Archived: Friday, October 29, 2021 2:31:52 PM
From: Wouters, Brad
Sent: Mon, 4 Oct 2021 18:11:52
To: secretariat (SRCR/SCRR)
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal

The UHN Research Quality Integration (RQI) team has developed a draft institutional response to proposed guidance related to the interpretation and implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 (2018)).*
To develop an institutional response, the RQI solicited feedback from the research community broadly as well as specific key stakeholders, including the Clinical Research Executive (Interim), UHN Research Legal, UHN Biobank, McEwen Stem Cell Institute and the UHN REB. The UHN REB will submit an independent response to the proposed guidance and was consulted to ensure that the UHN institutional and UHN REB responses are aligned.
Consultation was sought on the four proposed guidance documents linked below:
1. Ethics Review of Multi-jurisdictional Research
UHN is supportive of the proposal that multi-jurisdictional, minimal risk research undergo single REB review. This has the potential to streamline review of minimal risk research studies and reduce workload for researchers and institutional REBs.
Proper operationalization of this process will be crucial to ensure that the proposed changes effect their desired outcome to promote the expeditions review of research while maintaining appropriate protections for research participants.
In order to better understand how this process will be operationalized at institutions across the country, UHN would like to request clarification on the following issues.
1. **Will institutions be notified when they are listed as a site on a multi-site study submitted to another institution for REB review?** Notification of the institution *prior* to review by the REB of record will ensure that the institution is aware of research that is planned to take place under its jurisdiction. This will allow for a cursory, administrative acknowledgement that single-REB review and the REB of record are appropriate for the study.
2. **Whose responsibility is it to notify the local REB of the decision made by the REB of record?** When an institution enters into a contractual agreement it relies on knowledge of the review and approval by the REB of record. UHN recommends that the responsibility to share the review decision and associated final materials with local REBs lie with the REB of record, exclusively or jointly with the researcher, rather than with the researcher alone.
3. **How does the TCPS 2 define the scope of "local review"?** Without clear guidance outlining the scope of "local review" and "local circumstances," local REBs may be required to conduct a broad review of the research in order to identify areas that may be impacted by local circumstances. This will place undue burden on local REBs and increase the timelines for local REB acknowledgement. To this end, UHN recommends that the Tri-Council publish guidance outlining the scope of local REB review, including a clear definition of "local issues."
4. **How will the Tri-Council ensure consistency across institutions?** Consistency in the review process and terminology use across institutions will increase confidence in and endorsement of the single-REB review process. Standardized templates for documents such as the consent form will streamline single-REB review and alleviate concerns of inconsistency. It is UHN's experience that even across similar institutions, certain terms are applied differently. This causes complications when trying to uniformly apply principles and processes. Creation of overarching definitions for nuanced terminology would alleviate this issue.
a. In particular, UHN has found that institutions do not apply a single definition for "de-identified data." Creation of an overarching de-identification standard would ensure privacy risks are appropriately mitigated across institutions.
5. **How does this requirement apply to protocols that are directed to banking of data/materials for future secondary studies?** Protocols that involve a banking component of material and data for future secondary studies have specific privacy and consent requirements that are jurisdictional and may be difficult to address using a single REB. UHN recommends that additional guidance be put in place to clearly defining banking protocols and to ensure that participating institutions receive notice of proposals that include a banking component for future secondary studies, or that these protocols be removed from the mandatory single REB review requirement.
6. **How does this requirement apply to Quality Improvement/Quality Assurance activities?** It is not always clear whether certain projects are more properly defined as research or quality improvement/quality assurance. Clarification of the scope of these requirements as it relates to what may be quality assurance / quality improvement projects or research projects will ensure that REB and legal oversight are appropriately and consistently implemented.
7. **How should single REB review to applied to multi-jurisdictional research where one or more of the institutions involved are not Tri-Agency eligible?** Multi-jurisdictional research may include sites that fall outside the scope of the *TCPS 2 (2018)*, such as international institutions or private clinics that are not eligible to receive Tri-Agency funding. Clarification on how to apply the requirement for single REB review to studies that involve both institutions that are subject to the *TCPS 2 (2018)* and institutions that fall outside of the scope of the *TCPS 2 (2018)* will ensure that all research is subject to consistent and rigorous ethics review.
8. **When will this new process be implemented?** Operationalization of a change to process this significant will require sufficient time for institutions to establish new processes and workflows and train staff. Significant components of the new policy and process will need to be in place before it is appropriate to move to a single REB-review model for multi-jurisdictional research. How much lead time with the Tri-Council provide institutions before the new guidance comes into effect?
Additionally, UHN has some concerns about the current definition of "minimal risk research" and consistency of its application.
1. **Does research that uses third-party applications to collect participant data fall under the definition of "minimal risk"?** The current definition of "minimal risk" as defined in the TCPS 2 (2018) is "research in which the probably and magnitude of possible harms implied by participant in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research." This definition would seem to imply research that may rely on the use of third-party applications to collect personal data as the use of personal mobile applications is commonplace. However, the use of third-party applications in research carries specific risks to participant privacy that may require more intensive legal and privacy review from local institutions.

2. **How will the Tri-Council ensure that the application of the term "minimal risk" is applied consistently across institutions?** Institutions may apply the definition of minimal risk inconsistently. To ensure that the proposed single REB review of minimal-risk research is applied homogenously across institutions, UHN recommends that the Tri-Council provide additional guidance on the scope of "minimal risk research."

On a related note, UHN finds the term "auspices" as defined in the current TCPS 2 to be overly broad and asks for clarification of the intent of article 6.1. UHN, and many institutions across the country, have a majority of their faculty, staff and students who are affiliated with additional institutions, primarily the University of Toronto, but also a number of Canadian and international research hospitals, universities, community hospitals and private clinics.

As the article and application currently read, the policy requires that UHN faculty, staff and students conducting research at any location are required to obtain UHN REB approval, regardless of whether any of the research is conducted at UHN or uses UHN resources, if they make reference to their UHN affiliation on any publications. There is a feeling among the research community that, in the interest of full disclosure, authors should list *all* of their affiliations when they publish work. Taking these together, researchers will multiple affiliations who are conducting a research project at a single site, using only the resources of that institution, would still be required to submit the study the REBs of each institution at which they have an affiliation. This creates undue work for both the researcher and the institutional REBs.

UHN requests clarification on the expectations of the Tri-Council for institutional REB review under the circumstances outlined above.

2. Broad Consent in Research

UHN is supportive of published guidance on broad consent in research. Based on the proposed guidance presented here, UHN would like to request clarification of two points:

1. **Is reference to a specific repository required as part of broad consent?** UHN has a number of repositories across departments and sites and is requesting clarification for specific details that are provide in the consent.

2. **Please define "periodically."** The guidance indicates that participants "should have the option of indicating (and periodically confirming or withdrawing) their consent to be re-contacted." How frequently should participants be asked to re-confirm their consent to be re-contacted? What happens if the participant cannot be contacted?

Although not strictly related to broad consent in research, another question about the consent process that has come up at UHN is how the *TCPS 2 (2018)* understands the use of electronic consent. Will the *TCPS 2* acknowledge and accept the use of electronic consent moving forward?

3. Cell Line Exemptions

UHN is supportive of the proposed changes.

4. Research Involving Totipotent Stem Cells

UHN is supportive of the proposed changes.

Dr. Bradly G. Wouters
Senior Scientist, Princess Margaret Cancer Centre
Executive Vice President, Science and Research
University Health Network

R. Fraser Elliott Building, 1st Floor, Rm. 414
190 Elizabeth Street, Toronto, Ontario, M5G 2C4

E-mail: brad.wouters@uhnresearch.ca
Twitter: @bradwouters
Phone: 416-340-4407

Executive Assistant:
Sasha Howell
Email: sasha.howell@uhnresearch.ca
Phone: 416-340-4800 ext 2026

Patient Consent for Email:

UHN patients may provide their consent to communicate with UHN about their care using email. All electronic communication carries some risk. Please visit our website here to learn about the risks of electronic communication and how to protect your privacy. You may withdraw your consent to receive emails from UHN at any time. Please contact your care provider, if you do not wish to receive emails from UHN.