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From: Pandya, Rashmi SHA
Sent: Mon, 4 Oct 2021 19:07:15
To: 'Prebble, Caitlin'; 'Ara Steininger'; 'Reymond, Nicholas'; 'McKay, Gordon'; 'Sally.Gray@uregina.ca'; 'Martz, Diane'; secretariat (SRCR/SCRR)
Subject: TCPS 2 consultation
Sensitivity: Normal

Dear TCPS 2 Panel and Secretariat,

On behalf of the Chairs and REB Administrators of the Saskatchewan Health Authority, the University of Regina and the University of Saskatchewan Biomedical and Behavioural REBs, we are submitting our joint comments to the Secretariat on the proposed changes to TCPS 2. The SHA, U of R and USask REBs currently have a Reciprocity Agreement in place that allows for single site review of research within the Province.

Please see our comments on the revised changes to TCPS 2:

Proposed Changes to Multijurisdictional Research

3.3: In relation to the following:

"If the researcher(s) believe(s) that the REB of record should be from an institution other than that of the PI's institution, the onus would be on the PI to justify to their home REB why another REB would be better suited. They would also have to demonstrate that the other REB is willing to serve as the REB of record."

The would-be REB of record should also have some say, i.e., if the PI names their home institution the REB of record, but that institution's REB feels that a different REB with some connection to the study would be better suited to review the file for whatever reason, they should have the ultimate authority to make that decision, in collaboration with the REB that they would request take on the review instead.

There should be more clarity on how local site differences should be managed within study protocols.

3.4: There was some reservation on the specificity of the process in the interpretation. It seems it would be better if institutions could design their own process for meeting the principle espoused by the interpretation.

In relation to the following, "any further decisions by the REB of record during the course of the research must be communicated to the local REBs, and it is the responsibility of the researcher to do so", does this entail continuing review documentation as well as initial approval documentation? Does this mean that for every amendment, for example, the researchers again have to wait up to 3 weeks (or longer, if left up to the individual REBs) for acknowledgement/agreement before they can implement those changes? That could cause some significant delays and could be quite burdensome for the REBs as well, who at that point have essentially "signed off" on the research and have accepted the decision of the Board of Record. The requirement to provide ongoing documentation to all receiving REBs should be rethought if this was the intention of the prior sentence.

"No formal agreement between institutions is required to implement the process described above." There perhaps needs to be a statement that formal agreements that are in place should be respected.

There perhaps needs to be mention that researchers are responsible for assuring other institutional requirements such as Operational Approvals or agreements (e.g. data sharing agreements) for multijurisdictional research are satisfied, while the TCPS 2 are ethical guidelines it would be good to remind researchers that REB approval may not be sufficient for initiating projects.

3.5: This does not consider situations in which an above minimal risk study may have team members at other sites but there are no participants at those other sites (i.e., a multi-institutional, multi-disciplinary research team but where participants are at a single site). This should be considered and addressed.

Broad Consent

In practice to what extent can recommendations with regard to withdrawal of broad consent be implemented? At some point, participants and researchers are likely to lose one another's contact information. Even if researchers start off with the best intentions, as time goes on, it becomes less and less likely that researchers will continue to be diligent about reaching out to these old participants.

Cell Line Exemptions

No comments.

Proposed Changes Chapter 12, section F

No comments.

Please let us know if you require any further information from the SHA, USask or U of R REBs.

Sincerely,

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The Saskatchewan Health Authority works in the spirit of truth and reconciliation, acknowledging Saskatchewan as the traditional territory of First Nations and Métis People.