Guide on Quitlines and Research

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Note: this document contains multiple links to internal and external resources and is viewed better online in a PDF format. If you are viewing this document in a paper format, please remember to print all appendices and additional supporting documents as well as visit links to external resources contained within the document.
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INTRODUCTION

Quitlines are an effective intervention for treating tobacco dependence and have been widely adopted in North America and other regions. Yet much remains to be learned about ways to make quitlines more effective. The purpose of this Guide is to expedite the relationship-development process between quitlines and researchers, and to assure that issues likely to arise within the context of conducting research studies are anticipated by all parties.

The North American Quitline Consortium (NAQC) encourages its members to engage in research that will provide answers to important research questions such as how quitlines may better reach high prevalence and underserved populations, how service offerings can best meet the needs of current smokers, what type of service offerings are most cost-effective and how quitlines may best integrate new technologies into their service offerings.

To engage in studies with quitlines, researchers, quitline funders and quitline service providers will need to develop both an understanding of the context in which each works as well as working relationships that may anticipate and address issues likely to arise.

This Guide is geared towards all parties associated with quitlines such as funders, service providers, and evaluators, as well as researchers who currently work with or are interested in working with quitlines. It aims to educate the quitline community about the research process and practices, and to educate researchers about the complex nature of quitlines.

Additional resources have been created to serve as companion pieces to this Guide. These resources are provided online at NAQC’s website (http://www.naquitline.org/?page=researcharticles).

- **Appendix A** provides a glossary of terms often used by researchers and/or quitlines.
- **Appendix B** includes sample text and paragraphs that were gathered from existing quitline data use agreements and contracts. It was developed to provide additional assistance with quitline research.
- **A one-page checklist, The Basics for Quitlines: Questions to Ask of Researchers who Request Data,** was developed as a guide for quitlines when they are asked to provide quitline data. The checklist is intended as a guide for initiating and continuing discussions with researchers who are interested in quitline data. This one-page checklist is also included in Section III.

The Guide document was also developed to support progress in a larger research agenda for quitlines. The research agenda started with a scan of the literature to identify gaps and is structured around NAQC’s strategic goals. The agenda may not be a comprehensive list of potential research, but is useful as a starting point for discussion on quitline-related research. The agenda is used as a tool to help NAQC focus its efforts, as well as a tool for the Quitline community to be able to clearly state where researchers and quitline administrators/operators have common interests. The following descriptions are just a few examples of research questions, taken from the research agenda:

- **Descriptive studies with special focus on the reach of quitlines and diversity/disparities in use of quitlines such as:**
  - Who calls quitlines?
  - What services do callers select and what do they receive?
  - What percentage of quitlines offer nicotine replacement therapies (NRTs) or other medications?
- **Cost/cost-effectiveness studies**
- What is the cost effectiveness/cost benefit of various quitline services? How does this vary across population groups (e.g., light vs. heavy smokers)?

- What are effective and cost-effective models for delivering NRT/medications through quitlines?
  - Timing
  - Dosing
  - Funding strategies
  - New medications (e.g., varenicline)
  - Can we remove barriers for accessing NRT through a quitline model?

The full research agenda for quitlines can be found on NAQC’s website (http://www.naquitline.org/?page=RS#Agenda).

**Quitlines and Researchers: Things to Consider Before Research Project Initiation**

Quitlines are a unique tobacco cessation service and are poised to become involved in a wide-range of research opportunities. It is important for quitlines and researchers alike to enter into the collaborative research project with a shared knowledge and desire for a cohesive and beneficial project. Below are a few things for all parties to consider before project initiation:

a. Guiding Principles for Quitline Research
   - Focus on service and quality is a priority
   - Collaboration and reciprocity (mutual benefit) are key principles
   - Participatory nature of the collaboration and the importance of all collaborators, researchers and practitioners
   - Research should support a broader research agenda (for quitlines, tobacco control, state, local communities, etc.)
   - Findings should be applicable to the delivery of quitline services and should help to improve the delivery of services
   - Focus on priority and underserved populations
   - Sustainability of the intervention is important

b. Confidentiality agreements for external observers (non-quitline staff) might be necessary to maintain confidentiality for any quitline sessions (audio/video) or data reviewed.

c. When working with “real” quitlines the research partners need to determine how the study population is selected, and how anyone not in the study will be treated, paid for, etc. What are the implications for the non-study population? What are the implications for the quitline funder? Do the people in the study still “count” as having been served by the quitline? Are they included in reach or quit rate numbers that are reported to NAQC and the funding source?

d. Will the focus on direct application of the study findings to improving quitline service be a deterrent for research?

e. Will the complexity or cost of the research protocol or intervention be a deterrent for quitline administrators and their quitline clients?

f. If possible, consider the generalizability of the study results for all quitline service providers.
The Guide has four main sections.

1. **Getting Started** explains the layout and purpose of this document.
2. **Primer on Quitlines** is intended for use by researchers and provides a basic explanation of quitlines, their components, and additional resources.
3. **Primer on Research** was designed for review by all parties involved with quitlines and provides an overview of the research process and important practices.
4. **Multi-Site Studies** gives an overview on the benefits and possibilities of more complex research studies involving multiple quitline sites.

**I. GETTING STARTED**

When researchers and quitlines begin or continue to collaborate on research studies, it is important that there is a shared understanding about what each party can bring to the project, what each party hopes to gain from the project and what operational challenges or restrictions exist for each party. This Guide may be reviewed as a whole, or readers can examine the sections relevant to their needs.

The information provided here is intended to enhance and encourage future and continued research with quitlines through facilitation of more informed discussions between quitlines and researchers. By linking quitlines and researchers with additional tools and resources, we hope to familiarize them with each other’s working environment, thereby creating a foundation for an improved collaboration. Through the topics and resources covered in the following sections, we hope to facilitate the conduct of research involving quitlines as well as to advance the use of research that involves quitlines. The resources and topics contained in the final section aim to encourage the use of multi-site studies to advance research on quitlines.

**II. PRIMER ON QUITLINES (FOR RESEARCHERS)**

This section provides an overview of the many different, yet critical, components that form a public, tobacco cessation quitline. Quitlines are telephone-based tobacco cessation services that help tobacco users quit. Services offered by quitlines include coaching and counseling, referrals, mailed materials, training to healthcare providers, Web-based services and, in some instances, free medications such as nicotine replacement therapy (NRT). Although there are many similarities between quitlines, it is rare that any two quitlines are exactly the same with respect to structure, operations, or services provided. For more information on these and other details, NAQC has additional resources on public quitlines in North America including a profile of each quitline in the U.S. and Canada at [http://www.naquitline.org/map](http://www.naquitline.org/map).

Much research shows that quitlines are highly effective in helping tobacco users quit. Due to their ability to reach and serve tobacco users, regardless of location, quitlines have quickly spread across North America. Today, residents in all 50 states, the District of Columbia, each U.S. territory, all ten Canadian provinces and two territories have access to public quitline services.

NAQC has created multiple reference materials to provide detailed descriptions of quitlines, how they operate, and who they serve. The NAQC website provides links to many of these resources. Below is a list of informational fact sheets that could be helpful for review:

- **What is a Quitline?** ([http://www.naquitline.org/resource/resmgr/Sustainability/100812_what-is-a-quitline.pdf](http://www.naquitline.org/resource/resmgr/Sustainability/100812_what-is-a-quitline.pdf))
Quitline Basics: Telephone-based cessation services that help tobacco users quit. ([http://www.naquitline.org/resource/resmgr/docs/naqcfactsheet_quitlinebasics.pdf](http://www.naquitline.org/resource/resmgr/docs/naqcfactsheet_quitlinebasics.pdf))

The Quitline Basics: Telephone-based cessation services that help tobacco users quit Fact Sheet, listed above, describes the services, including counseling, provided by quitlines. Below is an excerpt: ([http://www.naquitline.org/resource/resmgr/docs/naqcfactsheet_quitlinebasics.pdf](http://www.naquitline.org/resource/resmgr/docs/naqcfactsheet_quitlinebasics.pdf))

Quitlines vary in structure, size, budget and service offerings. The most typical quitline models are smoking cessation quitlines where clients may call and speak directly with a counselor; calls go directly to a taped recording and callers hold while the call is dispatched to a counselor; or callers are presented with a telephone tree with options for selecting the services they need (e.g., materials, counseling, medication, referral). Some quitlines are small, with one or two staff managing the quitline, providing counseling and conducting promotions and evaluation; while larger, well-established quitlines may have 100 or more staff.

Quitlines offer telephone-based support for people who want to quit using tobacco. According to data from NAQC’s Annual Survey of Quitlines in North America (2010) the most common services provided by quitlines include:

- **Telephone counseling:**
  - Proactive counseling - Quitline initiates counseling call to interested tobacco user
  - Reactive counseling - Tobacco user calls quitline, and counseling is initiated
  - Single-session counseling - 10 minutes or longer
  - Minimal, brief intervention counseling - 10 minutes of less

- **Medications** – Many U.S. quitlines provide cessation medications or provide access to medications for their clients. In 2010, approximately 75% of U.S. quitlines provided some type of medication. The following is a list of the medications being provided:
  - Nicotine replacement therapy (NRT) – such as the patch, gum, or lozenge
  - Prescription medication – such as bupropion, nicotine inhaler, varenicline, or nasal spray

- Referrals – In the past seven years, quitlines have moved from a handful of states offering fax referral to about two-thirds of states offering such services. Fax referrals vary from passive processes to those well integrated into health care and other organizational systems. Quitlines provide referrals out to other local cessation services as well as receive referrals to the quitline from outside sources, notably from health care providers.

- **Training for health care professionals and the public**

- **Mailed materials** – Most quitlines mail materials. NAQC members reported having over 300 such materials, which included literature in a variety of languages and materials for special populations, including racial/ethnic groups, Lesbian, Gay, Bisexual and Transgender (LGBT) community, youth, elderly, low socio-economic status and pregnant women. While most materials were for smokers, some were also for family, friends and health care providers.

- **Web-based services** – Many quitlines provide or coordinate with a Web-based service provider to offer one or more of the following services:
  - Internet counseling and/or email messaging
  - Self-directed Web-based intervention
Quitline Components
Quitlines are not a single entity or organization. They are composed of multiple organizations that come together to create and run an operational quitline in a state, province, or territory. Each quitline has its own unique composition of organizations. The following list describes the types of organizations that make up public quitlines run by state and provincial governments.

- **Quitline Funder (aka Administrator):** The funder/administrator organization of the quitline directly provides the funds for the services. It is responsible for determining the type of quitline services that are offered to tobacco users who call. Often, the funder develops a Request for Proposal (RFP) to seek out a service provider who will provide the call center and counseling services. The funder negotiates a contract with the service provider that specifies the service levels, length of the contract, performance requirements and payment details. Examples of quitline funders are state or provincial tobacco prevention programs within departments of health, state tobacco prevention foundations, and territories.
  
  - **Role related to potential research project:** The quitline funder should be the first organization approached about the research project. They determine the overall budget, services, current research or project involvement, and future efforts and goals of the quitline. The administrator will also have knowledge of any restrictions to their quitline operations based on state or provincial regulations, as well as restrictions from the funding source. The point of contact within the funder organization will also work with the researcher to establish communication channels and timeline for the proposed project.

- **Quitline Coordinator:** There are two types of coordinator organizations for quitlines. The first is typically a separate organization from the quitline funder that fulfills many of the administrative responsibilities of the quitline funder described above, including developing RFPs, negotiating contracts for quitline services, and monitoring contract performance (e.g., reviewing monthly reports, monitoring quitline metrics over time, etc.). The second type of coordinator organization is typically found in Canadian quitlines, where a separate organization (often a provincial branch of the Canadian Cancer Society) is responsible for promotion and outreach related to the quitline.
  
  - **Role related to potential research project:** In the first example listed above where the coordinator organization acts very similarly to a quitline funder, the coordinator organization would likely need to be involved in any discussion of a potential research project, and in some cases, may do so in place of the quitline funder. In the second example, where the coordinator organization is tasked with quitline promotion and outreach, it is unlikely that it would need to be involved in initial discussions about a research project. Depending on the scope and topic of research, “promotional” coordinators may need to be involved at later planning or operational stages of the research project.

- **Funding Sources for quitlines:** There are many examples of funding sources for quitlines, such as federal grants (Centers for Disease Control and Prevention (CDC) or Health Canada), Master Settlement Agreement funds, state or provincial funds, tobacco tax revenues, or other government funds, third-party reimbursements, and non-profit organizations. Quitline funders can seek funds from multiple funding sources for financial assistance with quitline operations, services, promotions and/or medications for clients. It is possible that a funding source might have restrictions tied to their funding, such as reporting requirements, or specific restrictions on use of funds. Some funding sources may provide oversight of, and technical assistance to, quitlines. A list of FY10 and FY 11 funding sources

  - Chat rooms
  - Information about tobacco cessation
  - Automated email messaging
  - Information about the quitline
Role related to potential research project: The funding sources are usually not involved in routine decision-making or administration of the quitline. They might have specific regulations tied to their funding agreement with the quitline funder/administrator that could impact the research project. It is not customary for the researcher to interact with the funding sources; the administrator serves as the liaison, if needed.

- **Quitline Service Provider:** The service provider is the operator of the counseling services for the quitline and is often selected by the quitline funder through a competitive process such as a RFP. The service provider is composed of the call center and administrative and counseling staff, and provides additional services, guidance and expertise in the various protocols and options available to the quitline funder. The services and call protocols used for each quitline have been agreed upon through the contract between the funder and the service provider. A few examples of types of organizations that are service providers are healthcare organizations, research organizations, hospitals, and universities. They can be for-profit or non-profit organizations.
  
  - **Role related to potential research project:** Service providers are actively involved with quitline callers and collect all caller data. They create the database and its coding variables to input and store data. It is often necessary to bring the service provider into discussions about research projects since they maintain a quitline’s data and will have to set up access to, or provide researchers with, the data needed for the project. The quitline funder will often facilitate this discussion.

- **Quitline Evaluator:** Evaluators may be a part of the quitline funder’s organization, the service provider’s organization or an independent organization. Independent evaluators are contracted through an RFP process. Evaluators are often tasked with reviewing quality assurance, quitline caller satisfaction, as well as the reach of the quitline, quit rates, and overall effectiveness of the quitline. Many service providers also conduct evaluation of their services. Some evaluators are contracted to conduct evaluations for more than one quitline. It is important to note that not all U.S. and Canadian quitlines conduct follow-up evaluations.
  
  - **Role related to potential research project:** Evaluators may be involved in the research project but the decision about their involvement or level of involvement is determined by the quitline funder.

### Data from Quitlines

Quitlines in the U.S. and Canada received 947,211 calls in 2010 (920,790 in the U.S. and 26,421 in Canada). Of these, nearly 500,000 were unique calls from tobacco users seeking help in quitting. Quitlines in North America are distinctive in that they use the Minimal Data Set (MDS) as a standardized approach to collecting and evaluating data from callers. The MDS is comprised of 18 questions that all callers answer at intake and 12 questions that a sample of callers answers at 7-month follow-up. The MDS was implemented by quitlines beginning in 2005. NAQC continues to review and update the MDS through a NAQC member and workgroup feedback process. The questions that make up the MDS for intake and follow-up can be found on NAQC’s website at: [http://www.naquitline.org/?page=technical](http://www.naquitline.org/?page=technical). This webpage also contains the technical documents and provides the exact questions and explanations for the standard MDS questions. NAQC recently created a version of the MDS items that are more easily implemented in an online environment, which are also available at [http://www.naquitline.org/?page=technical](http://www.naquitline.org/?page=technical).

As part of the MDS, there are the 18 core intake and 12 core follow-up questions noted above. In addition, there are also several standardized optional questions that quitlines can adopt if they wish. Individuals and groups can also propose additional optional question using a standard process. The standard optional questions...
and additional optional questions proposed and approved by the MDS workgroup can be found at: http://www.naquitline.org/?page=optional.

Reach and Quit Rate Calculations
Along with the MDS, NAQC has collaboratively developed a standard calculation for measuring reach and quit rates for North American quitlines. While there are many ways to measure both reach and quit rates, the NAQC standard calculations provide a way to compare these measures with assurances that the calculations were performed in the same way. NAQC’s definition of “treatment reach” is the proportion of the target population for the quitline who receive an evidence-based treatment (counseling or medications) from a quitline.

Defining the quit rate for a given quitline is more complicated than offering up a percentage of successful quitters from the overall number of callers. NAQC recommends reporting a 30-day point prevalence abstinence measure collected seven months after registration, and using a “responder rate” rather than an “intent-to-treat” rate. In other words, quitlines or their evaluators should collect the quit rate data through the follow-up evaluation at seven months (after registration), and calculate the quit rate by dividing the number of individuals who report having been successful at abstaining from tobacco use for the past 30 days (at seven months post-registration) by the total number of tobacco users in the follow-up sample who have registered for services, started at least one counseling session, consented to follow up, and responded to the follow-up survey. NAQC’s quit rate definition is only one way to calculate a quit rate and was designed to allow quitlines to calculate the rate in the same way allowing for comparison to one another. It was not designed to replace any other method of calculating a quit rate. A good resource which discusses a variety of measures of abstinence, as well as recommends a measure of abstinence for use in clinical trials, can be found in Hughes, J. R., Keely, J., Niaura, R., Ossip-Klein, D., Richmond, R., & Swan, G. (2003). Measures of abstinence from tobacco in clinical trials: Issues and recommendations. Nicotine & Tobacco Research, 5, 13–25.

While there are different methods for calculating quit rates based on varying definitions of the numerator and denominator, there is also variation in data collection methods across quitlines. Most quitlines have the capacity to pull data in numerous ways, but researchers should inquire how quit rates are calculated and what data are available prior to engaging in a new project.

The issue papers and more detailed descriptions for measuring quitline treatment reach and responder rate quit rates can be located on NAQC’s website at: http://www.naquitline.org/?page=issuepapers.

Important Characteristics of Quitlines from NAQC’s 2010 Annual Survey Data
Below is a list of some important characteristics of quitlines:

- **Service offerings:** vary from quitline to quitline, depending on the budget. For details, see state and provincial quitline profiles at http://naquitline.org/map. Approximately 98% of all North American quitlines have counseling available for callers at least 5 days per week and 92% of U.S. and 80% of Canadian quitlines offer counseling at least 1 day of the weekend.
- **Quitline Budgets:** vary from quitline to quitline. In FY2010, the median total budget for the U.S. was $1,350,000 with a range from $175,500 to $15,019,979. In Canada, the median quitline budget was $157,951. The median state and Canadian quitline budgets have been impacted by the recession in 2010-2011, with overall budgets declining and many being cut at points throughout the year.
- **Spending per smoker:** National spending per smoker was calculated by taking the sum of the budget lines for services and medications, and dividing by the sum of the number of adult smokers in the states/territories reporting budget lines for services and medications. In FY2010, U.S. quitlines spent $1.89 per smoker on services and medications, while Canadian quitlines spent $0.67 per smoker on
services and medications. The CDC recommends spending $10.53 per smoker in order to serve 6% of smokers with counseling and/or medications.

- Call volume: varies from quitline to quitline. In 2010 alone, there were a total of 920,790 calls to U.S. quitlines and 26,421 calls to Canadian quitlines. Of those calls, in the U.S. 449,396 were calls from unique tobacco users and in Canada 10,180 were calls from unique tobacco users. Ninety-four percent (94%) of callers in the U.S. identified themselves as cigarette users.
- Quitline Treatment Reach: In 2010, 1.1% of the U.S. tobacco users and 0.31% of Canadian tobacco users received evidence-based tobacco cessation treatment (counseling or medications) through the quitlines.

III. PRIMER ON RESEARCH (FOR QUITLINES)

In this section, the important components of a quitline research proposal are described. By reviewing and understanding the general descriptions below, quitlines may become better equipped to discuss and become involved in future research endeavors.

Research projects are developed through rigorous methods. Before funding can be applied for or the project can be carried out, the research proposal planning and writing phase takes place. Many of the important areas of a research proposal and project are described below. An additional reference document is available that provides sample text and documents often used in data use agreements or other documents between quitlines and researchers in the context of conducting research projects. Please view Appendix B as a reference document. The following items are terms and concepts often used in the development of research proposals, and their implementation. Where applicable, links to additional examples or resource documents are included.

In addition to these somewhat lengthy definitions and descriptions, there is also a brief checklist of questions that quitline administrators/funders may want to ask researchers who are requesting the quitline’s participation in a research study in the form of data sharing. This list is located on page 14 of this document, and as a standalone form at http://www.naquitline.org/resource/resmgr/NCI_Guide/The_Basics_for_Quitlines.pdf. It may be useful as a “quick check” for quitline administrators/funders who are trying to appropriately field requests for quitline data.

- **Purpose, Scope, Objectives:** (for samples, view Appendix B)
  - Purpose: summarizes the entire project, usually in a few sentences or short paragraph
  - Scope of research: should include the time period the proposal will cover, the specific geographic area, population to be studied, and dissemination plans
  - Research aims, objectives and hypotheses: The aim of the study is what it is intending to prove. The objectives lay out the plan for supporting the study’s purpose. The hypothesis is what the research intends to test.

- **Study Population:** the group of individuals who are selected for the research project based on similar characteristics (i.e., age, race, ethnicity, gender, tobacco use status).

- **Proposed Intervention:** is often framed by a conceptual model or theory. The intervention describes the procedures/methods that will be used to answer the research hypothesis.

- **Research Design and Overall Project Plan:** (for samples, view Appendix B)
  - Project period: the length of time in which the research project will be completed, start to finish. Often coincides with the amount of time the project will be funded.
Planning: time during which the research proposal is formed along with the layout for obtaining funding, partners, researching the hypothesis, and formalizing the final proposal.

Timeline: documents the critical time points through the research proposal, for each project year. Also documents time points for the intervention.

Data collection: identifies the methods and determines the exact data elements to be collected, how the data will be collected, processed, shared, and analyzed in order to test the hypothesis.

- Coordination of data sources: If data is collected from multiple sources, a coordination of the collection and combination of data needs to be documented.
- Use of multiple quitlines/service providers: A research project may be conducted using multiple quitlines for data collection. It is possible the data collection systems, databases, and protocols are different.
- Modification or manipulation of data collection protocols: Quitlines already collect data from callers. A research project might require additional or different data elements to be collected. This should be determined prior to project initiation.
- Proprietary issues with data infrastructure: Some quitline organizations have ownership of their data or data collection methods. This may vary from quitline to quitline, and will have to be addressed before project initiation.

- **Principal Investigator (PI) or Project Director (PD):** usually the individual responsible for the overall research project. It is possible for multiple PIs to be on a single project (usually referred to as co-investigators, or co-PIs)
  - Guidance and Management structure: determined for the PI, any co-PIs and additional research project staff.
  - Budget and subcontracts: responsibility of the PI to create, manage, and keep track of all spending.
  - Discuss the terms and process of prioritizing, and authoring publications and presentations. See Appendix B for examples.
  - Consult authorship guidelines from a journal in the field in which you would like to publish. One sample guideline can be found here: [http://www.icmje.org/](http://www.icmje.org/). Note section on “Authorship and Contributorship.”

- **Infrastructure:** Responsibilities of collaborating institutions, i.e., in accordance with agreed upon terms.
  - Roles and responsibilities of each entity are determined prior to project initiation. See Appendix B for examples.
  - Graph or organizational diagrams: may be helpful to show how each institution, including their respective researchers involved, are related to the overall project.
  - Site authorization approvals: often necessary for work done on a research project outside of the researcher’s intuition (for example, at a community-based organization).
  - Deliverables: scheduled and agreed upon by each party/organization.
  - Role of quitline, both funders and service providers (and evaluators where applicable) within the research framework should be identified and documented.
  - Training requirements/needs prior to study initiation related to new procedures, data collection, service delivery changes may be addressed.
  - Collaboration: key for successful research projects and includes good communication channels.
  - Research findings could feed into additional funding and/or projects for the collaborative partners.
• **Advisory Committee or Research Team:**
  - Composition of the team: include representatives from all participating organizations.
  - Identify primary contacts and areas of expertise (epidemiology, technology, survey methodology, program content, etc.) for team members.
  - Identify data contact(s): individuals who are responsible for sharing the data between organizations.
  - Role and responsibility of the team should be established prior to study initiation. Could include some of the areas below:
    - Members of the research or advisory team may be appointed or elected.
    - Review of proposed publications and presentations: an important role for the team. See Appendix B for examples.
    - Review off-shoot research projects identified.

• **Community Based Participatory Research:**
  - Community-based participatory research (CBPR) is a partnership approach to research. It involves researchers and representatives of the subjects of the research equitably in all aspects of the research process. All partners contribute expertise and share decision-making and ownership of the research project. In the case of quitline research, application of CBPR principles would mean that quitline service providers, funders/administrators, counselors, and tobacco users would be included as partners in the research process along with the researchers. While involvement of all of these parties may not be practical depending on the research question at hand, inclusion of all creates an environment where the research questions and design reflect the issues of importance to the study participants, and the interpretation of the results can be much richer and thorough due to the inclusion of multiple perspectives.
  - Additional resources on CBPR research methodologies include:

• **Data Safety and Monitoring Plan** is developed in order to assure confidentiality of study population and data collection, sharing, and analysis.
  - Include quality assurance plan, collection standards for this project.
  - Access: identifies who will have permission to collect, access, and analyze the data, the methods for which they will access the data, and assurances of confidentially and HIPAA and IRB standards to be upheld. May require training.
  - Dataset ownership: identifies who will maintain and be responsible for the data collected in the research project and includes ownership of the analytic files.
  - Data use agreements, whether formal or informal, or Memorandums of Understanding with participating organizations may be useful for documenting data ownership, collection and analysis. Click here for sample documents.
Destruction of data: at end of study, or at a determined time, and receipt of data from subcontractors.

- **IRB and HIPAA.** The IRB and HIPAA approvals or waivers need to be obtained before the research project can commence. Both are governed by federal law.
  - IRB – Institutional Review Board. A formal committee that reviews, approves, and monitors behavioral and biomedical research that involves humans as the research subjects. The IRB has the task of overseeing the protection of the rights and welfare of the research subjects especially when vulnerable populations are included. There are multiple types of an IRB review process of research with human subjects, including Full, Expedited, and Exempt.
    - IRBs for research proposals are often located within universities. Each IRB has its own application formatting, process, review process, timeline for approvals, and is made up of members unique to that university or IRB. This can create a challenge when working with multiple organizations and multiple IRBs on a multi-site research project. In some cases, a single IRB needs to grant approval for the study and the other institutional IRBs agree to accept its approval. In other cases, multiple approvals need to be obtained for the study to move forward. We recommend that IRBs from each institution involved in the study be consulted to determine how many reviews need to be done. For more information on IRBs, click [here](http://www.pre.ethics.gc.ca/eng/index/).
  - HIPAA stands for Health Insurance Portability and Accountability Act of 1996. This act consists of two parts: the Privacy Rule and Security Rule. The Privacy Rule establishes the standards for the protection of certain individually identifiable health information. The Security Rules provides a national set of security standards for protecting the health information that is held or transferred in electronic form. For more detailed information, click here: [http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html](http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html).

- **Disclosures or Eligibility Requirements**
  - Researchers may be asked to declare relationships with tobacco companies, conflicting funds, financial disclosures. They may ask the same of any partnering organizations or individuals.
  - Identify the funding source.

- **Financial Support for the Research**
  - Funding agency: established organizations. They are sought out in support of a specific research proposal and funding is usually obtained through a competitive grant application process.
  - Some funding agencies have restrictions tied to their funding, such as reporting requirements, data sharing, restriction on provision of medications, and travel regulations.
  - There may be multiple sources of financial support for a single research project.
  - Quitlines may be asked explicitly to contribute funds or cost-share in a research project. In other cases the grant funds may pay for the cost of any protocol changes or reporting needed to be done by the quitline. In any case, the cost implications for changes in protocols, data collection, data cleaning, data reporting, project monitoring, or other activities should be discussed in advance and agreed upon before project activities begin. The responsibilities for each party involved in the research, including the role of the funder, should be identified.

### The Basics for Quitlines: Questions to Ask of Researchers who Request Data

This section can be helpful when there has been a specific request from a researcher or research institution for quitline data, especially individual-level data. The following list was created to guide quitline
administrators/funders and service providers through the discussion process and provides prompts in the form of questions to be asked of the person or organization requesting the data. This list was compiled based on recommendations from quitline staff and administrators to help obtain the information necessary to pursue successful collaborations. This section also exists online as a standalone document at http://www.naquitline.org/resource/resmgr/NCI_Guide/The_Basics_for_Quitlines.pdf.

<table>
<thead>
<tr>
<th>WHO is requesting the data?</th>
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</thead>
<tbody>
<tr>
<td>Who are all of the parties involved (identify any subcontracts the research will require as well as vendor, funder, administrative involvement)?</td>
</tr>
<tr>
<td>Who will have access to the data (include both individuals and organizations)?</td>
</tr>
<tr>
<td>Who will serve as the key contact person for your organization, for the researchers/organization requesting the data, and for the quitline vendor (if needed)?</td>
</tr>
<tr>
<td>Who is responsible for funding the data request and/or project?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WHY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why is the data being requested (include purpose, project summary, and a copy of the proposal)?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WHAT data are they requesting?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What data sets/variables will be shared? Is there a data dictionary, or will one need to be created to be able to appropriately interpret the data sets (this may also factor into cost)?</td>
</tr>
<tr>
<td>What is the funding commitment needed from the quitline in order to participate in the research project (e.g., staff time, administrative oversight of data sharing, changes needed to regular reports from service provider)?</td>
</tr>
<tr>
<td>What are the anticipated report deadlines (include in project timeline)? What reports are being requested? What information is necessary to capture to complete these reports?</td>
</tr>
<tr>
<td>What are the programming and/or software compatibility needs (e.g., version of Excel, Access, SAS, SPSS)? Is data shared electronically or in hard copy?</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>WHEN</th>
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</thead>
<tbody>
<tr>
<td>When does the project request begin? When is the data needed? How many data pulls will they need and for how long (one-time, quarterly, annually)?</td>
</tr>
<tr>
<td>When does the data permission end (include in project timeline)?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WHERE and HOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can the researcher produce the IRB-approved protocol to show the research is approved for appropriate Human Subjects and HIPAA protections? Does the data request include data on vulnerable populations such as pregnant women, children, or prisoners and are these individuals included in the IRB approval?</td>
</tr>
<tr>
<td>Where is the IRB (ethics review) on record?</td>
</tr>
<tr>
<td>Where will the data be stored?</td>
</tr>
<tr>
<td>How will the requested variables be pulled from the complete data set? Who will do that work? Will a data dictionary be provided? Who will be responsible for follow-up requests for additional information or clarification?</td>
</tr>
<tr>
<td>How many quitlines are involved in this data project (consider data compatibility issues)?</td>
</tr>
<tr>
<td>How will the data be protected? How will caller information privacy be maintained (de-identification of the data set)?</td>
</tr>
<tr>
<td>How will the data be returned or destroyed at the end of the project?</td>
</tr>
<tr>
<td>How will data use be monitored (including subcontractors’ data use)?</td>
</tr>
</tbody>
</table>
How will you be notified of a breach of privacy?
How will you be notified of the project’s progress and results?

IV. MULTI-SITE STUDIES

As a learning organization, NAQC seeks to facilitate research that will improve the quality and availability of quitline services. NAQC encourages quitlines to participate in multi-site projects that focus on answering key research questions that no single quitline could answer alone. For example, very few, if any, quitlines currently serve large enough numbers of certain priority populations (e.g., pregnant women) to be able to say anything meaningful about the outcomes obtained as a result of their treatment. However, multiple quitlines may serve enough of the population combined to generate a sample size large enough to obtain meaningful and generalizable results.

The information provided in this section is designed to provide resources to familiarize the quitline community with multi-site studies in general and issues that should be addressed by those who may collaborate on such a study.

In an article by Drs. Chung and Song (see full citation below), the authors provide a thorough step-by-step guide to planning and conducting a multi-site research study. In order to obtain diverse populations and capture the perspectives of other investigators across the country, a multi-site study should be investigated as a potential option. They also emphasize the importance of having a research question that is feasible, interesting, novel, ethical and relevant to current literature and science. It is important to note that multi-site studies can be costly due to travel and preparations; they require large time commitments; and often multi-site studies require a pilot phase with external (feasibility) or internal pilot studies prior to funding.

Below is a list of some resource materials specific to multi-site studies and networks, including the article described above.

Resources for Additional Examples:


2. Prevention Research Centers website: http://www.cdc.gov/prc/


If your organization wishes to collaborate with other institutions on a multi-site study, it is important that a framework for the project is identified and agreed upon before proceeding. This can be done through pilot testing with feasibility studies. The planning studies help layout the multi-site project but on a smaller scale.
Planning studies can help determine how to facilitate consensus, create a manual of operating procedures, finalize the study design, as well as determine the most accurate statistical analysis methods necessary for the larger study. There is usually one organization that takes the lead role as the coordinating center for the project and that can submit the grant application for funding the collaborative, multi-site project.

**Important Things to Consider with Multi-Site Studies:**

- **Define the multi-site study and describe the usefulness of this design in research.**
  - Identify the various collaborators and institutions who are participating in the project.
  - Identify geographic and organizational locations of the collaborators in the multi-site study (university, state government, federal, local).
  - Identify how organizations will work within the multi-site project and the lead organizations (flow chart diagram might be useful).

- **Explain the benefits to being involved in multi-site study.**
  - Some benefits may include:
    - geographic and ethnic diversity beyond the population your organization currently serves;
    - a larger sample size which may allow for greater statistical measurements; and
    - additional institutions and collaborators allows for more diverse expertise.
  - Address any known challenges to a multi-site project and provide explanations for them in the funding application.

- **Each organization can maintain an individual set of overall project guidelines which include their own roles and responsibilities.**
  - If organizations are collaborating on one funding proposal each organization should include the agreed-upon multi-site study guidelines with their proposal.
### APPENDICES

**Appendix A**

**Glossary of Terms**

The following terms are commonly used by quitlines and researchers. The definitions provided are general descriptions. There are additional references cited within some definitions to provide further explanation if needed.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse event</td>
<td>an adverse change in health or a side effect in an individual taking place in a research trial. What constitutes the event is defined in the IRB application and Consent Form. It is usually classified as serious or minor; expected or unexpected; and study-related, possibly study-related, or not study-related.</td>
</tr>
<tr>
<td>Call volume</td>
<td>total number of calls to a quitline in a pre-defined period of time. Often can be measured by day, week, month, and year.</td>
</tr>
<tr>
<td>Collaborating institution(s)</td>
<td>organizations that are working and communicating together, formally or informally, towards an agreed-upon goal or project</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Collaboration</td>
<td>working together to achieve a common goal. Most important aspect of a successful collaboration is communication. Shared passion for the project, careful planning and delegation, honesty, and respect are also keys to successful collaborations.</td>
</tr>
<tr>
<td>Consensus</td>
<td>group decision-making process that seeks agreement from most parties or individuals involved.</td>
</tr>
<tr>
<td>Coordinating center</td>
<td>the organization responsible for overall coordination of the project, including management duties, such as securing funding, additional site selection, and oversight of all performance sites. May or may not have contact with research subjects.</td>
</tr>
<tr>
<td>Ethnic diversity</td>
<td>“the marked differences between people of many ethnic groups, as well as slight variations in behavior of persons in the same ethnic group, that coexist within the greater culture.” (from <a href="http://www.racerelations.ws">www.racerelations.ws</a>)</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act of 1996. This act consists of two parts the Privacy Rule and Security Rule. The Privacy Rule establishes the standards for the protection of certain individually identifiable health information. The Security Rules provides a national set of security standards for protecting the health information that is held or transferred in electronic form. For more detailed information, click here: <a href="http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html">http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html</a>.</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board. A formal committee that reviews, approves, and monitors behavioral and biomedical research that involves humans as the research subjects. The IRB has the task of overseeing the protection of the rights and welfare of the research subjects especially when vulnerable populations are included. There are multiple types of an IRB review process of research with human subjects, including Full, Expedited, and Exempt (View Appendix B). Tribal Resolutions may be similar to the IRB process with American Indian tribes.</td>
</tr>
<tr>
<td>Multi-site study</td>
<td>involves more than one site or institution engaged in the project or research. American Indian tribes could also be involved as a partner site.</td>
</tr>
<tr>
<td>PHI</td>
<td>Protected Health Information. An individual’s identifiable...</td>
</tr>
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</table>

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DRAFT Guide on Quitlines and Research – October 2011
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<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI or PD</td>
<td>Principal Investigator or Program/Project Director.</td>
</tr>
<tr>
<td>Priority populations/underserved populations</td>
<td>populations most highly impacted by a specific health issues. Can be defined by demographic characteristics, ethnicity or race, geography, or specific location.</td>
</tr>
<tr>
<td>Quitline</td>
<td>telephone-based tobacco cessation services that help tobacco users quit. Services offered by quitlines include coaching and counseling, referrals, mailed materials, training to healthcare providers, Web-based services and, in some instances, free medications such as nicotine replacement therapy (NRT).</td>
</tr>
<tr>
<td>Quit rate</td>
<td>percentage of those receiving treatment who are successfully quit at 7-months post enrollment for at least the past 30 days (30-point prevalence abstinence). The standard NAQC definition includes a specific population for the numerator and denominator in the calculation. Additional information can be found in NAQC’s issue paper titled <em>Measuring Quit Rates</em>, located here: <a href="http://www.naquitline.org/resource/resmgr/docs/naqc_issue_paper_measuringqui.pdf">http://www.naquitline.org/resource/resmgr/docs/naqc_issue_paper_measuringqui.pdf</a>.</td>
</tr>
<tr>
<td>Reach</td>
<td>a measure of the proportion of a target population that is served by an intervention or program. There are many ways to measure reach. Quitline treatment reach is defined as the proportion of the quitline’s target population who receive an evidence-based treatment (counseling or medications) from a quitline. Additional information can be found in NAQC’s issue paper titled <em>Measuring Reach of Quitline Programs</em> located here: <a href="http://www.naquitline.org/resource/resmgr/docs/naqc_issue_paper_measuringrea.pdf">http://www.naquitline.org/resource/resmgr/docs/naqc_issue_paper_measuringrea.pdf</a>.</td>
</tr>
<tr>
<td>Research or performance site</td>
<td>site whose staff, facilities or private records of identifiable individuals are engaged in the conduct of research.</td>
</tr>
<tr>
<td>Study population</td>
<td>the group of individuals who are selected for the research project based on similar characteristics such as age, race, ethnicity, gender, or tobacco use status.</td>
</tr>
</tbody>
</table>
Appendix B

Data Use Agreements and Memorandums of Understanding: Sample Text and Documents

Appendix B, found here, contains sample text, language, and resource materials that can be tailored to meet the individual needs of quitlines and researchers engaging in research studies. The components and full documents shared in the appendix are from research agreements, data use agreements, and a memorandum of understanding. The purpose of Appendix B is to provide resource materials in order to expedite and encourage relationships and studies with quitlines and researchers. These resources are not exclusive and additional materials may be identified and included over time. Due to the length of Appendix B, the topic areas are outlined below with hyperlinks to the specific resource contained in the full document.

1. Identification of Parties to the Agreement

2. Purpose
   - Detailed description in purpose can vary depending on existing agreements or relationship with researcher/quitline.

3. Project Period (start/end dates)
   - Termination

4. Roles and Responsibilities
   - Deliverables/ for each party involved
   - Can include a timeline
5. **Publication**
   - Review process prior to publishing
   - Authorship

6. **Data**
   - Possible to have a data use agreement or a limited data agreement without the more formal research agreement
   - Limited data agreement defines only the portion of data that will be shared.
   - Define the uses and disclosures of data that are permitted.
     - Identify the name of the actual data set or variables to be shared.
     - Identify who will have access (e.g., subcontractors, agents, only necessary personnel).

7. **Unauthorized Use of Data**
   - Can not violate privacy rules/laws
   - Do not attempt to identify data.
   - Sharing with additional parties without written permission

8. **Breach of Privacy, Disclosure**
   - Process for notification about breach or accidental disclosure of data

9. **Return of Data**
   - Clear identification of ownership of data
   - Process for returning data/limited data sets or destruction

10. **Safeguards, Computer Security (password protection, hard-drive locks, etc.)**

11. **HIPAA and IRB**
    - Research population consisting of vulnerable populations (children, people with disabilities, pregnant women, prisoners, etc.)
    - Level of risk for participants in research

12. **Communication Plan**
    - Primary contacts

13. **Conflicts of Interest and Disclosure of Financial or Tobacco Company Ties**
    - Identify the funding source

14. **Amendments**

15. **Termination of Agreement**
    - Identify potential causes for early termination.
ADDITONAL RESOURCES AVAILABLE

- One-page checklist for quitline administrators
- Publication Initiation and Tracking Form
  (http://www.naquitline.org/resource/resmgr/NCI_Guide/RPIU_Form_generic.doc)
- Principal Investigator Project Initiation and Update Form
- Sample 1: Data Use Agreement
  (http://www.naquitline.org/resource/resmgr/NCI_Guide/generic_DUA_from_Clearway.doc)
- Sample 2: Data Use Agreement
  (http://www.naquitline.org/resource/resmgr/NCI_Guide/Sample_Data_Research_Agreeme.pdf)
- Sample: Memorandum of Understanding
- Sample: HIPAA Business Associate Agreement
  (http://www.naquitline.org/resource/resmgr/NCI_Guide/HIPAA_Business_Assoc_agreeme.pdf)
- Institutional Review Board (IRB) general information
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations and information

(http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html)
Appendix B

Data Use Agreements and Memorandums of Understanding: Sample Text and Documents

Agreements and memorandums of understanding are types of contracts and as such are legal documents. Contracts describe a business relationship between two parties and usually begin by identifying the parties involved. The contract then describes the parties’ mutual understanding of what each is agreeing to “give to” and “receive from” the other party. A contract is not valid if each party does not “give” something of value and “receive” something of value. It is not valid if there is not a “mutual understanding” about what is given and received.

All important terms should be included in writing in the contract. For example, a contract may specify that one party may give data and one party may pay for that data. If the data owner also expects that the data will be kept confidential and private or that s/he will have a role in determining how the data may be used, then these terms should be included in writing in the contract. From a legal perspective, all rights and obligations of the parties should be defined in the written contract. The term “agreement” will be used throughout this document. “Contract” and “agreement” are interchangeable terms. “Memorandum of understanding” is usually reserved for parties that already have other, more complex relationships. For instance, the Centers for Disease Prevention and Control may enter into a memorandum of understanding with the National Institutes of Health; both are agencies within the Department of Health and Human Services.

TABLE OF CONTENTS

1. Identification of Parties to the Agreement
2. Purpose
3. Project Period
4. Roles and Responsibilities
5. Publication
6. Data
7. Unauthorized Use of Data
8. Breach of Privacy, Disclosure
9. Return of Data
10. Safeguards, Computer Security (password protection, hard-drive locks, etc.)
11. HIPAA and IRB
12. Communication Plan
13. Conflicts of Interest and Disclosure of Financial or Tobacco Company Ties
14. Amendments
15. Termination of Agreement
1. IDENTIFICATION OF PARTIES TO THE AGREEMENT

The parties identified in the agreement should have authority to legally bind their organizations to all of the terms of the contract. The parties may be corporations, government agencies or individuals. It is important that the part of the organization that you will be working with is identified in the agreement and that the person signing the agreement has authority to legally bind the organization (i.e., a person who is an officer of a corporation or who has an executive position within the organization).

Example 1:
This data use agreement (“Agreement”) is effective upon execution, and is entered into by and between the Regents of the University of XYZ (“Recipient”) and Company ABC (“Data Provider”). (The underlined text identifies the parties.)

Data Provider and Recipient mutually agree to enter into this Agreement to comply with the requirements of Section 514(e) of the Privacy Rule, 45 Code of Federal Regulations (“C.F.R.”) § 164.514(e), issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). (The bold text shows the purpose of the contract.)

Example 2:
This memorandum of understanding will refer to a joint project between researchers at X University and at the University of Y. It will serve to clarify understanding of work roles and credit for all of the individuals involved in the aforementioned project. The joint project will focus on accessing and analyzing the publicly available tobacco industry documents, and the topic of the project will be “abc,” with a likely focus on a case study of marketing strategies. The individuals involved in this project are: Dr. A, Dr. B, Dr. C, and Dr. D. (The underlined text identifies parties; the bold text identifies purpose; the italicized and bold text shows research project participants.)

2. PURPOSE

- Detailed description in purpose can vary depending on existing agreements or relationship with researcher/quitline.
- This section is usually short and provides a global overview of the purpose of the agreement and may also describe the overall purpose of the project. The purpose section can also include the goals, objectives, project period, and rationale for the research.

Example 1:
This memorandum of understanding will refer to a joint project between researchers at X University and at the University of Y. It will serve to clarify understanding of work roles and credit for all of the individuals involved in the aforementioned project. The joint project will focus on accessing and analyzing the publicly available tobacco industry documents, and the topic of the project will be “abc,” with a likely focus on a case study of marketing strategies. The individuals involved in this project are: Dr. A, Dr. B, Dr. C, and Dr. D. (The bold text describes purpose of the agreement (or contract) and underlined text the purpose of the project.)

3. PROJECT PERIOD

The project period, which is the overall time required to complete the proposed project, should include both the start date and the end date of the project.
Example 1:
This Data Use Agreement is by and between X Company and The University of ABC (Recipient) and is effective this # day of Month, Year through # day of Month, Year.

Example of end dates:
The agreement will end on # day of Month, Year.

4. ROLES AND RESPONSIBILITIES

The roles and responsibilities included in the agreement help to clarify roles in advance of the project starting, which can be useful for maintaining good relationships between the parties. They are helpful for determining the cost of the project. Also, they will become the legally binding “obligations” of one party and “rights” of the other party named in the agreement.

Example 1:
This memorandum of understanding will refer to a joint project between researchers at X University and at the University of Y. It will serve to clarify understanding of work roles and credit for all of the individuals involved in the aforementioned project. The joint project will focus on accessing and analyzing the publicly available tobacco industry documents, and the topic of the project will be “abc,” with a likely focus on a case study of marketing strategies. The individuals involved in this project are: From X University, Dr. A and Dr. B; and from University of Y, Dr. C and Dr. D.

- Deliverables/for each party involved

- The roles and responsibilities in the agreement should only pertain to the parties who are part of the agreement.

Example 1:
Dr. A will devote at least 4-8 hours per week to this project between approximately Month Year and Month Year. Drs. A and C will communicate by email or phone at least twice per month (ideally weekly) to ensure timely progress, and to direct further data collection.

Dr. A will come to the Tobacco Center for Research and Education for at least a one week period for training in tobacco documents research and analysis methodology. This training will include but is not limited to: training on the Legacy Tobacco Documents Library, search terms and strategy, proper research documentation, standard tobacco document citations format and EndNote citations. Dr. A will also have opportunities to meet with full-time tobacco documents researchers at the Center. Dr. C will provide funding for Dr. A’s travel to San Francisco; University of Y will provide work space and a computer during Dr. A’s stay. Dr. C will devote most of her research time to working with Dr. A during this trip, and Drs. C and D will oversee the training.

- Can include a timeline

Example 1:
Preliminary timeline:
Document searches will take place between Month Year 1 and Month Year 2; data analysis, research memoranda writing, and subsequent searches will take place between Month Year 2 and Month Year 2. Manuscript writing will take place between Month Year 2 and Month Year 2. Our goal is to have a manuscript submitted by Month Year 2.
5. PUBLICATION

- Review process prior to publishing
- Discussion and documentation of authorship

**Example 1:**

**Writing and Authorship:**

We anticipate that at least one publication will result from this project. In addition, we anticipate that Dr. A will be available, if necessary, to travel to CITY for an intensive writing session with Drs. C and D for at least one week. Although this trip may not be necessary, in the experience of Drs. C and D it often vastly improves the quality of the finished product, as well as the efficiency of manuscript production. University of Y will provide funding for Dr. A’s travel for this trip. If one paper is written as a result of the project, Dr. A will do the majority of the writing and be the first author for the paper, and Dr. C will be the last author.

If a second paper is written based on this research, Dr. C will do the majority of the writing of the paper and be the first author of this paper, and Dr. A will be the second author. Drs. B and D, and other research contributors, may appear as authors on either manuscript dependent upon the weight of their respective contributions.

Dr. C will be the senior investigator on the project and will be responsible for the final negotiations and decision making regarding inclusion of Drs. B, D, or any other authors on any publications resulting from this work. Dr. C will solicit input from Dr. A about authorship on publications that result from this project.

**Example 2:**

Can include additional language to refer to quitline staff if they are interested in being part of the publication process or should wish to review what is being written, such as, “any draft publication will be provided to Ms. C (quitline contract manager) for review prior to submission. Ms. C will be offered the opportunity to serve as an author for any publication.”

6. DATA

- Limited data agreement defines only the portion of data that will be shared

**Example 1:**

[Organization] has agreed to disclose to Recipient a **Limited Data Set** consisting of the following: Pharmacy and Medical Claims from 2008 related to the Medication Therapy Management (MTM) Comprehensive Call Center beneficiaries, in order to measure the impact that those reviews had on 2009 utilization.

- Define the uses and disclosures of data that are permitted.
  - Identify the name of the actual data set or variables to be shared.
  - Identify who will have access (e.g., subcontractors, agents, only necessary personnel).

**Example 1:**

Recipient is permitted to use and disclose the **Limited Data Set** or **Individual** pieces of data contained therein as follows:
a) Assess the acceptance rate by health care providers of recommendations made by Recipient pharmacist;  
b) Assess the impact of MTM services on members’ utilization of healthcare services; and  
c) Assess the impact of MTM services on per member per month healthcare expenditures.  
Notwithstanding the foregoing, Recipient agrees that it shall not use or disclose such Limited Data Set or the Individual pieces of data therein such a manner that would cause “_____________” to be in violation of any federal or state law or regulation.

Example 2:  
Data Collection and Analysis:  
Dr. X will do the majority of the data collection and data analysis for the project, and Dr. Y will help with data collection and analysis in a smaller capacity. Drs. A and B may be requested to provide guidance for the research, or to assist with manuscript writing. We will utilize the following tobacco documents databases: Legacy Tobacco Documents Library, Tobacco Documents Online, the Philip Morris tobacco documents website, and other tobacco documents websites run by the tobacco industry.

7. UNAUTHORIZED USE OF DATA

- Address privacy rules and/or laws that govern the research and/or data.  
- Identifiable vs. de-identified data

The agreement should define unauthorized use of data if that is important to the parties. Any existing legal restrictions on the data, any agreements made with subjects of the data, and any limits that the data owner wants to place on use of the data by the other party should be incorporated into the agreement. For example, if the law requires privacy or if the subjects have been promised that the data will be kept confidential, these terms should be included in the agreement.

Example 1:  
Prohibition on Unauthorized Use or Disclosure.  
a) Recipient will neither use nor disclose the “Limited Data Set” for any purpose other than as permitted by Section x of this Agreement, as otherwise permitted in writing by Data Provider, or as Required by Law.  
b) Recipient is not authorized to use or disclose the “Limited Data Set” in a manner that would violate the Privacy Rule, 45 C.F.R. Part 164, Subpart E (http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html), if done by Data Provider.  
c) Recipient will not attempt to identify the information contained in the Limited Data Set or contact any individual who may be the subject of information contained in the Limited Data Set.  
- Sharing with additional parties without written permission

Example 1:  
Permitted Recipients, Subcontractors, and Agents. Recipient will require any agent or subcontractor, to which Recipient is permitted by this Agreement or in writing by Data Provider to disclose and let use the Limited Data Set, to agree to comply with the same restrictions and conditions that apply to Recipient’s use and disclosure of the Limited Data Set pursuant to this Agreement.
Example 2:
Recipient agrees not to use or further disclose the Limited Data Set or Individual pieces of data therein other than as permitted by the Data Use Agreement or as otherwise Required by Law. Recipient further agrees to use appropriate safeguards to prevent use or Disclosure of the information other than as provided for by this Data Use Agreement. Recipient shall promptly report to “____________” any use or Disclosure of the information not provided for by this Data Use Agreement of which Recipient becomes aware and shall ensure that any agents, including a subcontractor, to whom Recipient provides the Limited Data Set or Individual pieces of data therein agrees to the same restrictions and conditions that apply to Recipient with respect to such information. Recipient agrees that under no circumstance shall Recipient take steps to identify the information it receives from “__________________” or contact the Individuals about whom the information pertains.

8. BREACH OF PRIVACY, DISCLOSURE

If one party fails in their privacy obligations, disclosure of the breach of privacy to the other party is always required. The parties may also agree on ways to reduce harm due to a breach of privacy. If they have agreed that there will be penalties for breach (i.e., monetary or termination of the agreement), they should be included as a term.

Example 1:
Breath of Privacy Obligations. Recipient will report to Data Provider any use or disclosure of the Limited Data Set that is not permitted by this Agreement or in writing by Data Provider. Recipient will make the report to Data Provider’s Director of Research Programs within 7 days after Recipient learns of such non-permitted use or disclosure. Recipient’s report will at least:

a) Identify what corrective action Recipient took or will take to prevent further non-permitted uses or disclosures;
b) Identify what Recipient did or will do to mitigate any deleterious effect of the non-permitted use or disclosure; and
c) Provide such other information, including a written report, as Data Provider may reasonably request.
d) Identify the nature of the non-permitted use or disclosure;
e) Identify the Limited Data Set content used or disclosed;
f) Identify who made the non-permitted use or disclosure and who received the non-permitted disclosure;
g) Identify what corrective action Recipient took or will take to prevent further non-permitted uses or disclosures;
h) Identify what Recipient did or will do to mitigate any deleterious effect of the non-permitted use or disclosure; and
i) Provide such other information, including a written report, as Data Provider may reasonably request.

Example 2 (more severe, could be a condition or requirement based on funding):
a) Notification of Breach. During the term of this Agreement.

b) Discovery of Breach. To notify DHCS immediately by telephone call plus email or fax upon the discovery of breach of security of PHI in computerized form if the PHI was, or is reasonably believed to have
been, acquired by an unauthorized person; or within 24 hours by email or fax of the discovery of any suspected security incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Agreement, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the DHCS contract manager, the DHCS Privacy Officer and the DHCS Information Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves electronic PHI, notification shall be provided by calling the DHCS ITSD Help Desk. Business Associate shall take:

i. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment and
ii. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.

c) **Investigation of Breach.** To immediately investigate such security incident, breach, or unauthorized use or disclosure of PHI or confidential data. Within 72 hours of the discovery, to notify the DHCS contract manager(s), the DHCS Privacy Officer, and the DHCS Information Security Officer of:

i. What data elements were involved and the extent of the data involved in the breach,
ii. A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data,
iii. A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized,
iv. A description of the probable causes of the improper use or disclosure; and
v. Whether Civil Code sections 1798.29 or 1798.82 or any other federal or state laws requiring individual notifications of breach are triggered.

d) **Written Report.** To provide a written report of the investigation to the DHCS contract managers, the DHCS Privacy Officer, and the DHCS Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. The report shall include, but not be limited to, the information specified above, as well as full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure.

e) **Notification of Individuals.** To notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal laws and to pay any costs of such notifications, as well as any costs associated with the breach. The DHCS contract manager, the DHCS Privacy Officer, and the DHCS Information Security Officer shall approve the time, manner and content of any such notifications.

f) **DHCS Contact Information.** To direct communications to the above referenced DHCS staff, the Contractor shall initiate contact as indicated herein. DHCS reserves the right to make changes to the contact information below by giving written notice to the Contractor. Said changes shall not require an amendment to this Agreement or the Agreement to which it is incorporated.

<table>
<thead>
<tr>
<th>DHCS Program Contract Manager</th>
<th>DHCS Privacy Officer</th>
<th>DHCS Information Security Officer</th>
</tr>
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9. **RETURN OF DATA**

- Clear identification of ownership of data
- Process for returning data/limited data sets or destruction
Example 1:
Return of “Limited Data Set”

a) Upon termination or expiration of this Agreement, Recipient will, if feasible:
   i) return to Data Provider or destroy the “Limited Data Set”, and
   ii) obtain from each subcontractor, agent or other recipient, that received the “Limited Data Set” under Section x of this Agreement, the return or destruction of the Limited Data Set.

The return or destruction must include (1) the “Limited Data Set”, (2) all copies of the “Limited Data Set”, and (3) any work derived from the “Limited Data Set” that may allow identification of any individual whose information is contained in the “Limited Data Set”, in the custody or under the control of Recipient or of such subcontractor, agent or other recipient, whether in tangible or electronic medium. Recipient will complete such return or destruction as promptly as possible, but not later than 30 days after the effective date of the termination or expiration of this Agreement, and will within such period certify in writing to Data Provider that such return or destruction has been completed.

b) If return or destruction is not feasible, Recipient will, within 30 days after the effective date of the termination or expiration of this Agreement:
   i) provide Data Provider with a written explanation why return or destruction is not feasible, and
   ii) certify in writing to Data Provider that Recipient, or subcontractor, agent or other recipient under Section 5 of this Agreement, will neither use nor disclose the Limited Data Set for any purpose other than the purposes that make return or destruction of the Limited Data Set infeasible.

While users of data are responsible for adhering to the terms of the data use agreement, it is advisable for owners of the data to check on data sets currently in use by others, and either extend existing data use agreements or confirm return or destruction of data. The data owner may want to engage in a practice of sending a letter to verify the return or destruction of data.

10. SAFEGUARDS, COMPUTER SECURITY (password protection, hard-drive locks, etc.)

In order to protect the data and personal health information the data may contain, additional security measures should be in place. These safeguards can be written into the data use agreement or contract. Computer security passwords, hard-drive locks, locked offices and filing cabinets are just a few examples of data safeguards. Below are samples of text that could be included in the agreement or contract:

Example 1:
Recipient further agrees to use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Data Use Agreement. Recipient shall promptly report to X any use or disclosure of the information not provided for by this Data Use Agreement of which Recipient becomes aware.

Example 2:
Information Safeguards. Recipient will adopt and use appropriate administrative, physical, and technical safeguards to preserve the integrity and confidentiality of the Limited Data Set and to prevent its use or disclosure, other than as permitted by Section 2 of this Agreement, as otherwise permitted in writing by Data Provider, or as required by law.
Example 3 (if data set includes Personal Health Information (PHI)):
Is an adequate plan presented in the protocol to protect data from improper use, including the implementation of effective administrative, physical and technical safeguards?
- Locked cabinets or rooms? □ Yes □ No
- Computer password protected? □ Yes □ No
- Access is limited to authorized personnel only? □ Yes □ No
- Data transported by secure carrier only? □ Yes □ No
- Data not accessible to the Internet? □ Yes □ No
- Laptop computers never left unattended in cars or other unsecure sites? □ Yes □ No

Example 4 (if data set includes PHI):
Security. To take any and all steps necessary to ensure the continuous security of all computerized data systems containing PHI, and provide data security procedures for the use of DHCS at the end of the contract period. These steps shall include, at a minimum:

1) Complying with all of the data system security precautions listed in the Attachment A portion of this Agreement;

2) Achieving and maintaining compliance with the HIPAA Security Rule (45 CFR Parts 160 and 164), as necessary in conducting operations on behalf of DHCS under this Agreement;

3) Providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget in OMB Circular No. A-130, Appendix III-Security of Federal Automated Information Systems, which sets forth guidelines for automated information systems in Federal agencies; and

4) In case of a conflict between any of the security standards contained in any of these enumerated sources of security standards, the most stringent shall apply. The most stringent means that safeguard which provides the highest level of protection to PHI from unauthorized disclosure. Further, Business Associate must comply with changes to these standards that occur after the effective date of this Agreement.

Business Associate shall designate a Security Officer to oversee its data security program who shall be responsible for carrying out the requirements of this section and for communicating on security matters with DHCS.

11. HIPAA and IRB

The IRB and HIPAA approvals or waivers need to be obtained before the research project can commence. Both are governed by federal law.

The IRB, Institutional Review Board, is a formal committee that reviews, approves, and monitors behavioral and biomedical research that involves humans as the research subjects. The IRB has the task of overseeing the protection of the rights and welfare of the research subjects especially when vulnerable populations are included. There are multiple types of an IRB review process of research with human subjects including Full, Expedited, and Exempt.

HIPAA stands for Health Insurance Portability and Accountability Act of 1996. This act consists of two parts, the Privacy Rule and Security Rule. The Privacy Rule establishes the standards for the protection of certain
individually identifiable health information. The Security Rules provides a national set of security standards for protecting the health information that is held or transferred in electronic form.

**Example 1:**

**Description of Human Subjects Involved in the Study**

Limited datasets containing medical and pharmacy claims for patients enrolled in the state Medicaid program and are receiving health care services in one of the clinics participating in the pilot project will be provided by DHCS for the purpose of this evaluation.

**Description of the Use of Human Subjects**

Limited data sets constructed from pharmacy and medical claims will be provided by DHCS for the purpose of this evaluation. All data elements that directly identify subjects will be removed. The data sets will be stored in a secure area. Analytical data will be stored on password protected files and accessed only by researchers. Upon completion of this research project, data will be destroyed as soon as it is no longer needed.

- Research population consisting of vulnerable populations (children, people with disabilities, pregnant women, prisoners, etc.)
- Level of risk for participants in research

**Example 1:**

The risk level of this research is: Minimal □ Moderate □ High □

The risks of this research are (check all that apply):
- Physical □
- Psychological □
- Social □
- Economic □
- Data security and confidentiality □

**Example 2:**

Assessment of Risks:

No foreseeable risks to participants in this evaluation are anticipated.

**Example 3:**

“Protected Health Information” or “PHI” means any information, whether oral or recorded, in any form or medium that relates to the past, present, or future physical or mental condition of any individual, the provision of health and dental care to an individual, or the past, resent, or future payment for the provision of health and dental care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. PHI shall have the meaning given to such term under HIPAA and HIPAA regulations, as the same may be amended from time to time.

**12. COMMUNICATION PLAN**

- Primary contacts
Example 1:
Dr. X will devote at least 4-8 hours per week to this project between approximately Month Year 1 and Month Year 2. Drs. Y and X will communicate with the rest of the team by email or phone at least twice per month (ideally weekly) to ensure timely progress, and to direct further data collection.

Example 2:
Dr. X will come to the “Name Location here” for at least a one week period for training in tobacco documents research and analysis methodology. This training will include but is not limited to: training on the Legacy Tobacco Documents Library, search terms and strategy, proper research documentation, standard tobacco document citations format and EndNote citations. Dr. X will also have opportunities to meet with full time tobacco documents researchers at the Location. Dr. A will provide funding for Dr. X’s travel to City; “Organization name here” will provide work space and a computer during Dr. X’s stay. Dr. Y will devote most of her research time to working with Dr. X during this trip, and Drs. Y and B will oversee his training.

13. CONFLICTS OF INTEREST AND DISCLOSURE OF FINANCIAL OR TOBACCO COMPANY TIES

Many organizations will define what constitutes a conflict of interest. In many cases, a conflict of interest is limited to a situation where one of the parties would benefit financially from the execution of the agreement. Other organizations may define a conflict of interest more broadly. In some cases, disclosure of financial ties that might or might not be considered a conflict of interest is required of all parties. For some organizations, any relationship with the tobacco industry is explicitly included as a conflict of interest.

Example 1:
Conflict of Interest

This research project is funded by “State” HealthCare Foundation. Researchers and the institutions they are affiliated with have no financial or other relationships that could be perceived as affecting the objective conduct of this evaluation.

14. AMENDMENTS

Amendments can be made and should be anticipated for agreements, especially if the agreement spans more than 6 to12 months. Some amendments are required by law (i.e., agreements involving data covered by HIPAA will require that parties agree to automatically amend their agreement to include any changes to HIPAA law that occur during the term of their agreement). Other amendments result from changes that occur during the term of the agreement (i.e., the PI leaves an institution or the work is delayed and parties agree to change the end date or due date).

Example 1:
Amendment to Agreement. Upon the compliance date of any final regulation or amendment to a final regulation, promulgated by the U.S. Department of Health and Human Services pursuant to the Administrative Simplification provisions of HIPAA Title II, Subtitle F, that affects Limited Data Sets, this Agreement will automatically amend such that the obligations imposed on Recipient remain in compliance with the final regulation, unless either party elects to terminate this Agreement by providing written notice of termination to the other party at least 90 days before such compliance date. The obligations of Section x of this Agreement will apply to such termination and the obligations of Sections y and z of this Agreement will survive such termination.
Example 2 (non-legally mandated):
This agreement can be amended in writing at any time by mutual agreement of all parties.

- A change in the end date or an extension of the contract that is “mutually agreed to” by all parties involved

15. TERMINATION OF AGREEMENT

Agreements may be terminated for a variety of reasons. Most contracts specify the reasons that an agreement may be terminated “for cause.” In such cases, one party may terminate without having to gain consent of the other party. Agreements also may include a term for agreement by “mutual consent.” This usually requires that both parties agree in writing to terminate an agreement.

Examples of both are shown below:

Example 1:
This agreement shall remain in force until the earlier of <date> of either party provides notice of termination in writing. Notice of termination shall be at least 30 Days in advance of the termination date. However, the privacy protections set forth above shall survive the termination provisions of this Data Use Agreement.

Example 2:
The terms of this memorandum are agreed to by the undersigned, with the understanding that as the research progresses, details of these arrangements may require change. In addition, if the work does not progress as anticipated, or if other problems arise, this arrangement may be terminated by mutual agreement of the undersigned.

- Identify potential causes for early termination

Example 1:
Termination for Breach*. Data Provider may terminate this Agreement if it determines, in its sole discretion, that Recipient has breached any provision of this Agreement. Data Provider may exercise this termination right by providing Recipient written notice of termination that states the breach of this Agreement that provides the basis for the termination. Any such termination will be effective immediately or at such other date specified in Data Provider’s notice of termination. The obligations of Sections 3 and 10 of this Agreement will survive termination of this Agreement.

* Breach means failing to perform any term of a contract. For example, not finishing a job, failure to make payment on time, or failure to deliver goods.

Example 2:
Termination

A) Termination for Cause. Upon DHCS’ knowledge of a material breach of this Agreement by Business Associate, DHCS shall:

1) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by DHCS;

2) Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or
3) If neither cure nor termination is feasible, report the violation to the Secretary of the US Department of Health and Human Services.

B) **Judicial or Administrative Proceedings.** Business Associate will notify DHCS if it is named as a defendant in a criminal proceeding for a violation of HIPAA. DHCS may terminate this Agreement if Business Associate is found guilty of a criminal violation of HIPAA. DHCS may terminate this Agreement if a finding or stipulation that the Business Associate has violated any standard or requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceedings in which the Business Associate is a party or has been joined.

C) **Effect of Termination.** Upon termination or expiration of this Agreement for any reason, Business Associate shall return or destroy all PHI received from DHCS (or created or received by Business Associate on behalf of DHCS) that Business Associate still maintains in any form, and shall retain no copies of such PHI or, if return or destruction is not feasible, shall continue to extend the protection of this Agreement to such information, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.