University of Manitoba | Office of the Vice-President (Research and International)

202 Administration Bldg
66 Chancellors Circle
Winnipeg, MB
Canada R3T 2N2
T: 204 474 6915
F: 204 261 1318

October 4, 2021

RE: Panel on Research Ethics: Proposed Guidance for Public Consultation

Dear Panel on Research Ethics,

1. Province or territory: **Manitoba**
2. Affiliation: **university, University of Manitoba**
3. Capacity in which you are submitting the comments: **group, Human Ethics Resource Committee**
4. Your main discipline: **All disciplines**

Thank you for the opportunity to provide feedback regarding the proposed changes to the TCPS 2. Please see our comments below:

Multi-jurisdictional research	We agree with and welcome these proposed changes. These are in line with current UM policies and procedures. Currently some UM REBs already use the PI's home institution's application and approval letter to conduct a Chair review of the application for minimal risk studies. Our Health REBs are collaborating and participating in several initiatives that support multi-jurisdictional Research Ethics Board review that is very similar to the proposed changes outlined in the revised TCPS2. These proposed changes will have little impact on our review and resources. However, there may be instances where the REB of record and local REB don't agree on the level of risk of the study and therefore may not agree on the type of review needed. Clearer guidelines or a decision tree on minimal risk vs. more than minimal risk may help mitigate these potential disagreements.
Broad consent in research	While we can appreciate the potential need for a broad consent option, more information and guidance are needed for its use. More information and definitions are needed for repository and data repository. It is also unclear how researchers and institutions will operationalize these repositories. How will we ensure the data is accurate and only contain data by those who have provided consent? How are consent forms managed to ensure participant's rights are respected? How should consent forms in these cases be managed from a data management perspective? Who is checking for compliance? Who's responsible for the upkeep of these

	repositories and ensuring they are taken down/destroyed when stated? How are withdraw requests operationalized? If these individuals have not yet been consulted, it is imperative that data management specialists are involved in these conversations as they are the data experts. It would also be helpful to involve privacy specialists and people who work with personal health information. Standard repository language for consent forms would be helpful. Line 47- 'repository assumes those responsibilities' - Does this mean that when something is deposited, the onus of the researcher is transferred to the repository? What ongoing obligations are there to the 'owner' of the dataset? Line 71/72- participants 'must be able to request withdrawal of their stored data…' While this seems self-evident from an ethics perspective, practically this raises several questions: if a participant wishes to have their data removed from a repository, who is responsible? What is the responsibility of the REB to ensure this is done? What is the responsibility of the repository? Does takedown process/policy need to adhere to REB policy? How does privacy factor into any declarations of takedown? Line 76/77- 'Researchers must justify any limitations ….' This will likely require considerably more forethought and understanding of terms of use and nature of deposit by researchers. Training will be essential. Line 130- Precision here is likely needed. If something is deposited into a collection whose definition/name infers a specific purpose or group, then by extension that data is associated with said community. Line 132- This will seem burdensome to researchers and may discourage deposit. The nature of data reuse includes the possibility that you may not be able to predict how people may use it (i.e. hence the use of open platforms etc.). Line 137- Does this include minimal length of time? The intention of data deposit is also preservation over a considerable length of time. Will the researcher need to provide for the entire life cycle? More clarity would be appreciated here. Line 142- This will require a specific element in the signatory section. What does this mean in relation to bullet 3 (line 146) (i.e. limitations of withdrawing)? What does this mean in terms of aggregating/group anonymization of data?

	Line 153- This potentially opens up the repository to legal liability. Since the researcher signs a waiver from the repository on deposit, the onus is put back on researcher. Therefore, what is the responsibility of the institution? Line 167- This will require ongoing relationship/communication between the REB and repository to ensure repository policy can meet these requirements. Line 202- This would be the case for the vast majority of data deposits. Also, what is the obligations of the repository to ensure appropriate consent was obtained? Does the repository need to retain copies of consent? Will the researcher need to prove consent upon request?
Research involving cell lines	We agree with the proposed changes and find them to be reasonable.
Research involving totipotent stem cells	We agree with the proposed changes and find them to be reasonable.

Sincerely,

Dr. Annemieke Farenhorst, P.Ag., Drs.
Chair, Human Ethics Resource Committee, University of Manitoba
Associate Vice President Research, Office of the Vice-President (Research and International), University of Manitoba
Professor of Soil Science, Faculty of Agricultural and Food Sciences, University of Manitoba
& Associate Editor, ACS Agricultural Science and Technology
& Secretary, IUPAC Division VI Chemistry and the Environment