



January 3, 2018

Panel on Research Ethics
Secretariat on Responsible Conduct of Research
16th Floor Mailroom
350 Albert Street
Ottawa, ON K1A 1H5
e-mail: Secretariat@rcr.ethics.gc.ca

To the Secretariat and Panel Members:

This letter is from the International Society for Biological & Environmental Repositories (ISBER) in response to a request for comments on the Proposed Changes to TCPS 2 (2014) Guidance for Research involving Human Cells and Cell Lines.

ISBER is an international organization addressing the technical, legal, ethical, and managerial issues relevant to repositories of biological and environmental specimens (see www.isber.org for additional information). Although not restricted to human specimens intended for research, the great majority of ISBER members focus on providing human tissues for research, either procured specifically for research purposes, or from residual clinical specimens obtained during the course of routine medical care. ISBER membership and expertise in the area of human tissues used for research is extensive, longstanding, ongoing, and representative of best practices in the field. ISBER's thought leaders in this area are worldwide.

As such, we have a keen interest in this regulation and its implications for research within Canada as well as globally.

ISBER applauds the effort by the panel to remove unnecessary research requirements that do not confer additional protections for research subjects. However, some aspects of the proposed changes need further consideration and discussion. ISBER fully supports the comments and suggestions of CTRNet and University of British Columbia Office of Biobank Education and Research in this regard. (See attached). In addition, we offer the following comments for further consideration by the panel:

1) As noted in the comments submitted by the above-referenced groups, there is a need to clarify the scope of the exemption (is it intended to apply only to human cells and cell lines or does this also include tissue, DNA, RNA, etc.?). The definition of a biobank in the TCPS refers to "human biological material" more broadly and not

just human cells or cell lines. If the exemption is intended to apply to only human cells and cell lines and not other types of human biological materials, the ethical justification for the distinction is not clear. On the other hand, if the exemption is intended to apply to non-identifiable human biological materials more broadly, there would be implications for other aspects of the TCPS2 that would need to be further thought through and addressed (e.g. consent for future use of human specimens). We encourage further consultation and discussion of these aspects with the above-referenced groups.

2) The definition of biobank is very broad and would apply to human pathology archives and other specimens collected during the course of routine care that could be used for research. Given that the proposed revisions lay out specific requirements for biobanks, it would be important to clarify that these requirements would only apply to biobanks for the purposes of meeting the proposed exemption from REB review of non-identifiable human cells/cell lines. In other words, biobanks that do not meet the requirements stipulated for meeting the exemption would still have the option of seeking IRB approval for the use of non-identifiable human cells/cell lines.

Thank you for the opportunity to comment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Zisis Kozlakidis', with a long horizontal flourish extending to the right.

Zisis Kozlakidis, PhD, AKC, MBA
ISBER President