# University of Ottawa comments TCPS 2 Consultation – Proposed Guidance for Public Consultation

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Submitted by:

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University of Ottawa REBs review research projects in the following disciplines: Arts, Behavioural Sciences, Education, Engineering, Health Sciences, Humanities, Interdisciplinary, Management, Natural Sciences, Social Sciences. We do not review clinical trials.

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We thank the Panel on Research Ethics and the Secretariat on Responsible Conduct of Research for this opportunity to provide comments on the proposed revisions to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 (2018)) and guidance.

We consulted the University community (researchers, deans, REB members, and Office of Research Ethics and Integrity staff) and integrated comments we received into this document.

# 1 ETHICS REVIEW OF MULTIJURISDICTIONAL RESEARCH

## 1.1 BACKGROUND – UOTTAWA REVIEW PROCESS FOR MULTIJURISDICTIONAL RESEARCH

At the University of Ottawa, we have two processes for projects that have been approved by another TCPS 2- compliant REB. In all instances, the list of forms and documents that must be provided by the researcher to our REB are the same as described in the proposed guidance (lines 122-124). Both these processes are usually completely in one to two weeks (or less).

1) Agreement with REBs at affiliated hospitals:
    a. If REB approval is first obtained at an affiliated hospital, and no research activities are taking place on campus, we conduct an administrative review. The REB is not involved in

this process; it is completed by REB Office staff, usually the Director. This process mirrors exactly what is described in the proposed guidance.

b. If research activities are taking place on campus, we conduct an expedited review. The chair and one staff (protocol officer) review the submission. This is a REB delegated review, not merely an administrative approval.

2) Projects approved by other REBs: If approval for a minimal risk study is obtained from a non-affiliated site, we conduct an expedited review, i.e., by the Chair and one staff (i.e., delegated review).

In all such instances, a short form is completed by researchers to obtain their names, affiliation, and a brief description of the project, which helps to assess the risk level as well as the location of research activities.

The great majority of research reviewed by the expedited process is approved either without changes being requested or with few comments.

However, what we have noticed, and which may be a challenge should the proposed process be made mandatory for all types of minimal risk research, is the following:

- Not all REBs ask for the same information in their forms. This means that despite there not necessarily being an ethical issue with a project, the information provided is sometimes incomplete, and we need to ask for additional information.
- Not all REBs assess risk the same way. We have had projects that were submitted as full board and which we assessed as minimal risk, and vice versa.

Below are detailed comments and questions regarding the proposed revisions.

## 1.2 COMMENTS ON THE PROPOSED REVISIONS

Researchers who responded to our consultation were generally in favour of the proposal, but we also received feedback indicating that the current agreement with hospitals described above works well.

From a REB and REB administration perspective, we agree with the goal to harmonize the ethical review of multijurisdictional minimal risk research and we agree with the proposal that a formal agreement is not required in order to conduct a delegated review of previously approved projects (line 146), particularly where no research activities are conducted and local sites. The timelines proposed, i.e., three weeks to complete the process and send an acknowledgment, are also very reasonable.

However, we have concerns regarding the mandatory nature of the proposition. We also noted that there will be logistical implications and challenges for our institution that likely reflect concerns that other universities will have.

### 1.2.1 Scope

One concern is that all research activities are considered equally in the guidance, i.e. (lines 75-80) the guidance is “mandatory for all minimal risk research conducted under the auspices of multiple

institutions; research conducted using the resources of more than one eligible institution; research involving researchers from one eligible institution and resources from another". This means that, for example, a study where recruitment and participation are taking place at secondary sites is treated the same as when a co-researcher is merely analyzing data or involved in developing methodology. We believe a distinction should be made between activities where there is direct contact with participants (e.g., recruitment, data collection) and where there is not (e.g., data analysis, receiving biological material, team of researchers affiliated with different institutions, researcher who has multiple institutional affiliations).

### 1.2.2 Quality and consistency of Review

The following statements appear in the proposed guidance:

> Line 36: We are unaware of evidence that multiple ethics reviews provide commensurately greater protection for research participants.
>
> Line 58: Similarly, all REBs must review research based on those same common ethics principles and guidance.

From the uOttawa REBs' experience, most REBs do a good job of evaluating minimal risk projects.

There is, however, a **difference in the quality of ethics review**, including noticing ethical concerns and assessing risk, between REBs who review many studies and those who do not. For example, we have had a study submitted to our REB that was evaluated as minimal risk at the primary REB, despite involving participants with a history of depression and drug use and where there were risks to participants' wellbeing that were not considered and therefore not managed. If the local REB has to accept the REB of Record assessment of risk level, this could place participants at risk. Conversely, some of those REBs have a heightened perception of risk, and do not distinguish between risk encountered by participants in everyday life from those that are directly linked to the research.

Also, given that our REB accepts to review files that have been approved by other REBs without completing our form, we have seen that **not all REBs do in fact collect the same information** from researchers. Some information, including for example data conservation, is not as complete in other institutions' form. The absence of a standard submission form is therefore an issue (note that separate forms should exist for biomedical vs. non-biomedical studies).

**Assessment of risk level**: As stated above, not all REBs assess risk the same way. It isn't clear within the proposed guidance how to proceed should the local site not agree with the REB of Record's assessment regarding risk.

> Lines 108-109: Exceptionally, a local REB may advise the REB of record to reconsider its decision in light of local circumstances or a substantive issue that had not been addressed.

**Inability to refuse site approval:** There is concern regarding the local REB's ability to refuse to provide administrative approval. Though this likely would not happen often, there is a possibility that the local REB may have **serious ethical concerns** with a study that was approved by the REB of Record. With the current proposal, it seems that neither the REB nor the institution can refuse a study. This could place participants and the institution at risk.

**Local circumstances:** Beyond the ethical review of a project, REBs also ensure that the institutions' rules and regulations are enforced. These must be taken into account even though they may not relate to risk, for example uOttawa has a bilingual population so most documents recruiting our students or professors should be provided in French and English. We also have a system where students can participate in research projects (for psychology and other groups) with its own guidelines and a process for involving medical students (who are highly sought after) in research. Considering that many institutions likely have various local requirements, it is not clear how the REB of Record could expect to know if the local information provided by the PI (perhaps via the local PI) is accurate, or whether there is missing information.

We feel that putting ownership on the REB of Record to know about all local requirements would be a challenge, as some of these requirements and processes are difficult for the primary REB to know, and could also be difficult for a co-researcher to know, particularly if there is no local co-investigator.

This is a concern both from the point of view of being the REB of Record, as the expectation that we would be able to assess local requirements when researchers themselves may not be aware of them is unrealistic, and from that of a local site, since with the current proposed revisions, it seems we would not be able to refuse a study that has been approved by the REB of Record.

There were also concerns raised regarding **leaving the researcher out of the conversation** when the local REB has issues or comments. Our REBs have worked hard to develop relationships with our researchers, both student and professors, and feel this could be impacted by a mandatory system that does not provide a feedback mechanism that involves the local researcher.

> Lines 82-85: The expectation is that a single REB of record will conduct the ethics review. Its decision and reasons, along with the final study materials, would then be available to the REBs of all sites, for acknowledgment. Ideally, that consideration and acknowledgment would be done by a single individual at the local REB.

Clarification: Does "consideration and acknowledgment" mean that there is no ethical review at the local REB level, and that the administrative review is therefore an institutional and not a REB approval?

Clarification: It is unclear what happens to existing projects where the PI is at another site; can institutions choose to renew projects as administrative vs. regular files, particularly if these are above minimal risk?

## 1.3 OTHER LOGISTICAL AND PRACTICAL QUESTIONS

It is not clear how the local site and the REB of Record would coordinate regarding ongoing review. Does the local researcher have to submit an annual report to its institution? If not, how can the local site know that the study is still approved by the REB of Record? Would reminders regarding expiry go to the Board of Record?

Information on the ethics certificate, e.g., research team ember names, type of review: Many REBs only indicate the PI name on ethics certificate, and many do not indicate the type of review conducted (delegated vs. full board). Many will need to change their forms and certificates in order to put such a process in place.

How are local vs. overall changes to the project handled? If the REB of Record is meant to review all changes, how is the local REB informed of this?

In cases where we are the PI's REB, we have moved away from asking researchers to provide us the approvals of other sites. This would be a step backwards for our REB, and would add a burden and a complexity to the review process.

There is concern regarding the proposal that all issues be brought to the REB of Record. The REB may not be easily reachable and this could cause delays, rather than speed up the process for researchers.

There are also logistical challenges, particularly since most REB systems are based on interactions between the REB / REB Staff and researchers, rather than with another REB. Changes would have to be made to systems, which could be costly.

### 1.4 CONCLUSION

While we agree that there should be mechanisms in place to facilitate and expedite the review of multijurisdictional projects, we do not agree with a mandatory acceptance of ethical review of minimal risk projects conducted by a single REB of Record except where:

- The local researcher is not involved in any data collection
- There is no recruitment of participants (e.g., students, employees) at the local site

We do appreciate the statement that there is no need to have an inter-institutional agreement in place even if the research surpasses minimal risk, particularly if the above applies.

We therefore do not think that a mandatory process where one REBs' decision is automatically accepted by local REBs should be put in place.

## 2 BROAD CONSENT

There was general agreement that this would be a positive change but some aspects require clarification.

- It is not clear if this guidance is meant to apply mostly to biological materials and the biomedical domain or if it is meant to also include data such as interviews, language tests, video recordings, etc.; does apply to other health-related and behavioural longitudinal studies of individuals and populations? It would be helpful to have additional examples of types of data for which this guidance would apply.
- In section 3, it is stated that "This guidance can be applied to other communities when appropriate (Article 2.11)"). It is not clear how this would be applied.
- Comment from researcher: “As long as the participants are made fully aware of the new consent processes and the implications then this will be very beneficial. A process for allowing participant to consent at different levels (for specific vs. broad use) should still be maintained.”
- There is a statement that “For practical reasons, the onus may be on the participant to provide the repository with any updates to their contact information, and to confirm their ongoing consent.”
- **Ongoing consent**:
    - What happens if the participant does not renew their information?
    - Who is responsible for re-contacting participants? The researcher? The Biobank / repository?
    - What is the priority between protecting the identities of participants vs. making sure consent is ongoing? It may be difficult to have both. Ongoing consent can be an issue and not feasible long terms; more of an issue for some types of research.
    - Commentaire de professeur: « Dans certains domaines, il est considéré normal de conserver et d'archiver les données de façon anonyme sans date de destruction. Il manque cependant de lignes directrices sur la façon dont les données devraient être gérées après la retraite ou le décès des chercheurs et la proposition ne soulève pas ces questions. Il est aussi illusoire de penser qu'on peut rester en contact avec les participants sur des décennies et la proposition de consentement continu ne semble pas prendre cette question en compte. »
    - Lines 208-210 ongoing consent for kids: What are the guidelines for the REB? Who should be checking for this, the researcher or the person responsible for the repository?
- REB member comment: The following statement seems to place an impossible burden on the researcher, especially where the research involves a large number of participants: "The researcher should consider what information is meaningful to the participant’s decision to participate at the time of consent, and what information might be more appropriate as an addendum, which may be of more interest to them later." Note the inconsistency between "the [individual] participant" and the entire participant population ("them").
- Also in section 5, there is an apparent inconsistency between "For broad consent to be informed, it must include information about..." and "The following is a more detailed description of these requirements that can be used...." How will researchers and REBs decide what information is actually required?
- How does this work in the context of open science?
- Definition: It is not clear what constitutes a “data repository.” Are there requirements for this and for a data back?
- Line 76: “Researchers must 76 justify any limitations to the withdrawal of data or human biological materials to their REB.” What is a good vs. a bad justification?
- It would be helpful to clarify that the goal is re-use not merely the storage of data.

- It would be helpful to add information or guidance regarding the timing of the initial consent, since a participant's understanding of the initial project and potential uses of the data could evolve following their participation, which could lead them to be more or less comfortable providing broad consent. It is also possible that a project evolve and that new uses be discovered that were not planned at the outset. It may therefore be beneficial to obtain consent for re-use later on vs. at the time of initial consent.
- Il faudrait clarifier dans les textes de consentement que les données collectées ont été collectées pour un projet défini.
- Dans l'EPTC, il faudrait mentionner que ceci ne cherche pas à favoriser la collecte de données sans lien direct à un projet.
- If the data collected was for student research (the student is the PI), and the student is no longer affiliated with an institution, how should this be handled?

# 3 THE REVIEW OF RESEARCH INVOLVING CELL LINES

The University of Ottawa did not receive many comments on the proposition that de-identified cell lines be exempt from REB review, but overall we agree with this proposition.

Two comments received from professors:

> "This is good, but in addition we need something like this for de-identified data."
>
> "As long as the participant (cell donor) is aware of this though the consent process then this will be very beneficial."

The latter comment raises the issue of ensuring that consent was obtained in order for the data to be included in the repository. This is more easily done with some data banks than others, for example if data is collected by a co-researcher from a hospital, it will be easy to determine how consent was obtained. Some private data banks have clear information on consent, others do not. Should the latter be included in the exemption?

The main challenges with this exemption would be logistical, i.e.:

- Would this apply to projects that have current REB approvals? It may not be easy to identify these.
- For new projects, who would determine whether the project is exempt – the researcher or the REB? This issue exists for all other types of exemptions, however, and could be resolved with new information documents and communication with the groups that are most likely to submit such research projects for review.

# 4 RESEARCH INVOLVING TOTIPOTENT STEM CELLS

There were no objections to the proposed changes.