RESEARCH ETHICS

a how-to guide

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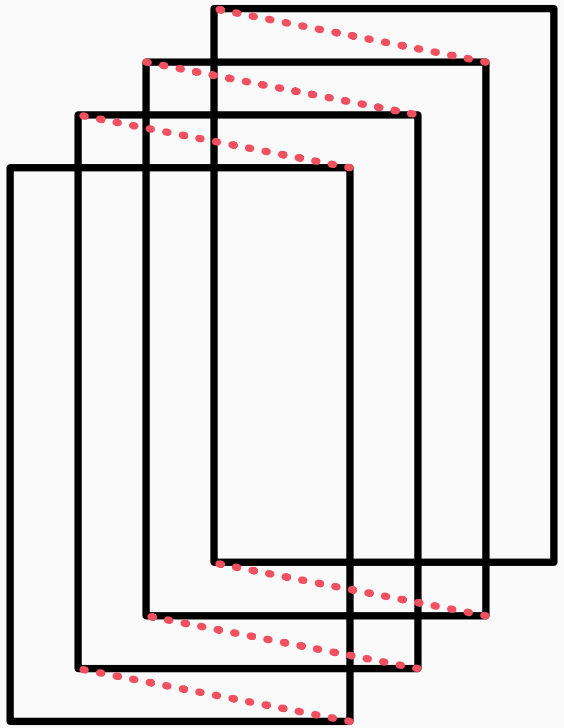

EMM LAB GUIDE

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Experimental Methods and Media

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GETTING PAST REB

...and taking your research to the good place

Introduction

This guide is based on EMM Lab's skill share workshop on writing and submitting a research ethics application for human participant research projects. The information shared in this guide is specific to the research ethics process followed by Trent University, Peterborough ON, Canada. This guide explains the application process and highlights best practices for preparing the application and submitting it. It is intended for anyone who is preparing to apply for the first time or is in need of a refresher before preparing their next application.

The guidance provided here is based on successful applications for **minor-risk human participant research projects that use qualitative research methods such as surveys, interviews, and ethnographic research conducted online.** However, this is not the only kind of research that requires ethical consideration nor are these the only methods of conducting human-participant research. Even if the general process remains the same, the demands of the application and the nature and amount of documentation required will be significantly different. As such, the information provided here is not applicable to projects that fall under moderate or high risk categories or research that does not qualify as human-participant research. This guide might help you get started, but the nature of your research project will ultimately determine the contents of your application package.

Guidelines and requirements for REB applications are also subject to periodic revisions. These updates are available on the Office and Research and and Innovation's website, which is the primary and official source of information for research ethics at Trent University. You should always refer to the Office of Research and Innovation[1] to determine the nature ethical review required of your project and find information best suited to the demands and design of your study. Graduate students should also consult their supervisors for support specific to their projects. You can find links to additional resources at the end of this guide as well.

This guide is a good place to begin if you feel lost and daunted by the whole research ethics situation. It will help you unravel the process and prepare you to hit submit on the application sitting in your drafts folder.

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[1] Office of Research and Innovation, Trent University: https://www.trentu.ca/ori/research-services/ethics

THE RESEARCH ETHICS BOARD

> Trent University, through Senate, establishes the Research Ethics Board (REB) to approve, propose minor or major modifications to, or terminate any proposed or ongoing research involving human participants that is conducted under the auspices of Trent University, using the considerations set forth in the Trent University Senate Policy for Research Involving Human Participants as a minimum standard.

Trent University Senate Policy for Research Involving Human Participants

https://www.trentu.ca/governance/sites/trentu.ca.governance/files/documents/Research%20Involving%20Human%20Participants%20Policy.pdf

Human Participant Research

Trent like every university in the world has policies and protocols for ensuring ethical research across disciplines. Anyone who wants to conduct research that involves experimentation or data collection from external sources (animals, humans etc) needs to get through the REB.

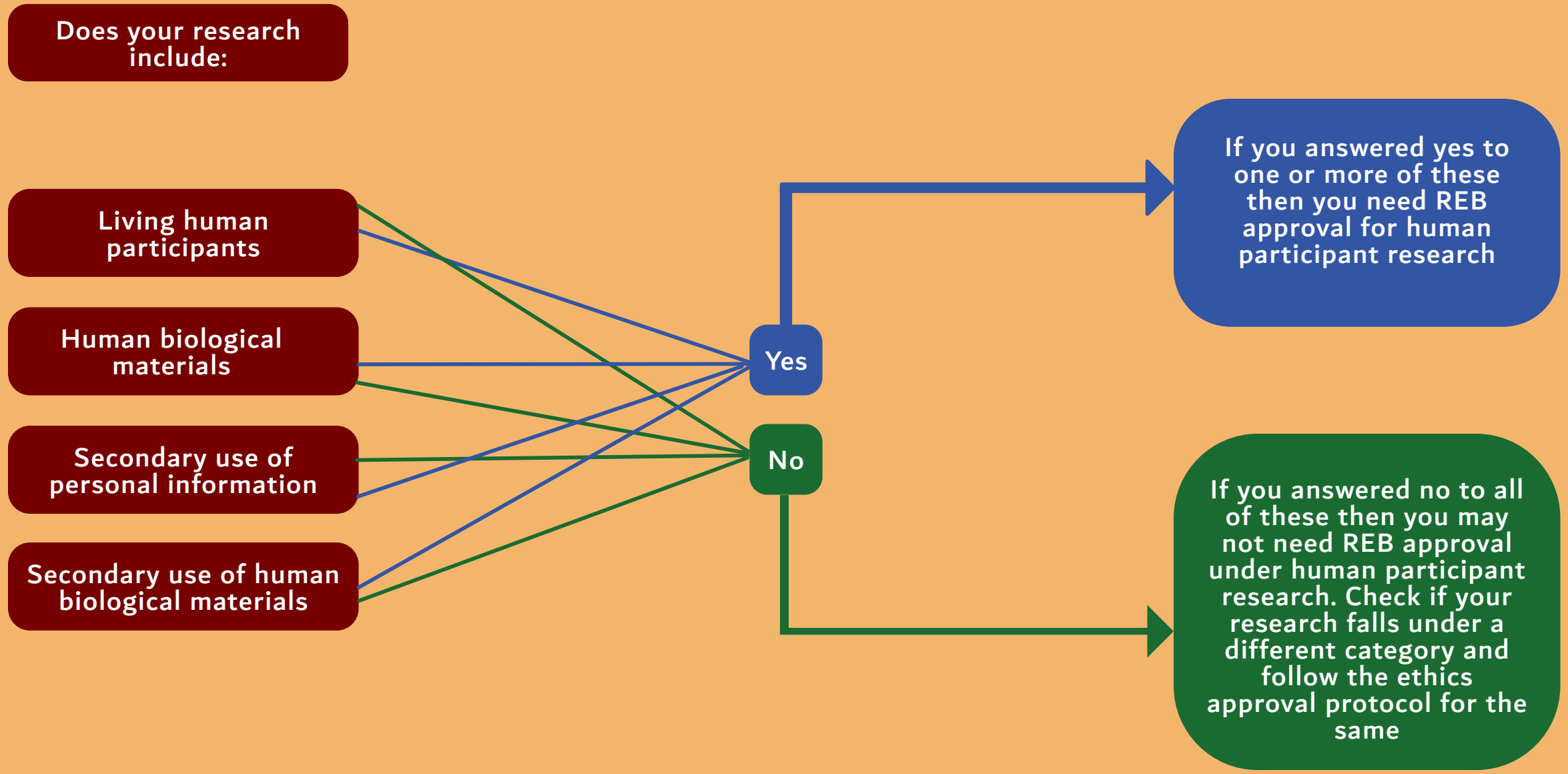
Human participant research is one of the many categories of such research. According to the Office of Research and Innovation, human participant research includes:

- Living human participants;
- Human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals;
- Research involving the secondary use of personal information, whether collected for research purposes from a previous study, or through other activities (clinical, administrative), regardless of whether the data will be identifiable or de-identified; and
- Research involving the secondary use of human biological materials whether collected for research purposes from a previous study, or through other activities (clinical), regardless of whether the specimens will be identifiable or de-identified.

"All University-based research involving human participants, whether funded or non-funded, faculty or student, scholarly, commercial, or consultative, is subject to review by the University's Research Ethics Board."

Office of Research and Innovation, Trent University

https://www.trentu.ca/ori/research-services/ethics/human-participant-research


Does your research include:
Living human participants
Human biological materials
Secondary use of personal information
Secondary use of human biological materials
Yes
No
If you answered yes to one or more of these then you need REB approval for human participant research
If you answered no to all of these then you may not need REB approval under human participant research. Check if your research falls under a different category and follow the ethics approval protocol for the same

Application Process

The REB application process involves a few steps and, depending on the nature of your project, a tedious amount of documentation. In an ideal but rare scenario, the REB will approve your study right away. It is more likely that you will receive a round of comments from the REB before they approve your study. You will be required to respond to the REB comments and resubmit a revised application to address questions or concerns raised by the committee. The REB will approve your application if it is satisfied with your revisions. If not, you will receive another round of comments before your application is approved.

This also means that you must give your self enough time to prepare and then follow through with your application till it has been approved. At the same time, you need to consider the timeline for conducting and completing your research. It is best to apply as early as possible so you have REB approval in time to successfully complete your research.

Check the REB's latest meeting schedule and corresponding submission deadlines to plan your application. This information is published on the Office of Research and Innovation's website at the beginning of every academic. Submission deadlines correspond with dates on which the REB meets to review applications. Make a note of these dates and plan your submission to make the best of these timelines.

While this may sound stressful, it is important to remember that the REB intends to works with you to approve the study, and rarely rejects an application. The path may seem long-winded but there is success at the end!

Complete TCPS2 CORE-2022 Certification

Submit application form and documents on the Romeo portal

Revise and resubmit form and documents Respond to REB's comments

Get REB approval and celebrate!

PREPARING THE APPLICATION


PANEL ON RESEARCH ETHICS
Navigating the ethics of human research

TCPS 2: CORE 2022

Certificate of Completion

This document certifies that

[redacted]

successfully completed the Course on Research Ethics based on the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2: CORE 2022)

[redacted]

[redacted]

TCPS 2: CORE 2022

First up, get that TCPS 2: Core 2022 certificate! You need to score 80% to pass this online course and get the certificate. The REB requires TCPS 2 certificates of all researchers and co-researchers involved in the project. Student researchers need to include TCPS 2 certificates of their supervisor. Check-in with your supervisor in advance to ensure they have a valid TCPS 2 certificate.

Though the certification can be completed anytime before submission, it's good to do it before getting into the main REB application. While this might feel like a painful process, the TCPS 2 course is an excellent resource for understanding the ethics review process. Your application will be reviewed by the board against these protocols. Therefore, understanding the language of the protocol and using it in the application will make for easier assessment.

Remember to take notes for sections of the TCPS 2 that are relevant to your project. The following sections will be relevant for most projects:

- Risk and Benefits,
- Consent, Fairness and Equity,
- Privacy and Confidentiality

You do not have to quote the TCPS 2 in your application, nor will any of the sections in the form test your knowledge of the protocols. However, demonstrating familiarity with the protocols by incorporating its vocabulary in your application and subsequent correspondence with the REB can strengthen your submission.

REB Application Form

Next up is the Romeo Research Portal: or the place where your application begins and ends. Activate your account on the portal through MyTrent and dive in!

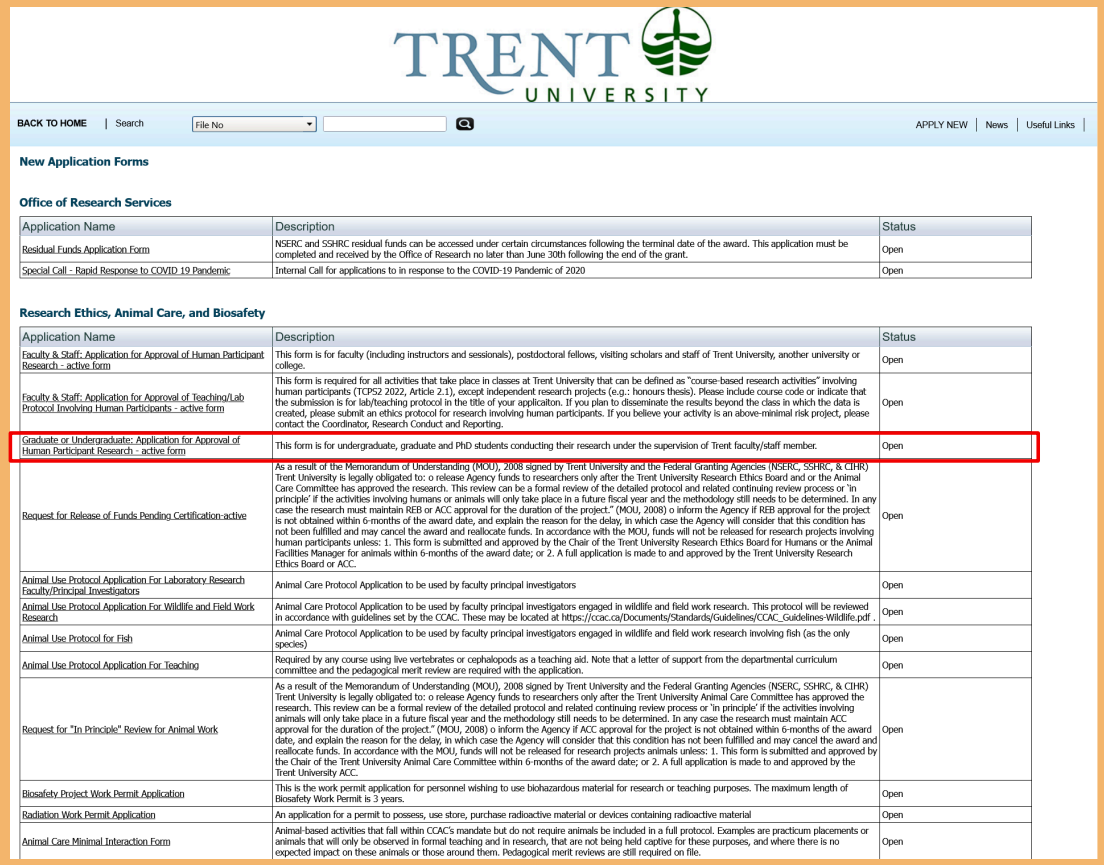
Once you are set-up, select the correct application form number and start by filling out your basic information in the form. Save the form and download it as a word document file. Now you can work on the rest of the form offline at your own pace. Once you are done, simply copy-paste your response from the word doc into corresponding sections on the online form.

To save time, it is best to have a research proposal and project outline ready beforehand. You can copy generic information such as your research question, its significance and contribution, your recruitment strategy, methodology, inclusion/exclusion criteria, study duration etc. from existing documents into relevant sections of the REB application form.

Pay attention to the following sections and ensure that your response is consistent with TCPS 2 and all project specific documentation that include similar sections:

- Section 3: Study Design and Intervention
- Section 4: Study Participants
- Section 6: Risks and Benefits
- Section 7: Anonymity and Confidentiality
- Section 8: Informed Consent

These sections are important as they are directly related to TCPS 2 protocol and define the ethics of your study. This list, however, might look different depending on the specifics of your project.



TRENT UNIVERSITY

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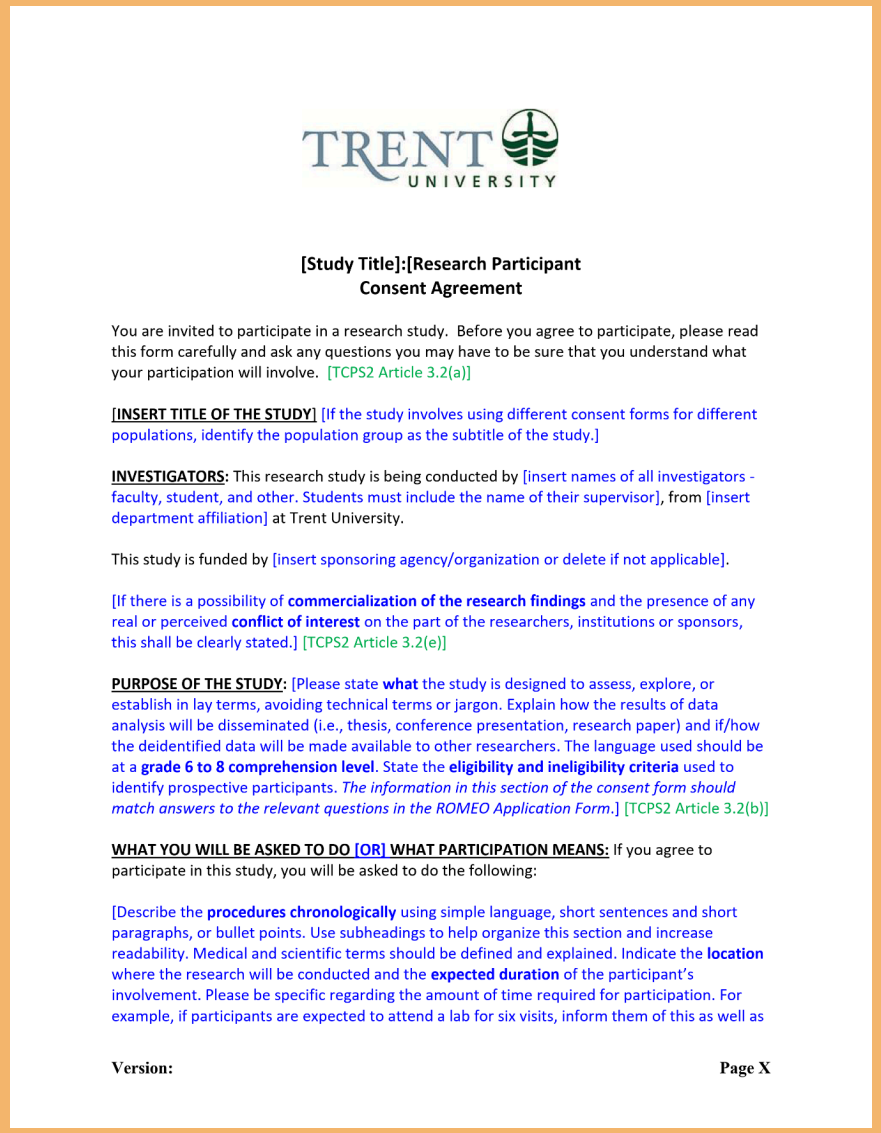
New Application Forms

Office of Research Services

Application Name	Description	Status
Residual Funds Application Form	NSERC and SSHRC residual funds can be accessed under certain circumstances following the terminal date of the award. This application must be completed and received by the Office of Research no later than June 30th following the end of the grant.	Open
Special Call - Rapid Response to COVID 19 Pandemic	Internal Call for applications to in response to the COVID-19 Pandemic of 2020	Open

Research Ethics, Animal Care, and Biosafety

Application Name	Description	Status
Faculty & Staff: Application for Approval of Human Participant Research - active form	This form is for faculty (including instructors and sessionals), postdoctoral fellows, visiting scholars and staff of Trent University, another university or college.	Open
Faculty & Staff: Application for Approval of Teaching/Lab Protocol Involving Human Participants - active form	This form is required for all activities that take place in classes at Trent University that can be defined as "course-based research activities" involving human participants (TCPS2 2022, Article 2.1), except independent research projects (e.g.: honours thesis). Please include course code or indicate that the submission is for lab/teaching protocol in the title of your applicaiton. If you plan to disseminate the results beyond the class in which the data is created, please submit an ethics protocol for research involving human participants. If you believe your activity is an above-minimal risk project, please contact the Coordinator, Research Conduct and Reporting.	Open
Graduate or Undergraduate: Application for Approval of Human Participant Research - active form	This form is for undergraduate, graduate and PhD students conducting their research under the supervision of Trent faculty/staff member.	Open
Request for Release of Funds Pending Certification-active	As a result of the Memorandum of Understanding (MOU), 2008 signed by Trent University and the Federal Granting Agencies (NSERC, SSHRC, & CIHR) Trent University is legally obligated to: o release Agency funds to researchers only after the Trent University Research Ethics Board and or the Animal Care Committee has approved the research. This review can be a formal review of the detailed protocol and related continuing review process or 'in principle' if the activities involving humans or animals will only take place in a future fiscal year and the methodology still needs to be determined. In any case the research must maintain REB or ACC approval for the duration of the project." (MOU, 2008) o inform the Agency if REB approval for the project is not obtained within 6-months of the award date, and explain the reason for the delay, in which case the Agency will consider that this condition has not been fulfilled and may cancel the award and reallocate funds. In accordance with the MOU, funds will not be released for research projects involving human participants unless: 1. This form is submitted and approved by the Chair of the Trent University Research Ethics Board for Humans or the Animal Facilities Manager for animals within 6-months of the award date; or 2. A full application is made to and approved by the Trent University Research Ethics Board or ACC.	Open
Animal Use Protocol Application For Laboratory Research Faculty/Principal Investigators	Animal Care Protocol Application to be used by faculty principal investigators	Open
Animal Use Protocol Application For Wildlife and Field Work Research	Animal Care Protocol Application to be used by faculty principal investigators engaged in wildlife and field work research. This protocol will be reviewed in accordance with guidelines set by the CCAC. These may be located at https://ccac.ca/Documents/Standards/Guidelines/CCAC_Guidelines-Wildlife.pdf .	Open
Animal Use Protocol for Fish	Animal Care Protocol Application to be used by faculty principal investigators engaged in wildlife and field work research involving fish (as the only species)	Open
Animal Use Protocol Application For Teaching	Required by any course using live vertebrates or cephalopods as a teaching aid. Note that a letter of support from the departmental curriculum committee and the pedagogical merit review are required with the application.	Open
Request for "In Principle" Review for Animal Work	As a result of the Memorandum of Understanding (MOU), 2008 signed by Trent University and the Federal Granting Agencies (NSERC, SSHRC, & CIHR) Trent University is legally obligated to: o release Agency funds to researchers only after the Trent University Animal Care Committee has approved the research. This review can be a formal review of the detailed protocol and related continuing review process or 'in principle' if the activities involving animals will only take place in a future fiscal year and the methodology still needs to be determined. In any case the research must maintain ACC approval for the duration of the project." (MOU, 2008) o inform the Agency if ACC approval for the project is not obtained within 6-months of the award date, and explain the reason for the delay, in which case the Agency will consider that this condition has not been fulfilled and may cancel the award and reallocate funds. In accordance with the MOU, funds will not be released for research projects animals unless: 1. This form is submitted and approved by the Chair of the Trent University Animal Care Committee within 6-months of the award date; or 2. A full application is made to and approved by the Trent University ACC.	Open
Biosafety Project Work Permit Application	This is the work permit application for personnel wishing to use biohazardous material for research or teaching purposes. The maximum length of Biosafety Work Permit is 3 years.	Open
Radiation Work Permit Application	An application for a permit to possess, use store, purchase radioactive material or devices containing radioactive material	Open
Animal Care Minimal Interaction Form	Animal-based activities that fall within CCAC's mandate but do not require animals be included in a full protocol. Examples are practicum placements or animals that will only be observed in formal teaching and in research, that are not being held captive for these purposes, and where there is no expected impact on these animals or those around them. Pedagogical merit reviews are still required on file.	Open



[Study Title]:[Research Participant Consent Agreement

You are invited to participate in a research study. Before you agree to participate, please read this form carefully and ask any questions you may have to be sure that you understand what your participation will involve. [TCPS2 Article 3.2(a)]

[**INSERT TITLE OF THE STUDY**] [If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.]

INVESTIGATORS: This research study is being conducted by [insert names of all investigators - faculty, student, and other. Students must include the name of their supervisor], from [insert department affiliation] at Trent University.

This study is funded by [insert sponsoring agency/organization or delete if not applicable].

[If there is a possibility of **commercialization of the research findings** and the presence of any real or perceived **conflict of interest** on the part of the researchers, institutions or sponsors, this shall be clearly stated.] [TCPS2 Article 3.2(e)]

PURPOSE OF THE STUDY: [Please state **what** the study is designed to assess, explore, or establish in lay terms, avoiding technical terms or jargon. Explain how the results of data analysis will be disseminated (i.e., thesis, conference presentation, research paper) and if/how the deidentified data will be made available to other researchers. The language used should be at a **grade 6 to 8 comprehension level**. State the **eligibility and ineligibility criteria** used to identify prospective participants. *The information in this section of the consent form should match answers to the relevant questions in the ROMEO Application Form.*] [TCPS2 Article 3.2(b)]

WHAT YOU WILL BE ASKED TO DO [OR] WHAT PARTICIPATION MEANS: If you agree to participate in this study, you will be asked to do the following:

[Describe the **procedures chronologically** using simple language, short sentences and short paragraphs, or bullet points. Use subheadings to help organize this section and increase readability. Medical and scientific terms should be defined and explained. Indicate the **location** where the research will be conducted and the **expected duration** of the participant's involvement. Please be specific regarding the amount of time required for participation. For example, if participants are expected to attend a lab for six visits, inform them of this as well as

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Consent Form

Next is the consent form. The Office of Research and Innovation at Trent has a template for drafting consent forms. Download the template and follow detailed instruction in it to draft your consent form. Remove sections that are not applicable to your project and where ever possible make use of the placeholder text in the template.

The key thing to remember while drafting the consent form is that the information provided here must correspond with that in the REB application form. If you change something in the consent form then you must also revise the application form to reflect changes. The process of maintaining consistency across documents should be followed whenever you revise them at different stages of the review process, or make amendments post-approval.

Pay attention to the following sections while drafting your consent form. These should be consistent with the TCPS2 protocols and the REB application form.

- WHAT YOU WILL BE ASKED TO DO [OR] WHAT PARTICIPATION MEANS
- WHAT ARE THE POTENTIAL RISKS TO YOU AS A PARTICIPANT
- CONFIDENTIALITY
- VOLUNTARY PARTICIPATION AND WITHDRAWAL

Once again, this list will vary depending on the specific requirements of your research project.

Research Collaterals

Finally, draft separate documents for all other research collaterals these include: recruitment scripts, permission letters, questionnaires and any other public-facing document relevant to your research.

Prepare these collaterals as separate documents. They can be uploaded as word docs or PDF on the Romeo portal. Student researchers must share these documents with their supervisors for approval before submission. This is necessary because you will be required to sign a declaration at the end of your REB application to confirm that your supervisor is aware of the contents of your submission and has approved it prior to submission.

You will be ready to submit your application once you have prepared all your collaterals, consent form, TCPS 2 certificates for all researchers involved in the study, the offline REB application, and approval from your supervisor (for student applicants). Now you can head back to the Romeo portal and copy responses from your word doc into corresponding sections of the online form. Upload your research collaterals, consent form, TCPS 2 certificates, and any other documents relevant to your research in the "Attachment" section of your form.

Once everything is in order, sign the declaration and submit!

All recruitment materials, including emails, posters, and social media advertisements

Information and consent forms

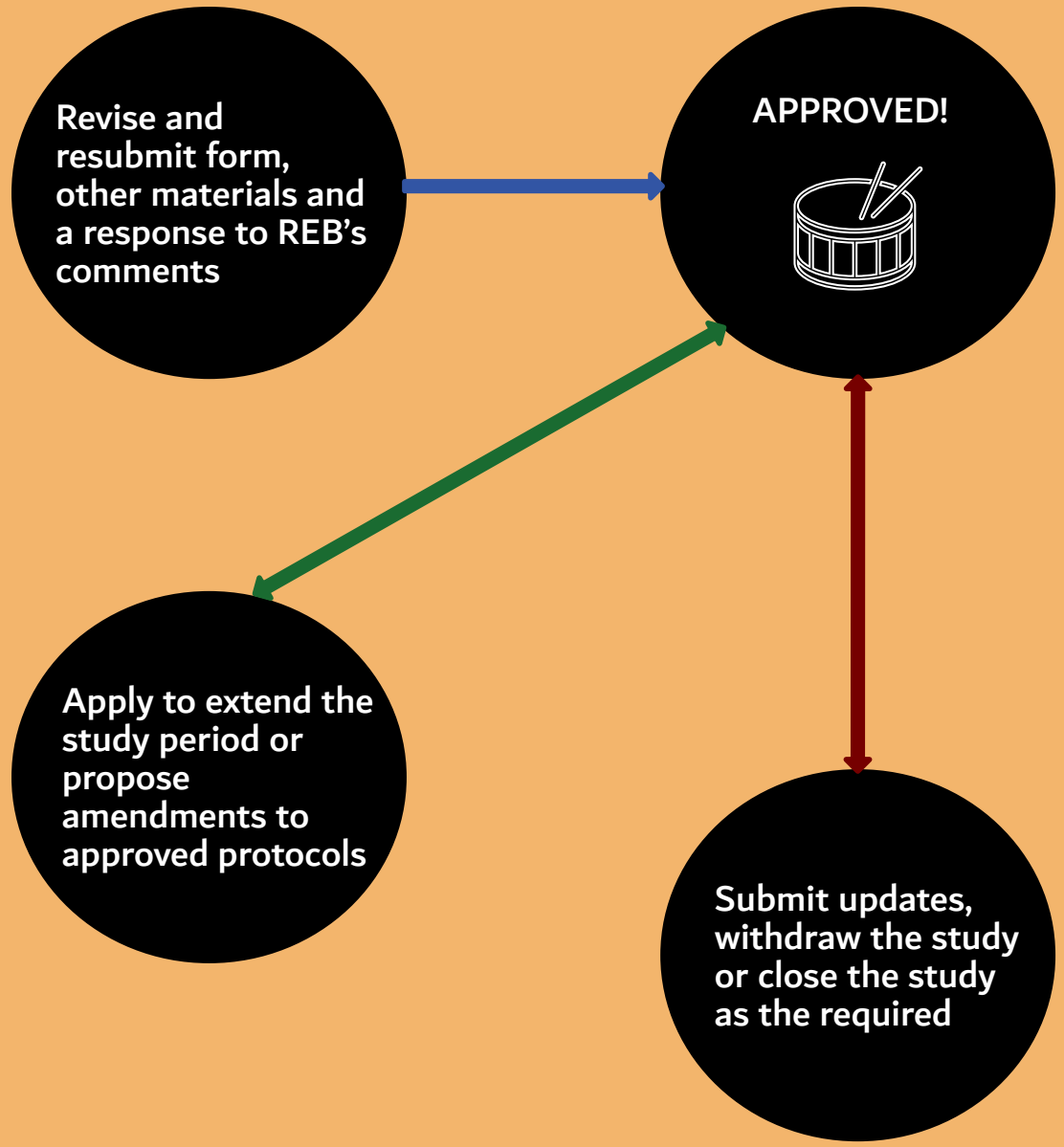
Confidentiality agreements signed by translators/transcribers, student researchers, research assistants etc.

REB approvals from other institutions

All questionnaires, interview questions, visual displays or scenarios that may be presented to participants

Letters of agreement with community research partners

POST-SUBMISSION



Submission, Revision and Amendments

You will receive an email from the REB after they review your application. If you are super lucky this email will simply be an approval. However, it is more likely that you will receive comments from the committee, asking for explanations and suggesting revisions. While this can be annoying, it is super helpful!

Best case scenario you can incorporate all their suggestions and resubmit for approval. Sometimes, you may not want to incorporate all their suggestions. In that case provide a strong explanation for your reasons for doing so in your response to comments.

In either scenario you will need to edit the form and all corresponding documents and resubmit them on the Romeo portal. You will also be asked to include a response to the comments in a separate letter.

You will most likely get an approval or more comments in a couple of days.

Depending on your research timeline, the REB might ask you to submit a project update at the end of a calendar year to renew the approval granted to your study. You can also amend your protocols, extend your research timeline, or withdraw your study after getting approval. Finally, you will be asked to submit a closure form once your study is complete. All these processes can be completed by submitting specific forms on the Romeo portal.

Highlights

- TCPS 2 sounds bureaucratic but is a great resource. **Make note of key words** and phrases and use them effectively in your application.
- Be exteremly clear about procedures for participant **consent, confidentiality, and withdrawal** in your project.
- If you intend to offer monetary compensation or incentives to participants, then **explain how, when, and who will be paid**. Follow relevant TCPS 2 protocols on research benefits and incentives for participation.
- Assume nothing; explain everything! It might seem obvious, but it still needs to be written down. **Devil is in the details**.
- Wherever necessary **make connections** between the application form and other material. For example: if you've included consent withdrawal in your recruitment emails mention it in the form.
- Cross-check to ensure information is consistent across documents. This includes terminology. **If you change one; change all**.
- Submit the application even if it is not perfect. You will get **comments from the committee** to take it to perfection. This makes it easier to get approval.
- Remember, you can always **submit amendments** to the study after it has been approved.

Resources

- **Office of Research and Innovation, Trent University:** https://www.trentu.ca/ori/research-services/ethics
- **Research Ethics:** https://www.trentu.ca/ori/research-services/ethics
- **Human Participant Research:** https://www.trentu.ca/ori/research-services/ethics/human-participant-research
- **Outline of a Standard Consent Form or Statement:** https://www.trentu.ca/ori/research-services/ethics/human-participant-research/outline-standard-consent-form-or-statement
- **TCPS 2: CORE-2022 (Course on Research Ethics):** https://tcps2core.ca/welcome

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