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From: Lynda McNeil
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Subject: TCPS 2 Consultation
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Please find below the comments of the McGill Advisory Council on Human Research Ethics on the proposed revisions to the TCPS 2.

Requested demographics 1. Quebec 2. McGill University 3. Submitted on behalf of the McGill Advisory Council on Human Research Ethics 4. The ACHRE membership is representative of all the disciplines at McGill where research is conducted including biomedical, humanities, social and behavioural sciences, engineering and natural sciences. Submitted by Lynda McNeil, Associate Director, Research Ethics; Member, McGill Advisory Council on Human Research Ethics

Multi-jurisdictional Research:

Point 3.1 states that ' ….a single, comprehensive review of minimal risk research studies, should, in the vast majority of cases, be sufficient to provide the appropriate protection to participants.' The guidance, however, states that this guidance is mandatory and does not describe how any exceptions to the requirement for a single review can be done. There has to be an allowance for the local REB to determine that the project is not minimal risk and chooses to conduct their own review. There may also be instances where local regulations require review by the local REB. An example is in Quebec where research falling under Article 21 of the Quebec Civil Code requires review by an REB designated by the Ministry of Health and Social Services. Consideration also has to be given where a local REB determines that there are important ethical issues that the REB of record have not addressed and the REB of record does not agree with. Can the local REB determine that their researcher then cannot take part in the study? Can the local REB decide that a local REB review must take place? For the most part, it is expected that there will be collaboration and consultation between REBs. However, there needs to be a process in place to deal with those situations that won't fall under the 'vast majority of cases'.

There needs to be clarity on what situations the REB of record should report directly to the local REB where there is a local researcher involved and a time frame in which it should be reported. Examples include serious or continuing non-compliance; suspension or termination of REB approval by the REB; founded participant complaints.

There should be a sentence that each REB agrees to make available, as may be required, all REB records pertaining to a collaborative study approved under the terms of this agreement, to authorized individuals for the purposes of auditing, monitoring and investigation of complaints or research misconduct.

As stated, there are several multi-jurisdictional agreements which have been negotiated and consideration give to local and institutional policies and procedures as well as legal and liability issues. It's not clear how this guideline, if it is obligatory, would affect these formal agreements already in place, particularly if they do not align.

Point 3.4 – A timeline is suggested but it's not made clear if the research can be started by the lead researcher but not by the co-researcher who has not yet received the local REB. Point 3.5 mentions the research not starting at a local site but in many cases, there is only one site but several researchers. Of course, even with the REB of record approval, if there is a local site involved, the study cannot start at that site before local acknowledgement is given. This needs to be clearly stated.

It's not indicated if the lead researcher has to provide all the local REB acknowledgements to the REB of record.

Broad Consent:

Point 5.2 – Depending on the nature of the data, it might be helpful to ask participants to complete a check list covering potential areas in which their samples might be used e.g. anything related to a specific trait, anything related to a general category of traits, anything at all. Given that it is impossible to predict all types of studies that might be done (as new methods are being developed on a rapid basis), focusing on the traits under investigation, whether clinical or not, is perhaps both more generalizable and better appreciated by participants than focusing on technologies.

Ideally, all samples will undergo some form of anonymization before they are made publicly available, and this does indeed impact the freedom to withdraw samples and/or data. This situation should also be explained in full in the consent form.

Point 5.4 - it's suggested to include a bullet point ensuring that samples will only be made available to those with a legitimate scientific purpose and not to the general public. This would require that the repository have a committee structure to review requests and evaluate their appropriateness.

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