Archived: Monday, November 1, 2021 9:35:47 AM
From: Caric, Nikola
Sent: Tue, 5 Oct 2021 11:37:10
To: secretariat (SRCR/SCRR)
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal

Hello,

Apologies for the late submission, hopefully it can still be considered.

1. Ontario

2. McMaster University

3. Comments from McMaster REB

The following comments are not an "official", unified response from MREB, rather it is a collection of comments and thoughts from MREB members and support staff.

Review of Multijurisdictional Research

- A positive direction for researchers, brings multijurisdictional review into line with how it is done in other countries.
- For a social-behavioural REB like MREB, this would be helpful as the majority of its multijurisdictional reviews involve a McMaster researcher as co-investigator on a study taking place off-campus or a McMaster PI wanting to collect data at multiple institutions. However, I can see that for medical REBs this would be more difficult given the unique needs of the local site and especially in cases of inter-provincial studies where the board of record may not have the expertise in provincial legislation.
- The current plan for the other sites to receive the documentation after the review and to make requests for local needs then could create more work overall than just involving those other REBs at the start of the process, when they could communicate local requirements to the BOR.
- Some of the multi-jurisdictional review issues could be resolved by giving institutions greater flexibility in determining when use of their resources requires REB review – e.g., some may choose not to review when all an external researcher is doing is sending a request to a department to pass on a recruitment email. It would be helpful for PRI to augment the interpretation on use of resources with categories – what types of institutional resources mandate REB review, what type do not require review (e.g., public email), and what types are left up to the institution to decide (like requesting emails be sent via internal lists, or putting up posters).
- The guidance is light on what happens after the initial review. Presumably the BOR handles amendments, annual reports, unanticipated events, etc. – but is it the BOR's responsibility to inform all the sites when these are submitted/cleared and send copies to the other sites? Is it the PI's responsibility? Other sites should be aware of these events.
- Institutions should be given the flexibility to expand this guidance to ethics reviews done in other countries. For example, if a Canadian REB is satisfied that the PI's delegated or full IRB review done in the States is sufficient, then they could accept that review. Especially as the Tri-Agencies are encouraging international collaboration in research (this would

remove one barrier to that).

- Would Indigenous communities or a partnership of several communities be able to establish a community REB based on following the TCPS2 in addition to Indigenous ethical principles and act as the BOR for studies taking place in the community?

Broad Consent

- It's important to highlight the need for participants to receive/find information about how their data is being used in the future, such as what studies are being done with the data from the repository.
- It should be clear if this guidance is only for data repositories with restricted access, or also applies for depositing data in public access repositories, or for researchers who only want to keep data for their own future use in related studies. The guidance for the former may not be applicable to the latter two scenarios.
- A major concern is the mandating of seeking separate specific and broad consent, as this seems to come into conflict the new Tri-Agency push (see RDM policy) to make data accessible for other researchers. If some data is removed due to a certain percentage of participants refusing broad consent, then it makes it difficult for other researchers to replicate the analysis. At the least, for non-identifiable data being deposited the risk to participants is very low and so the concern of undue influence is likewise lowered. In those cases it should be fine for participants to be informed both about the specific use and the data deposit and consent to both, or if they are not comfortable then they are free to not participate. REBs could determine if in these cases, due to the study's particulars, instead a separate consent was required. Perhaps it should only be for identifiable data being deposited that separate consent is required by the TCPS2. This would mirror, in a way, the guidance on secondary use of info in 5.5a-b, where non-identifiable data is treated less stringently than identifiable data. In general, it is better to give REBs the flexibility to determine for each study whether separate consent is needed or if simultaneous consent to both specific and broad use is justified.

Click here for MREB FAQs on Ethics Review during COVID-19

Nick Caric | Assistant Director, Research Ethics

McMaster Research Ethics Board Secretariat

Research Office for Administration, Development and Support (ROADS)

location: Gilmour Hall, 305-L
phone: 905.525.9140 ext. 26117
email: caricnt@mcmaster.ca

BRIGHTER WORLD

McMaster University