TCPS2 Consultation : Response to SRCR request for comments

Multijurisdictional Research

We have good examples of and experience with harmonized ethics review for large multisite studies. The proposed policy is aimed primarily at minimal risk research with the identified potential of REB of Record review for more than minimal risk research.

The responsibilities of the lead investigator with regard to the REB selection, the management of necessary documents and materials to and from the REB of Record and to and from the designated research contact at each site and proposed timelines is clear. *The guidelines do not provide guidance in the event the research project has Co-Principal Investigators who are from different sites.*

The fact that no formal agreements between institutions is required is wise.

With regard to more than minimal risk research in 3.5 of the proposed guidelines- the statement says that the research may begin if one site has not returned their acknowledgement/approval of the main review in 4-6 weeks*. What happens if two or more sites have not responded within the time frame?*

Broad Consent in Research

Obtaining broad consent for the future use of research participants' data and material stored in a data repository or biobank, facilitates research in specific areas and in the international sharing of research material and data. The guidelines provided in this section are clear and comprehensive. The challenge is for the researcher to provide enough information for the consent to be free and informed and that the participant understands that ongoing consent could be limited and in certain situations, impossible. Section 5.1 is very helpful. *The effectiveness of these guidelines will be dependant on the comprehensiveness and clarity of the information given to participants at the time consent is obtained*.

Exemptions from REB review for de-identified cell lines and for re-use of identified cell lines

Article X outlines 4 conditions in which REB review is not required for research that relies on the re-use of de-identified human somatic cell lines. It is stated that all members of the research team must comply with these conditions. *Is there a proposed process for this compliance to be registered as having been accepted by the entire research team?*

Article Z outlines 4 conditions in which REB review is not required for research that relies on the re-use of identified human somatic cell lines.

In the application sections of the above proposed policy guidelines, the word ***should*** *is used where the word* ***must*** *may be more appropriate. When researchers are in doubt about the applicability of a condition of exemption, they must consult their REBs. The word should implies that compliance is not required.*

Revisions to Chapter 12, Section F of the TCPS (2018) with the inclusion of research involving totipotent stem cells.

The revisions are necessary and integrated appropriately. The three footnotes would be more useful if located with the definitions.

Article 12.10 (2) is titled Research Not Conforming to this Policy and has been in existence prior to this consultation. Eight potential types of stem cell research are listed as not conforming to policy. The message could be interpreted that there is the potential for this research and it may exist but the TCPS does not address these types of research. Does this section condone or condemn or avoid addressing these issues?

Denise Alcock, PhD, Ontario, University of Ottawa (retired)
At the request of the SRCR
Health Sciences