendations, it will likely be necessary to consider some of the following basic issues:

**Issues**

The need for guidance
1. Existing guidance (what, where, how specific, what authority)
2. “Case examples”: Instances where practical guidance would be helpful in determining most equitable, ethical, and legal means of using a sample?
3. Besides aiding in conflict resolution, is there other value to having specific guidance?

Who “owns” donated tissue samples? And what does it mean to “own” a sample?
1. Nomenclature (science v. legal)
2. Participants v. clinicians v. researchers v. hospital v. institution v. other
3. Role of informed consent documents, common law (recent reported cases), policies, other existing agreements vis-à-vis foreseeable expectations re ownership and use
4. What “rights” exist to human tissue samples in the first place?

Role of and composition of tissue oversight committees
1. When should oversight committees exist?
2. Who should be part of these?
3. What is their scope?
4. What would be costs of implementing?
5. What should they consider in making decisions? Can there be a meaningful algorithm for committees to look to? If so, what are the elements to consider and what weight to give them?

Next steps to moving forward in development of recommendations
Bischof, Remo
Elpro
Langeaaulistrasse 62
Bluchs, 9470
USA

Black, Jodi
NHBLI, NIH
6701 Rockledge Drive
Rockledge Building 2, Room 7104
Bethesda, MD 20892
USA
(301) 496-5861
jodi.black@nih.gov

Blazes, Michael
Wheaton Science Products
1501 North 10th Street
Millville, NJ 8332
USA
jackie.garrison@wheaton.com

Bober, Christina
Soventec GmbH
Hauptstraße 49
Dannewerk, 24867
USA

Bok-Ghee, Han
National Institute of Health, KCDC
194 TongIl-Lo
Eun Pyung-Gu
Seoul, 122-701
Republic of Korea
+82 2 380 1522
bokghee@korea.kr

Boon, Jan
Trinean
Dulle Grietlaan 17/3
Gentbrugge, B-9050
USA
jan.boon@trinean.com

Bosch-Comas, Anna
IDIBAPS
Villarroel 170
Barcelona, 8036
Spain
34 93227 5400
abosch1@clinic.ub.es

Brehm, Susanne
BioStorage Technologies Inc.
2655 Fortune Circle West
Suites A&B
Indianapolis, IN 46241
USA

Brink, Amy
Washington University Siteman Cancer Center
660 S. Euclid Ave.
Campus Box 8109
St. Louis, MO 63110
US
314-454-7615
abrink@wustl.edu

Broach, Steve James
Nexus Biosystems
12140 Community Road
Paway, CA 92151
USA
(619) 517-8587
sbroach@nexusbio.com

Brooks, Andrew I.
RWJ-UMDNJ/Rutgers, The State Univ.
170 Frelinghuysen Rd
Room 236H
Piscataway, NJ 8854
USA
(732) 445-0225
brooks@eohsi.rutgers.edu

Brooks, Erik Ryan
Vanderbilt University Medical Center
1161 21st Ave South
4920 TVC Bldg
Nashville, TN 37232
USA

Brown, Andrew
Progeny Sofeware, LLC
130 S. Main Street, Ste. 420
South Bend, IN 46601
USA

Brynzeel, Dick
Wheaton Science Products
1501 North 10th Street
Millville, NJ 8332
USA
+31 166 654008
jackie.garrison@wheaton.com

Burnett, Edward
Health protection Agency Culture Collections
Cepr
Porton Down
Salisbury, NA SP2 7LS
UK
019-806-12512
edward.burnett@pha.org.uk

Bush, Katherine
Brigham & Womens Hospital
Channing Blood Lab
221 Longwood Ave, Rm#611
Boston, MA 2115
USA
617-732-5613
nhkmb@channing.harvard.edu

Camacho, Paulo
INCA - Brasil
Rua Do Rezende 195/30
Rio De Janeiro, 20521-210,
Brazil
+55 21 39703900
camahno@inca.gov.br

Cambron Thomsen, Anne
INSERM
101 Rue de Tolbiac
Paris, 75013
France
33 5 61 14 59 59
cambon@citc.fr

Campbell, Lori D.
ATCC
602 Webb Gin House Rd
Bldg C
Lawrenceville, GA 30045
USA
(770) 339-5994
borl@cdc.gov

Campos, Antonio Hugo
A.C. Camargo Hospital
Rua Professor Antonio Prudente, 211
Sao Paulo, SP, 01509-900
Brazil
+55 1121895185
ahcampos@hcancer.org.br

Cappelletti, Leonardo
Angelantoni Industrie SpA
Massa Martana, 6056
Italy
roberta.molho@angelantoni.it

Carmanah, Jason
Mayo Clinic
200 1st Street SW
Rochester, MN 55905
USA
(507) 538-0709
carnahan.jason@mayo.edu

Carpenter, Jane
Australian Breast Cancer Tissue Bank
Darcy Rd
Westmead, NSW, 2145
Australia
+61 02 9845 9006
jane.carpenter@sydney.edu.au

Carroll, Leslie E
Information Management Services, Inc.
12501 Prosperity Drive
Suite-200
Silver Spring, MD 20904
USA
(301) 680-9770
carroll@imsweb.com

Carter, Anne
OnCore UK
Devonshire House, Manor Way
Borehamwood, WD6 1QQ
UK
44 (0) 2087314595
anne.carter@oncoreuk.org

Casali Da Rocha, Jose Claudio
Instituto Nacional de Cancer
Rua Andre Caval Canti
No 37
Rio De Janeiro, RJ, 202.31-050
Brazil
+55 21 3233 1338
crocha@inca.gov.br

Chapatte-Delapierre, Laurence
Fondation du CePO - CHUV
Rue Du Bugnon 46
Lausanne, 1011
Switzerland
412-131-44691
laurence.chapatte-delapierre@chuv.ch
Chavan, Vishwas  
Global Biodiversity Information Facility (GBIF)  
Denmark  
vchavan@gbif.org

Chuaqui, Rodrigo  
NIH/NCI  
6130 Executive Blvd  
Rm-6035A  
Rockville, MD 20892  
USA  
(301) 594-5786  
chuaquir@mail.nih.gov

Clark, Brian  
onCore UK  
Oncore Uk  
Devonshire House, Manor Way  
Borehamwood, WD6 1QQ  
UK  
004-420-87314591  
brian.clark@oncoreuk.org

Clements, Judith  
Australian Prostate Cancer Bioresource  
Brisbane, QL 4059  
Australia  
j.clements@qut.edu.au

Cohen, Yehudit C  
Sheba Medical Center  
Ramat Gan  
Tel Hashomer, TA 52621  
Israel  
972-353-08153  
cohen.yehudit@gmail.com

Compton, Carolyn C.  
NCI/OOD  
MSC 2580, Building 31/10A03  
Bethesda, MD 20892  
USA  
(301) 594-2212  
comptcar@mail.nih.gov

Coomeran, Ann  
Tissue Solutions Ltd  
Titan Enterprise, 1 Aurora Ave  
Clydebank, West Dunbartonshire, TA  
G81 1QQ  
UK  
44-419-517885  
ann@tissue-solutions.com

Cormier, Catherine Yvonne  
Arizona State Univ, Biodesign Institute  
1001 S. McAllister Avenue  
Tempe, AZ 85287-6401  
USA  
(480) 965-2857  
catherine.cormier@asu.edu

Corrochano, Virginia  
Center for Biomedical Network Research on Rare Diseases (CIBERER)  
Alvaro De Bazán, 10-bajo  
Valencia, 46010  
Spain  
+34 96339 4789  
vcorrochano@ciberer.es

Counsell, Mike  
AM Robotic Systems, Ltd  
10 Craneleigh Close  
Warminster, WA4 6SD  
UK  
+44 1942 418147  
mike.counsell@amroboticsystems.co.uk

Craven, James  
HighRes Biosolutions  
Unit 1, Chownley Business Park  
Chester  
Cheshire, CH39ax  
UK  
441-829-771244  
jcraven@highresbio.com

Crone, Ian  
BioStorage Technologies Inc.  
2910 Fortune Circle West  
Suite E  
Indianapolis, IN 46241  
USA  
(317) 390-1866  
ian.crone@biostorage.com

Crous, Pedro  
CBS Fungal Biodiversity Centre  
Utrecht, Netherlands  
crous@cbs.knaw.nl

Currat-Zweifel, Christine  
Foundation du CePO - CHUV  
Rue Du Bugnon 46  
Lausanne, NA 1011  
Switzerland  
412-131-4491  
christine.currat@chuv.ch

Dahlof, Bjorn  
Astrazeneca R&D  
Molndal, 43183  
Sweden  
+46 31 7762151  
bjorn.s.dahlof@astrazeneca.com

Dassesse, Thibaut  
GlaxoSmithKline Biologicals  
Rue De L Institut 89  
Rixensart, NA 1330  
Belgium  
32-626-5881  
thibaut.s.dassesse@gskbio.com

Davey, Claire  
Artificial Intelligence in Medicine  
2 Berkeley St, Suite 403  
Toronto, ON M5A 2W3  
Canada  
ecooke@aim.on.ca

De Jong, Bas  
Erasmus MC  
Josephine Nefkens Institute, Rm- BE  
235B  
P O Box 2040  
Rotterdam, 3000 CA  
Netherlands  
+31 10 704421  
b.dejong@erasmusmc.nl

De Wilde, Annemieke  
Universitair Ziekenhuis Antwerpen  
UZA Anatomie Pathologie  
Witrijkstraat 10  
Edegem, NA 2650  
Belgium  
32-821-3730  
annemieke.de.wilde@uz.be

De Gref, James R  
GenoLogics  
29, rue Tronchon  
75008 Paris, France  
+33 1 49 24 05 05  
michel.depont@cryobiosystem-imv.com

Depaertere, Stany  
Innogenetics NV  
Technologiepark 6  
Zwijnaarde, B-9052  
Belgium  
+32 9 329 1432  
ingricas@innogenetics.be

Deschenes, Mylene  
P3G Consortium  
3333 Chemin, Queen Mary Road  
Suite 590  
Montreal, QC H3V 1A2  
Canada  
(514) 373-7001  
mdeschenes@p3g.org

Deutsch, Gail  
GAPPS-Seattle Children’s Hospital  
4800 Sand Point Way Ne  
M/s A-6901  
Seattle, WA 98105  
USA  
011-206-9872103  
gail.deutsch@seattlechildrens.org

Didenko, Max  
Rouro US Inc.  
3932 Braveheart Circle  
Frederick, MD 21704  
USA

Diercks, Kai  
Soventec GmbH  
HauptstraBe 49  
Dannevern, 24867  
USA  
Kai.Diercks@soventec.de
Dubois, Jean-denis  
Ecogene-21  
305, Rue Saint-vallier  
Pavillon Des Augustines  
Chicoutimi, QC G7H 5H6  
Canada  
141-854-11077  
jean-denis.dubois@ecogene21.org

Edgar, Joanne  
Victorian Cancer Bank  
1 Rathdowne Street  
Carlton, Vic, 3053  
Australia  
joanne.edgar@cancervic.org.au

Elliott, W Mark  
James Hogg iCAPTURE Ctr for  
Cardiovasc & Pulm  
1081 Burrard St  
Rm 166  
Vancouver, BC V6Z 1Y6  
Canada  
(604) 806-8346  
Mark.Elliott@hli.ubc.ca

Elsener, Donat K  
Innoco GmbH  
Hoehweg 12  
Thun, BE,  CH-3600  
Switzerland  
+41 79 438 1030  
donat.elsener@innoco.ch

Elshof, Michel  
LabVantage Solutions Inc.  
1160 US Highway 22 East  
2nd Floor  
Bridgewater, NJ 8807  
USA

Eng, Chon Boon  
NUH/NUS Tissue Repository - National University Hospital  
5 Lower Kent Ridge Rd  
Main Building 1 Level 3  
Singapore, 119074  
Singapore  
65 67722379  
chon_boon_eng@nuhs.edu.sg

Falavigna, Maurizio  
BioRep S.R.L.  
Via Gaudenzio Fantoli 16/15  
Milano, 20138  
Italy  
39 335 8376253  
maurizio.falavigna@isenet.it

Fellman, Dennis  
Fisher BioServices  
14665 Rothgeb Drive  
Rockville, MD 20850  
USA  
(301) 315-8450  
dennis.fellman@thermofisher.com

Fernandez, Anna  
Booz Allen Hamilton - NIH - CBIIT  
One Preserve Parkway  
Suite-200  
Rockville, MD 20852  
USA  
(301) 838-3866  
fernandez-anna@bah.com

Ferrari, Maura  
Istituto Zooprofilattico Sperimentale  
Via A. Bianchi 9  
Brescia, NA 25124  
Italy  
+39 030 2290 248  
maura.ferrari@bs.izs.it

Fiboakk, Morten  
BioBank AS  
BioBank AS, Holsetg 17  
Hamar, NA NO-2317  
Norway  
+ 47 6250 9920  
morten.fiboakk@biobank.no

Flook, Robyn  
Finders University  
Department Of Human Physiology  
Fmc, Flinders Drive  
Bedford Park, Sa, NA 5042  
AU  
618-820-44107  
robyn.flook@finders.edu.au

Fore, lan  
National Cancer Institute  
2115 E Jefferson St  
Rockville, MD 20852  
USA  
(301) 496-3355  
forei@mail.nih.gov

Frey, Martin  
Hamilton Storage Technologies  
103 South Street  
Hopkinton, MA 1760  
USA  
mfrey@hamilton.ch

Fugman, Douglas  
Rutger's Univ Cell & DNA Repository  
604 Allison Rd  
Piscataway, NJ 8854  
USA  
(732) 445-7024  
fugman@biology.rutgers.edu

Gaffney, Eoin  
St James Hospital  
James Street  
Dublin 8,  
Ireland  
+353 1 416 2906  
egaffney@tcd.ie

Gandour-Edwards, Regina  
U California, Davis Health System  
4400 V St  
Path Building  
Sacramento, CA 95817  
USA  
(916) 734-2571  
regina.gandour-edwards@ucdmc.ucdavis.edu

Greenspan, Renata  
Walter Reed Army Medical Center  
6900 Georgia Ave, NW  
Bldg 1, Room A109  
Washington, DC 20307  
USA  
(202) 782-5147  
renata@greenmiller@us.army.mil

Grizzle, William E.  
University of Alabama at Birmingham  
703 S 19th St  
ZRB 408  
Birmingham, AL 35294-0007  
USA  
(205) 934-4214  
wrgrizzle@uab.edu

Groft, Stephen  
NIH  
6100 Executive Blvd  
Rm 3A-07  
Rockville, MD 20852-7518  
USA  
(301) 435-6041  
stephen.groft@nih.gov
McClusky, Marie  
Qiagen Ltd  
Dept Marketing  
Qiagen House, Fleminh Way  
Crawley, RH10 9NQ  
UK  
44 2103 2416402  
marie.mcclusky@qiagen.com

McGarvey, Diane  
CHTN Eastern Division  
3400 Spruce St. 566 Dulles  
Philadelphia, PA 19104-4283  
USA  
(215) 662-8204  
dfitzsim@mail.med.upenn.edu

McGrath, Michael  
U California, San Francisco  
1001 Potrero Ave, Bldg 3, Rm-207, Box 1317  
San Francisco, CA 94110  
USA  
(415) 206-8204  
mmcgrath@hemeonc.ucsf.edu

McKechnie, Douglas  
AstraZeneca  
Astrazeneca  
Alderley Park  
Macclesfield, NA SK10 4TG  
UK  
016-255-16569  
douglas.mckechnie@astrazeneca.com

McNally, James Walter  
NACDA Program on Aging  
330 Packard Street  
Ann Arbor, MI 48109  
USA  
(734) 615-9520  
jmcnally@umich.edu

McQuillan, Adrian  
AM Robotic Systems, Ltd  
10 Cranleigh Close  
Warrington, WA4 6SD  
UK  
+44 161 408 1125  
adrian.mcquillan@amroboticsystems.co.uk

McNally, James Walter  
NACDA Program on Aging  
330 Packard Street  
Ann Arbor, MI 48109  
USA  
(734) 615-9520  
jmcnally@umich.edu

McNally, James Walter  
NACDA Program on Aging  
330 Packard Street  
Ann Arbor, MI 48109  
USA  
(734) 615-9520  
jmcnally@umich.edu

Michels, Rick  
Dataworks Development, Inc.  
6608 216th Street, SW  
Suite-100  
Mountlake Terrace, WA 98043  
USA  
(425) 673-1974  
rick@dwdev.com

Michels, Cheryl  
Dataworks Development, Inc.  
PO Box 174  
Mountlake Terrace, WA 98043  
USA  
(425) 673-1974  
cheryl@dwdev.com

Miles, Sunita  
Kaiser Permanente  
2000 Broadway  
Oakland, CA 94612  
USA  
(510) 891-3456  
sunita.miles@kp.org

Mills, F. John  
BioStorage Technologies Inc.  
2910Fortune Circle West  
Suite E  
Indianapolis, IN 46241  
USA  
(317) 390-1866  
miriam.wagner@biostorage.com

Miranda, Lisa  
Biobusiness Consulting, Inc.  
lisa.miranda.007@gmail.com

Moore, Robert  
Fluidx  
Monks Health Hall, Chelford Road  
Nether Alderlay, Cheshire,  
UK  
robert@fluidx.co.uk

Moore, Helen  
NCI/OD  
31 Center Drive  
31/10A03  
Bethesda, MD 20892-2590  
USA  
(301) 496-1550  
moorehe@mail.nih.gov

More, Christophe  
Thermo Scientific  
Robert-Basch- Str. 1  
Langenselbold, 63505  
Germany  
Christophe.Morel@thermofisher.com

Morrin, Helen  
Cancer Soc Tissue Bank, Univ of Otago, Christchurch  
P O Box 4345  
2 Riccarton Avenue  
Christchurch, 8140  
New Zealand  
+64 3 364 0558  
helen.morrin@otago.ac.nz

Muller, Rolf  
Biomatrica  
5627 Oberlin Drive  
#120  
San Diego, CA 92121  
USA  
rmuller@biomatrica.com

Muller-Cohn, Judy  
Biomatrica  
Suite 124  
San Diego, CA 92121  
USA  
(858) 550-0308  
jmullercohn@biomatrica.com

Mulvihill, Dave  
Washington University in St. Louis  
Campus Box 8118  
660 South Euclid  
St. Louis, MO 63110  
US  
314-747-6785  
lscantlan@path.wustl.edu

Nadarajan, Jayanthi  
Royal Botanic Gardens KEW  
UK  
j.nadarajan@kew.org

Neff, Patrik  
Elpro  
Langeaulistrasse 62  
Buchs, 9470  
USA  
patrik.neff@elpro.com

Meir, Karen  
Israel National Tissue Bank  
Department Of Pathology, Pob 12000  
Hadassah-hebrew University Medical Center  
Jerusalem, NA 91120  
Israel  
972-508-946961  
karenm@hadassah.org.il

Meisner, Angela  
U New Mexico School of Medicine  
MSC08 4640, Surge Bldg Room 215  
1 University of New Mexico  
Albuquerque, NM 87131  
USA  
(505) 272-2422  
axmeisner@salud.unm.edu

Messier, Michael  
AutoGen, Inc.  
84 October Hill Rd  
Holliston, MA 1746  
USA
Neri, Christiana
Angelantoni Industrie SpA
loc. Cimacolle
Massa Martana, Perugia, 6056
USA
cristiana.neri@angelantoni.it

Newton, John
Computype Inc.
2285 West County Rd C
St. Paul, MN 55113
USA

Nicholson, Sarah Leigh
UK Children’s Cancer and Leukaemia Group (CCLG)
Cellular Pathology, Level 3 New Victoria Wing
Royal Victoria Infirmary, Queen Victoria Road
Newcastle Upon-tyne, NE1 4LP
UK

Nordstrom, Lora
TGen
445 Fifth Street
Suite-600
Phoenix, AZ 85004
USA
(602) 343-8560
lnordstrom@tgen.org

Nunez, Rene
Genvault Corporation
6190 Corte Del Cedro
Carlsbad, CA 92011
USA

Obergriesser, Frank
Fraunhofer Institut für Biomedizinische Technik
Industriestraße 5
Sulzbach, D-66280
Germany
frank.obergriesser@ibmt.fraunhofer.de

Oelmueller, Uwe
QIAGEN GmbH
Max Volmer - Str 4
Hilden, 40724
Germany
u.oelmueller@de.qiagen.com

O’Hare, Anthony B
PerciEnz Technologies, Inc.
708 Heartland Trail
Suite-1800
Madison, WI 53717
USA
(608) 826-6000
abhare@percienz.com

Oomen, Monique Maria
Erasmus MC
Dr Molewaterplein 40
Rotterdam, South Holland, 3000 CA
Netherlands
+31 10 7044460
m.oomen@erasmusmc.nl

Oste, Christian
Bioscope International
Calle Berruguete, 120, 4-1
Barcelona, E-08035
Spain
+34 669 571654
bioscope@earthlink.net

Palit, Liv
Folkhelseinstituttet/ Norwegian Inst of Public Health
Box 4404, Nydalen
OSLO, 403
Norway
+47 21076712
liv.palit@ffi.no

Paris, Monique
Institute for Breeding Rare and Endangered African Mammals
Yaleaana 114, 3584cm, Utrecht, The Netherlands
Department Of Equine Sciences
Utrecht, NA 3584CM
Netherlands
313-025-31331
m.paris@uu.nl

Parker, Emily
Monash University
Caulfield Hospital, 260 Kooyong Road
Caulfield South, VI, 3162
Australia
emily.parker@monash.edu.au

Parr-Jones, Alison
Wales Cancer Bank
Grove Mews
1 Coronation Rd
Birchgrove, Cardiff, CF14 4QY
UK
44 29 2052 9226
parry-jonesa@cf.ac.uk

Partanen, Audrey
Wesley Research Institute
451 Coronation Drive
Auchenflower
Queensland, 4066
Australia
+61 07 3721 1519
apartanen@wesleyresearch.com.au

Pattenden, Nick
Planer PLC
110 Windmill Road
Sunbury, Middlesex, TW167HD
USA
NPattenden@planer.co.uk

Pe Benito, Ruth
Garvan Institute of Medical Research
384 Victoria St
Darlinghurst, 2010
Australia
+02 92935834
r.pebenito@garvan.org.au

Pennington, Walt
Biomatrica
5627 Oberlin Drive
#120
San Diego, CA 92121
USA
858-550-0308
wpennington@biomatrica.com

Petel, Hemal
FSTRF
4033 Maple Road
Amherst, NY 14226
USA
716-834-0900
petel@fstrf.org

Peters, J.
Linde Gas Cryoservices
Postbus 121 - Koningskampen 5A
Hedel, 5321 JK
USA

Petrakova, Eva
NIADD, NIH
6700B Rockledge Dr
Bethesda, MD 20892-7624
USA
(301) 402-0132
petrakoe@mail.nih.gov

Pfeister, E.
Askin GMBH
Gewerberpark Keplerstraße 17-19
Gera, D-07549
USA

Piovezza, Michele
BioRep s.r.l.
Via Fantoli 16/15
Milano, 20138
Italy
m.piovezza@biorep.it

Pirrotte, Patrick
Integrated BioBank of Luxembourg
6 Rue Ernest Barbe
Luxembourg, L 1210
Luxembourg
352 27446440
arlette.fischbach@ibbl.lu

Pitt, Karen E.
National Cancer Institute-DCEG
6120 Executive Blvd
Suite 6110
Bethesda, MD 20892
USA
(301) 402-7750
pittk@mail.nih.gov

Potapova, Olga
Cureline, Inc.
1849 Bayshore Hwy
Suite-280
Burlingame, CA 94010
USA
(650) 692-6400
olga-potapova@cureline.com

Powell, Charles
Nexus Biosystems
12140 Community Road
Poway, CA 92064
USA
cpowell@nexusbio.com

Pennington, Walt
Biomatrica
5627 Oberlin Drive
#120
San Diego, CA 92121
USA
858-550-0308
wpennington@biomatrica.com

Petal, Hemal
FSTRF
4033 Maple Road
Amherst, NY 14226
USA
716-834-0900
petel@fstrf.org

Peters, J.
Linde Gas Cryoservices
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Luxembourg, L 1210
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Pitt, Karen E.
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Bethesda, MD 20892
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Suite-280
Burlingame, CA 94010
USA
(650) 692-6400
olga-potapova@cureline.com

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Nexus Biosystems
12140 Community Road
Poway, CA 92064
USA
cpowell@nexusbio.com

Pennington, Walt
Biomatrica
5627 Oberlin Drive
#120
San Diego, CA 92121
USA
858-550-0308
wpennington@biomatrica.com

Petal, Hemal
FSTRF
4033 Maple Road
Amherst, NY 14226
USA
716-834-0900
petel@fstrf.org

Peters, J.
Linde Gas Cryoservices
Postbus 121 - Koningskampen 5A
Hedel, 5321 JK
USA

Petrakova, Eva
NIADD, NIH
6700B Rockledge Dr
Bethesda, MD 20892-7624
USA
(301) 402-0132
petrakoe@mail.nih.gov

Pfeister, E.
Askin GMBH
Gewerberpark Keplerstraße 17-19
Gera, D-07549
USA

Piovezza, Michele
BioRep s.r.l.
Via Fantoli 16/15
Milano, 20138
Italy
m.piovezza@biorep.it

Pirrotte, Patrick
Integrated BioBank of Luxembourg
6 Rue Ernest Barbe
Luxembourg, L 1210
Luxembourg
352 27446440
arlette.fischbach@ibbl.lu

Pitt, Karen E.
National Cancer Institute-DCEG
6120 Executive Blvd
Suite 6110
Bethesda, MD 20892
USA
(301) 402-7750
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Potapova, Olga
Cureline, Inc.
1849 Bayshore Hwy
Suite-280
Burlingame, CA 94010
USA
(650) 692-6400
olga-potapova@cureline.com

Powell, Charles
Nexus Biosystems
12140 Community Road
Poway, CA 92064
USA
cpowell@nexusbio.com
Sexton, Katherine  
University of Alabama at Birmingham  
703 S. 19th Street ZRB 449  
Birmingham, AL 35294-0007  
USA  
(205) 934-6071  
sexton@uab.edu

Shannon, Jim  
REMP  
P O Box 13953  
Research Triangle Park, NC 27709  
USA  
(919) 361-5200  
jim.shannon@remp.com

Shea, Kathi  
SeraCare BioServices  
8425 Progress Dr M  
Frederick, MD 21701  
USA  
(301) 775-7775  
kshea@seracare.com

Sheedy, Donna  
The Univ of Sydney  
Blackburn Bld. Camperdown  
Sydney, NSW 2006, Australia  
-14882  
donnas@med.usyd.edu.au

Sluss, Patrick  
Massachusetts General Hospital  
Mgh, Edwards 003, 55 Fruit St  
Boston, MA 2114  
USA  
617-724-1463  
sluss.patrick@mgh.harvard.edu

Smith, Frank  
GenoLogics  
4464 Markham St Suite 2302  
Victoria, BC V8Z 7X8  
USA  
510-891-3651  
david.p.smehurst@kp.org

Sobel, Mark  
ASIP  
9650 Rockville Pike  
Bethesda, MD 20814  
USA  
301-634-7130  
mesobel@asip.org

Somieri, Stella  
Windber Research Institute  
620 Seventh St.  
Windber, PA 15963  
USA  
(814) 467-9844  
s.somieri@windber.org

Starkweather, Robert  
FSTRF  
4033 Maple Road  
Amherst, NY 14226  
USA  
716-834-0900  
starkwea@fstrf.org

Suh, Edward  
TGEN  
445 N 5th St  
Phoenix, AZ 85004  
USA  
(602) 343-8434  
esuh@tgen.org

Sullivan, Robert  
AutoGen, Inc.  
84 October Hill Rd  
Holliston, MA 1746  
USA  
(508) 429-5965  
bobs@autogen.com

Sun, Menghong  
Fudan University Cancer Center  
270 Dong/lan Road  
Shanghai, 300032  
China  
86 21 64175590  
menghong@hotmail.com

Sui, Shu-Ming  
NUH-NUS Tissue Repository, NUHS, Singapore  
Nuh-nus Tissue Repository, Nuhs Research Office  
Dept Of Pathology, 5 Lower Kent Ridge Road  
Singapore, 119074  
Singapore  
65-772-2310  
shi_min_tan@nuhs.edu.sg

Suljic, Jasa  
The George Washington University  
1201 23rd St NW  
Washington, DC 20037  
USA  
(202) 994-3281  
suljic@gwu.edu

Tembakha, Riad  
Biobanque de Picardie  
BP 90007  
Saleux, 80480  
France  
+33 3 2233 1150  
tembakha@biobanque-picardie.com

Thompson, Anne  
Victorian Cancer Bank  
1 Rathdowne St  
Carlton, NA 3053  
Australia  
+613 9635 5439  
anne.thompson@cancervic.org.au

Toke, David  
Rutgers' Univ Cell & DNA Repository  
604 Allison Rd  
Piscataway, NJ 8854  
USA  
732-445-2457  
toke@biology.rutgers.edu

113
Wilson, Edmund C L
Titan Software
2 Newhams Row
London, SE1 3UZ
UK
442-073-676842
edmund.wilson@titian.co.uk

Winters, Ryan M
Rutger's University
604 Allison Rd
Piscataway, NJ 8854
USA
(732) 445-7190
winters@biology.rutgers.edu

Womack, Chris
AstraZeneca
Merseyide, Alderly Park
Alderley Park
Macclesfield, Cheshire, NA SK10 4TG
UK
+44 1625 233688
chris.womack@astraZeneca.com

Yaffe, Robert
GE Sensing
Sickleville, NJ 8081
USA
(856) 228-8180
rob.yaffe@ge.com

Yang, Nannan
Institute of Community Medicine
Univ of Tromso
Tromso, 9037
Norway
+47 77644838
nannan.yang@uit.no

Zaayenga, Andy
HighRes Biosolutions
1730 W Circle Drive
Martinsville, NJ 8836
USA
(732) 672-4452
azaayenga@highresbio.com

Zatloukal, Kurt
Medical University of Graz
Auenbruggerplatz 25
Graz, 8036
Austria
kurt.zatloukal@meduni-graz.at

Zetzsche, Holger
DNA Bank Network, BGBM
Königin-luise-strasse 6-8
Berlin, NA 14195
Germany
493-083-850139
h.zetzsche@bgbm.org

Zimmermann, Heiko
Fraunhofer Institut for Biomed Technik
Ensheimer Strasse 48
St Ingbert, 66386
Germany
+49 6894 980 257
heiko.zimmermann@ibmt.fraunhofer.de
Organizational Members are organizations and vendors from government, academia, and industry that manage repositories and provide services and products for specimen collection and repository management. Members designate one Delegate to represent the organization/company as well as Alternate Delegate(s) as follows:

- **Small Organization:** One Alternate Delegate
- **Medium Organization:** Three Alternate Delegates
- **Large Organization:** Five Alternate Delegates

**Organizational Member Benefits:**

- Delegates and all Alternate Delegates receive access to the ISBER Members-only listserv. Additional company employees can be added to the ISBER Member Listserv for an additional fee of $80/year.
- ISBER MarketPlace on the ISBER website - Members can choose to have descriptions of their products and services, logo, links, and their company contact information listed.
- ISBER provides a perfect forum for organizations and companies to reach their target/niche audience. Through links and announcements on the ISBER website, ads, peer-reviewed articles in *Biopreservation and Biobanking* (BIO), and exhibits at the annual meeting, members can interact directly with, and showcase their products very cost-effectively to, the repository community.
- Online subscription to *BIO*, the official journal of the Society, for Delegates only
- Delegates may choose to upgrade to the Print subscription of *BIO* and Alternate Delegates and employees of Organizational Members may subscribe to *BIO* online and/or in print at a reduced rate
- Periodic ISBER newsletters published in *BIO* and online at www.isber.org
- Reduced registration for Society meetings for all employees
- Discounted exhibit space rental at the Annual Meeting
- Members receive one vote, to be cast by the Delegate.
- Delegates and Alternate Delegates are eligible to hold office on the ISBER Council and Committees.
- Contribute to planning the annual meeting and exhibits
- Communicate directly with the ISBER Council
- Online jobs board at: www.biobankingjobs.com
- Delegates are ISBER Affiliate Members of the American Society for Investigative Pathology (ASIP).
- Website: www.isber.org

**Institution Name**

Institution ____________________________________________________________

Dept. ______________________________________________________________

Address _____________________________________________________________

City ___________________________ State ___________ Zip ______________

Country ____________________________________________________________

Tel ___________________________ Fax ________________________________

Email ______________________________________________________________

Description of Institution or Organization’s repository activity:

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Number of employees: ________________________________________________

Website: ____________________________

**2010 Membership Dues (Annual):**

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PAGE 1 of 2; Applications cannot be processed without both pages
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- Store biologicals
- Store environmental samples
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- Store own materials
- Supplier to repositories
- Utilize/purchase material from repositories

Type of Repository, Check all that apply
- Animal Specimen Repository
- Environmental Repository
- Human Specimen Repository
- Microorganism Culture Collection
- Museum Repository
- Plant/Seed Repository
- Other________________________

Interest Groups, Check all that apply
- Cell/Culture
- Cryogenics/Cell Preservation
- Legal and Ethical Issues
- Non-Human Specimens
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Membership Information, continued...

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**Individual Member Benefits:**
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- Website: www.isber.org
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International Society for Biological and Environmental Repositories
9650 Rockville Pike, Bethesda, MD 20814 (USA)
Tel: +1 301 634 7990
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