RESEARCH ETHICS BOARD WHAT'S NEW AT THE REB AND TIPS AND TRICKS

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KEY POINTS TODAY

Changes and Common Comments of Chairs to consider prior to submission

New Indigenous Research Toolkit

REB Exemption form and Guidance (pdf form) and Amendments and Renewals now on Converis

REB PURVIEW

The following require ethics review and approval by an REB before the research commences:

(a) research involving living human participants;

(b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells (applicable to materials derived from living and deceased individuals);

c) Research utilizing retrospective or prospective personal data;

Research is defined by TCPS 2 2022 as "An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation."

Projects that are not deemed to be research are Exempt from REB review, but good to check with the REB prior to initiating project and to fill in an Exemption form as we cannot review retroactively:

Quality Improvement/Quality Assurance/Program Evaluation

Creative Endeavours

Observational studies or studies using publicly available data

(**Require Submission for REB to issue an Exemption Letter**)

Please note that for student research it is your Supervisor that is the lead PI—both the Supervisor and the Student should be listed as the PI on Applications and once the student is completed their project, they should be removed from the application if the study is continuing. If the student will stay on the project as a Co-Investigator post-graduation then an amendment will be required to make that change and it will need to be endorsed by the Student PI via a written statement that reflects the student is endorsing the change of PI to the Supervisor alone.

Note: This in no way undermines the student's Intellectual Property, but is to reflect that Supervisors are held accountable for the ethical conduct of the research throughout the lifecycle of the research project.

ARE YOU READY TO SUBMIT YOUR REB APPLICATION

- Have you taken required and/or recommended training (TCPS 2 2022, IRLET, BRICC or OCAP)?
- If research in specific communities, have you done appropriate early engagement and do you have some form of agreement and/or letters of support from the community on roles on responsibilities?
- If you require other approvals or letters of support do you have those ready? In some cases you may require REB approval prior to applying for other approvals but state that in the application.
- Do you have all study documents prepared (i.e. recruitment material (all scripts submitted), consent forms, surveys, protocols for study procedures if experiments or interventions that are complex, interview or focus group guides/script, consent logs if collecting oral consent, data variable lists if collecting data variables)?
- If you are using internet platforms such as Qualtrics, ZOOM or Otter.AI are you clear on the data security of those platforms and can you explain the security and retention times on your application?
- Other considerations while thinking of your plan of execution of the research prior to applying:
- With recruitment note that consent should be sought prior to organizations or individuals sharing contact information with you about potential participants.
- Do you have a secure way of sharing data amongst the study team—IS recommends setting up a TEAMS group but REDCap and Nextcloud offer Canadian options (https://www.uregina.ca/research/assets/documents/ethicsforms/important-notice-for-university-of-regina-researchers.pdf).
- Do you have a strong data security process in place?
- Have you considered all risks to potential participants?
- Have you provided information on the mitigation of risks in your application and the consent form?

USING AI SOFTWARE IN RESEARCH

- Please note that if you are using AI transcription services or AI software where participant data will shared with the AI, there are important steps to consider prior to starting your REB application:
- What the Participant Privacy and Confidentiality stipulations of the software—is participant data retained for example to train the AI?
- De-identify data prior to sharing with AI, being mindful re-identification is possible and taking care to mitigate that participant risk
- Be sure you understand how data can be deleted from the AI permanently.
- **Do not submit the link to the Privacy Policy of the AI company,** without explaining the data security of the data with that company, **it is the researchers responsibility to understand the data security risks of using AI software and information on those risks needs to be in the REB application and clearly articulated, along with a mitigation of risks plan, in the consent form as well please.**

CONSIDERATIONS OF WHETHER YOUR CONSENT PROCESS IS INFORMED

Are you clear on the purpose of the study and time commitment and have you listed all members of the study that will interact with participants or have access to their data? **Are you using appropriate language level to assure your participants understand the purpose and procedures of the study?**	**If in person, have you considered whether spaces are private and accessible?** **Were participants provided the consent form prior to research intervention, so they can review and have you addressed reviewing the consent form with participants to address questions?**	**Have you clearly explained the voluntariness of consent and the ability to withdraw from the study to participants (including limitations to withdrawal? Note participants should still be compensated.**
Have you clearly explained how you will protect participant confidentiality? Have you explained how the data will be used and for how long? (If future use is possible for similar research, have you clearly explained that future use?) Do you have a plan of sharing results of the study with participants that is clearly stated?	Recommendation: Provide at least 72 hours to consider participation; be realistic on whether time commitments required are feasible for most participants; consider whether your research is asking sensitive questions or working with vulnerable populations and build that into your mitigation strategies of risks.	Culturally Appropriate-consideration to the values and customs of others. Recruitment must not be coercive and without undue influence.

COMPENSATION AND PARTICIPANT ELIGIBILITY: THE REB HAS BEEN HEARING ABOUT PARTICIPANTS WHO DO NOT MEET THE ELIGIBILITY CRITERIA SIGNING UP FOR STUDIES. PLEASE CONSIDER BUILDING IN A WAY TO ASSESS ELIGIBILITY IF OFFERING COMPENSATION. PLEASE NOTE THAT FINANCE HAS REQUIREMENTS FOR REPORTING FOR FUNDED RESEARCH (PROCEDURES FOR CASH AND CASH EQUIVALENTS) EARLY RELEASE OF FUNDS IS AVAILABLE FOR NON PARTICIPANT RELATED ACTIVITIES: HTTPS://WWW.UREGINA.CA/RESEARCH/FORMS-AND-GUIDINES/INDEX.HTML

DATA SECURITY

Often too-vaguely described in the application

Sometimes researchers say data will be stored on a “university drive” but it isn’t clear what that means – local server, Teams or OneDrive?

If Teams or OneDrive are used, is there a statement about data being housed in the U.S. on the consent form? (https://www.uregina.ca/research/assets/documents/ethicsforms/important-notice-for-university-of-regina-researchers.pdf)

If using a program not vetted by the UofR, you will need to provide additional information about privacy policies, security features—if you do not understand those you can not appropriately mitigate for risks to participants.

If transcription is used: specific software is named, with security features described?

If broad consent is being sought, is there sufficient detail provided?

If uploading data on an open science platform, is it outlined in the consent form?

Student projects: supervisor responsible for data storage

CONTRACTS/AGREEMENTS REQUIREMENTS AT U OF R

- Please note that it is the researcher's responsibility to ensure that all the required have executed contracts or agreements which are fully executed prior to initiating research. Any REB approvals are conditional on contract/agreement final execution (i.e. research cannot be initiated till agreements are finalized in most cases).
- At the University of Regina, research contracts are required in the following circumstances:
- • External funding or sponsorship of research projects where an external partner provides financial or in-kind support.
- • Shared terms regarding intellectual property (IP), publication rights, confidentiality, liability, or deliverables that cannot be managed through informal mechanisms.
- • Multi-institutional or externally collaborative research projects that commit University resources or impose compliance, reporting, or risk management obligations.
- • Any formal arrangements that legally bind the University, including agreements for services, testing, transfer of data or material sharing, clinical research, and industry partnerships.
- In short: If the project creates legal, financial, intellectual property (IP) or ethical obligations for the University, a contract is required.
- For further guidance on when contracts or agreements are required and on the applicable institutional policies, please contact the Office of Research Partnerships and Innovation with any questions in regards to when contracts or agreements are required and with questions on the relevant policies that apply: Research.Partnerships@uregina.ca

MULTIJURDISDICTIONAL RESEARCH REQUIREMENTS

The U of R REB has a full reciprocity agreement with the SHA and USask REBs, if you have approval here you do not require review at either of the other two institutions and vice versa. Please apply to the University where your primary affiliation is.

If conducting research in other provinces the researcher is responsible for checking if local ethics review is required. Most Canadian REBs will do a delegated review of studies approved at other institutions.

Researchers should check if local review is required and what local Guidelines or Regulations apply when conducting international research.

For international projects approved by an IRB outside Canada and recruiting in Canada we will be requiring an application be submitted to our REB to assure Canadian guidelines are followed.

Please note the researcher should forward any other approvals required for their research once they have those.

Check if data-sharing or other agreements are required.

TIPS FOR STUDENT RESEARCH APPLICATIONS

Please list both yourself and your Supervisor as the PI in the study.

Use our consent form templates and be sure all required documents are submitted for review.

Use the Student Application form.

Your Supervisor must be responsible for data retention for the full life cycle of the project.

NOTE, THE QUALITY OF AN APPLICATION WILL DETERMINE IF THE REVIEW IS ONEROUS OR NOT—IF THIS IS YOUR FIRST APPLICATION SET UP AN APPOINTMENT AS WE CAN ASSIST IN MAKING THE PROCESS EASIER **BUT NOT WITH RESEARCH METHODOLOGY WHICH YOUR SUPERVISOR SHOULD ASSIST YOU WITH AS THEY ARE THE SUBJECT MATTER EXPERTS IN YOUR FIELD.**

Your Supervisor should be involved in the ethics application process from start to finish, while the REB can provide guidance we cannot assist with writing the application and commenting on study design other than ethical concerns.

REB RISK CLASSIFICATION AND TIMELINES

- Minimal Risk Study or Above Minimal Risk Study?
- Minimal Risk studies will undergo a delegated review process and a Notice of Ethical Review (NER) requesting revisions will be issued or an approval letter will be sent to researchers.
- Minimal risk studies can be submitted to the REB at any time, there are no deadlines for submission.
- Above Minimal Risk Studies are reviewed at monthly board meetings and need to be submitted 10 working days prior to the next REB meeting
- The REB has a range from lowest risk to a higher Minimal Risk category—lowest risk undergoes a delegated review by Compliance and the Chair and the turn around is usually about 10 working days
- Minimal Risk (above lowest risk) are pre-reviewed by Compliance, sent to two REB reviewers and then on to the Chair for review (minimum time 15 working days-to a maximum of 30 working days usually depending on quality of application submitted and REB volume, **please note if REB volume is high timelines may exceed our normal 30 maximum review timelines**).
- Above Minimal Risk studies are reviewed by the full board and must be submitted in a completed state two weeks prior to full board meetings, once reviewed a Notice of Ethical Review will submitted to researcher within 10 working days post REB meeting where study is reviewed.

CONTINUING REVIEW

- REB Approvals are valid for 1 year from the date of Approval. A fully filled out Renewal form must be submitted prior to expiry of approval on Converis, otherwise the REB will close the study. If you are closing the study, a closure form with information on the study progress must also be submitted via email (not available online).
- Any changes to study design or participant recruitment or consent processes must be submitted via an amendment form with accompanying documents in track changes please. Please note that changes to the approved processes cannot be initiated until the REB approves the amendment changes.
- Submit an Amendment form for changes to research team members—when making changes to study team also submit updated recruitment and consent documents with those changes in track changes please.
- Both the renewal and amendment forms are on Converis now and there are simple Quick Sheets and short You Tube videos to take you through the submission process available here: https://www.uregina.ca/research/office-research-services/human-research/ethics-forms.html
- THE REB HIGHLY RECOMMENDS REVIEWING THE QUICK SHEETS AND SHORT VIDEOS TO ASSURE YOU ARE SUBMITTING APPROPRIATELY.

PLEASE NOTE THAT THE REB WILL BE REQUIRING RESUBMISSION AFTER FIVE CONSECUTIVE YEARS OF A STUDY RUNNING TO ASSURE ANY CHANGES TO THE REB GUIDELINES FOR ETHICAL RESEARCH ARE TAKEN INTO ACCOUNT AND TO BE SURE THE LATEST ITERATION OF A STUDY HAS BEEN APPROPRIATELY REVIEWED BY THE BOARD.

HOW CAN WE ASSIST?

- We are available for pre-submission discussion and discussion during and after review.
- We can recommend strategies for improving your application prior to starting the process (send proposals).
- For community engagement research we do have two Research Engagement Managers under the VPR that can assist with international, national and provincial community engagement recommendations: research.engagement@uregina.ca
- We can facilitate Early Release of Funds for projects requiring REB submission.
- We can assist with information on requirements to conduct research in Saskatchewan.
- We can facilitate connection with Research Contracts Facilitators for studies where agreements are required.

ETHICS FORMS PAGE WITH CONVERIS ACCESS INFORMATION AND TEMPLATES AND GUIDANCE DOCUMENTS AS WELL AS CONVERIS RESEARCHER MANUAL, AND AMENDMENT AND RENEWAL QUICK SHEETS AND SHORT TUTORIAL: HTTPS://WWW.UREGINA.CA/RESEARCH/OFFICE-RESEARCH-SERVICES/HUMAN-RESEARCH/ETHICS-FORMS.HTML

TCPS 2 TUTORIAL (REQUIRED FOR ALL HUMAN RESEARCH): HTTPS://TCPS2CORE.CA/WELCOME

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