# Human Research Ethics Board - Trinity Western University

# Request for Ethical Review of Human Research

 HREB File No.:

 Date Received by HREB:

**Note**: This form is for all studies conducted by **faculty, staff, or graduate students** involving data collection from human beings. **The Request for Analysis of Existing Data** form should be used for studies that only involve secondary analyses of *existing* data sets.

**Please read the “Guidelines for filling out the Request for Ethical Review Form” before filling out this form.** It contains important information that will assist you in completing this form. You will find the guidelines in the same section of the HREB webpage as this application form.

|  |  |
| --- | --- |
| **Principal Investigator:**        | **Phone:**      -     -       |
| **Department:**        | **Email:**        |
| **Address:**        |

 (Street Address or PO Box, City, Province, Postal Code)

**You are:** [ ]  Faculty [ ]  Staff [ ]  Masters Student [ ]  Doctoral Student [ ]  Research Fellow

***If you are a student/research fellow:***

|  |  |
| --- | --- |
| **Name of Supervisor:**        | **Phone:**      -     -      ext.        |
| **Department:**        | **Email:**        |
| **Address:**        |

 (Campus Office Location)

## A. General Information

### 1. Title of project:

### 2. Have you applied for funding for this project?

**[ ]** Yes**[ ]** No

**List all sources of funding (e.g. granting agencies, internal funding, corporate funding). Give exact titles of all grants.**

### 3. List all other investigators in this project.

**Name:**

**Institutional Affiliation:**

**Email:**

### 4. Proposed research expected to be conducted between       and

 (mm/dd/yyyy) (mm/dd/yyyy)

### 5. Location where the research will be conducted:

**Off-campus?** [ ]  Yes [ ]  No

**School board or community agency?** [ ]  Yes [ ]  No

**Location(s) in Canada?** [ ]  Yes [ ]  No

**International location(s)?** [ ]  Yes [ ]  No

**Online?** [ ]  Yes [ ]  No

**Other?** [ ]  Yes [ ]  No

**Please provide details for all items to which you answered yes.**

### 6. Describe the scholarly review of this project. Check all that apply.

[ ]  Approved by a thesis committee or equivalent.

[ ]  Departmental/local peer review prior to submission for ethics review.

[ ]  External scholarly review prior to funding. Specify review committee:

[ ]  No scholarly review.

[ ]  Other – please specify:

### 7. Who will actually conduct the project, and what are their qualifications (e.g. a course in research methods; a completed PhD; training in interview skills)?

**(a) Describe any training that will be provided to research assistants.**

**(b) If the project involves community members in the collection and/or analysis of data, describe their status within the research team (e.g. employees, volunteers, participants) and the type of training they will receive.**

### 8. Real or potential conflict(s) of interest:

**(a) Will the researcher(s), members of the research team, and/or their family members receive any personal benefits?**

[ ]  Yes [ ]  No

**If yes, specify.**

**(b) List any pre-existing relationships between the researcher(s)/assistant(s) and research participants (e.g. classmates, colleagues, counsellor-client, professor-student, pastor-congregant).**

**If** **the researcher(s)/assistant(s) are in a *position of responsibility or* *power over* the participants (e.g. their teacher, pastor, supervisor, employer), describe the steps that will be taken to ensure that potential participants feel no pressure to participate in the project.**

**(c) Describe the type of decision-making processes that are in place for collaborative research studies. Attach Terms of Reference if they exist.**

## B. Summary of Proposed Research

### 1. Describe the purpose and scholarly rationale for the project. Comment on the question(s) you intend to answer/the knowledge you hope to generate.

### 2. Describe the methods chosen to fulfill the purpose of the study. Be specific and provide details. Assume that HREB members are not familiar with the norms of your discipline.

**(a) What procedures, formal or informal, will be used to collect data (e.g. on-line surveys, experimental manipulation, open-ended interviews, focus groups, unscripted conversation)? Attach copies of all questionnaires, interview scripts, experiment protocols, and/or other non-standard test instruments. Note: If you are using a published survey or test instrument, give the full citation to identify it and its author and source.**

**(b) What kinds of data will be generated (e.g. standardized test scores, audio-recordings, journal entries), and where and how will they be obtained?**

**(c) What are your anticipated analysis procedures (e.g. statistical analysis of aggregated data, qualitative analysis of interview transcripts)? Explain how these procedures will achieve the intended purpose of the study.**

## C. Selection and Recruitment

### 1. Indicate the source of participants (e.g. first year psychology student participant pool, other Trinity students, elementary or high school students, medical patients, aboriginal peoples or communities, general public). What will be the criteria for selection and exclusion?

### 2. Will vulnerable populations be recruited (e.g. children, people who are cognitively or mentally challenged, economically marginalized, institutionalized)?

**[ ]** Yes **[ ]** No

**If yes, describe the steps that will be taken to ensure that there will be no coercion to participate in the project, and the measures in place to protect participants from being harmed through their participation.**

### 3. Describe how and by whom participants will be recruited. Attach a copy of all recruitment materials (e.g. letters, flyers, posters, emails) in the form in which they will be used. If recruitment will be oral, attach a script.

**(a) Is it reasonable to anticipate that some or all of those to be recruited do not speak English or speak English as a second language with varied degrees of proficiency?**

[ ]  Yes [ ]  No

**If yes, describe how recruitment will occur, if recruiters will speak the language of potential participants, and/or if recruitment materials will be translated or interpreters will be used. Attach any translated materials.**

**(b) Will participant observation be used?**

[ ]  Yes [ ]  No

**If yes, explain how the researcher will participate in the community (e.g. living there for a period of time, visiting at regular intervals, attending public functions).**

### 4. Minimum number of participants required:

### 5. Amount of time commitment required per participant (for all parts of the study):

## D. Risks and Benefits

### 1. Risks to participants as individuals or community members may take various dimensions. Will this research involve:

**(a) Questions about personal, sensitive, or incriminating issues?**

[ ]  Yes [ ]  No

**(b) Psychological or emotional risks (e.g. feeling uncomfortable, anxious, embarrassed, upset)?**

[ ]  Yes [ ]  No

**(c) Physical risks (e.g. physical discomfort, administration of any substance, invasive contact for taking of samples)?**

[ ]  Yes [ ]  No

**(d) Economic or social risks (e.g. possible loss of status, privacy, reputation)?**

[ ]  Yes [ ]  No

**(e) Legal risks (e.g. potential apprehension, arrest, association with a legally compromised group)?**

[ ]  Yes [ ]  No

**(f) Risks due to potentially controversial research procedures (e.g. shock, treatments with potentially harmful side-effects)?**

[ ]  Yes [ ]  No

**(g) Danger due to location (e.g. war torn country, political instability, area of disease outbreak)?**

[ ]  Yes [ ]  No

**(h) Risks not mentioned above?**

[ ]  Yes [ ]  No

**(i) More than minimal risk, i.e., risks beyond that which the participant encounters in their usual daily life?**

[ ]  Yes [ ]  No

**If you answered yes to any of the above, describe the risks involved and explain the measures that will be taken to manage or minimize them.**

### 2. Will deception or intentional non-disclosure be involved in the research (e.g. an approach that withholds, misrepresents, or misconstrues the purpose for which the study is being undertaken)?

**[ ]** Yes **[ ]** No

**If yes, describe and justify.**

### 3. Benefits may take various forms. Describe:

**(a) Potential direct benefits to participants from involvement in the study.**

**(b) Potential direct benefits to the community from involvement in, or hosting of, the study.**

**(c) Potential benefits to the scientific/scholarly community or broader society that justifies the involvement of participants in the study.**

### 4. Will an incentive or compensation be offered to participants?

**[ ]** Yes **[ ]** No

**If yes, provide details and justification for the type and value of incentive or compensation offered.**

**If no, explain why.**

**Where incentive or compensation is offered, describe how it will be affected should a participant choose to withdraw from the study.**

## E. Informed Consent Process

### 1. Investigators are required to obtain informed consent from all participants before they become involved in the study. Use the guidelines found at [twu.ca/research/research-services/research-ethics/guidelines-informed-consent](http://www.twu.ca/research/research-services/research-ethics/guidelines-informed-consent).

### *A copy of the consent form should be left with the participant* (does not require signatures).

**(a) Informed consent from parents or guardians is required when research participants are less than the age of majority (the exception is underage university students, who are assumed to be capable of consenting for themselves), or incapable of giving fully informed consent (e.g. persons with cognitive impairments). Where consent is provided by a parent or guardian, assent should also be obtained from the research participant to the extent possible.**

**The age of majority varies depending on the province where you will be conducting your research. It is:**

* **18 years of age in Alberta, Manitoba, Ontario, Prince Edward Island, Quebec, and Saskatchewan;**
* **19 years of age in British Columbia, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, and Yukon.**

**Please indicate who will consent to your study:**

[ ]  Research participant [ ]  Parent/Guardian

 **(b) Will consent be in written form? (Note: Consent is ordinarily to be obtained in written form unless there is justifiable reason for oral consent.)**

[ ]  Yes [ ]  No

**If no, explain why oral consent is preferred and how consent will be recorded. Justification must be given as to why oral consent needs to be used instead of written consent.**

**(c) Describe the process that will be followed to obtain informed consent (and assent, if applicable) and attach all related documents (e.g. letter of information, screening materials, consent form, script for oral consent and/or assent).**

**(d) Will any information collected in the screening process be kept from those who are excluded or do not choose to participate?**

[ ]  Yes [ ]  No

**If yes, describe how individuals will be informed that they will not have access to this information.**

**If no, describe the process and conditions under which the information will be made available.**

**(e) Consent Form Checklist**

**The following information *must* be included (check off each item used).**

[ ]  Pages are numbered appropriately.

[ ]  The final version must bear the actual date of approval by the HREB as a header or footer on every page. Subsequent versions of the consent form must bear subsequent dates of approval.

[ ]  Potential participants should be referred to in the second person (“you,” not “I”).

[ ]  Lay and age appropriate language is used throughout.

[ ]  Title of project.

[ ]  Name, department, institution and telephone number of all investigator(s) and faculty advisors.

[ ]  Description of the purpose of the project and procedures in which participants will participate.

[ ]  Statement ensuring the confidentiality of the participant unless not required.

[ ]  Statement of the time commitment required of a participant (for each stage, if the study is being conducted in multiple stages).

[ ]  Statement of any reasonably foreseeable potential risks, discomforts, and inconveniences to the participant for participating in the project, and how these will be managed.

[ ]  Statement of the possible benefits to the participant.

[ ]  Detailed statements of confidentiality including how data will be stored and disposed of and, if applicable, how long it will be retained after the study is complete.

[ ]  Details of any remuneration, compensation, or incentives to be offered to the participants, including how and when it will be awarded and what will happen should a participant withdraw.

[ ]  Statement: “If you have any questions or desire further information with respect to this study, you may contact [Principal Investigator’s Name] or one of (his/her) associates at [telephone number and/or e-mail address].”

[ ]  Statement: “If you have any concerns about your treatment or rights as a research participant, you may contact Elizabeth Kreiter in the Office of Research, Trinity Western University at
604-513-2167 or researchethicsboard@twu.ca.”

[ ]  Statement of consent, explaining the participants’ right to refuse to participate or withdraw at any time without jeopardy.

[ ]  Statement of the steps to be taken in order to withdraw along with a clear indication of any point after which withdrawal is no longer possible.

[ ]  Statement indicating what will be done with data gathered from participants who withdraw.

[ ]  Statement: “Your signature below indicates that you have had your questions about the study answered to your satisfaction and have received a copy of this consent form for your own records.”

[ ]  Statement: “Your signature indicates that you consent to participate in this study.”

[ ]  Where relevant, add the following to the above statement: “and that your responses may be put in anonymous form and kept for further use after the completion of this study.”

[ ]  (For parental consent forms only, statement: "I consent/I do not consent (circle one) to my child's participation in this study.")

[ ]  Spaces for the participant’s (or parent/guardian’s) signature(s), date, and printed name.

**Note: If you are using an online survey, instead of the statements above regarding signatures, use the following statement. (If you are collecting data anonymously or do not wish to retain the data for further use, modify the statement accordingly.)**

[ ]  By clicking "continue" you are indicating that you consent to participate in this study and that your responses may be put in anonymous form and kept for further use after the completion of this study. Please print a copy of this consent form for your own records.

### 2. If the project involves using information, people, or facilities from a recognized community (e.g. Aboriginal group), or agencies or institutions outside of TWU (e.g. schools, hospitals, other universities, churches, businesses), permission must be obtained.

**(a) If the agency/institution has its own REB, obtain and attach a copy of the Certificate of Approval from that REB. If it does not have an REB of its own, attach a copy of a letter from someone in authority at that agency/institution granting permission to use their information, people, and/or facilities.**

**Permission letters should be on agency/institution letterhead and *must* include the following:**

[ ]  Date (must be current).

[ ]  Name of investigator(s) who is being permitted to conduct the project.

[ ]  Name or description of the study that is being approved.

[ ]  Name, signature, and position of the person who is providing the permission.

**Permission should be obtained from other agencies/institutions prior to or simultaneously with your application to the TWU HREB. Please provide a list of the agencies/institutions involved.**

**(b) If written consent is not appropriate for cultural or other reasons, provide justification and describe any alternative forms of consultation.**

## F. Privacy: Anonymity and Confidentiality

### 1. Will data be collected in a manner that enables researchers or others to match the identity of participants with the information provided?

**[ ]** Yes **[ ]** No

**If yes, explain.**

### 2. Will data be treated as confidential during research and dissemination processes?

**[ ]** Yes **[ ]** No

**If no, describe any condition in which confidentiality cannot be guaranteed or must be breeched (e.g. use of focus groups, duty to report) OR reasons why confidentiality is not necessary in this study.**

### 3. Will data be collected over the Internet using commercial online survey tools (e.g. Survey Monkey)?

**[ ]** Yes **[ ]** No

**If yes, please describe what measures are in place to ensure that no identifying information, including email addresses, will be collected OR what steps will be taken to inform participants that full confidentiality cannot be guaranteed.**

**Note: If the commercial online survey tool has servers located in the United States (e.g. Survey Monkey), participants must be informed that their data will be stored in the United States and participant to the US Patriot Act.**

### 4. Will anyone other than the researcher(s) and assistant(s) listed in this application have access to the data?

**[ ]** Yes **[ ]** No

**If yes, explain:**

**If the services of others are required (e.g. transcriptionist, interpreter) will they sign a confidentiality agreement?**

**[ ]** Yes **[ ]** No

**If yes, attach relevant documents. If no, explain.**

### 5. Please describe the procedures for handling data.

**(a) Explain how hard copies, written records, computer files, videotapes, audio recordings, etc., will be kept secure during the research process and how data will be disposed of after the study is completed. Indicate who is responsible for data monitoring, analysis, and disposal.**

**(b) Will data be kept for future use after the study is completed?**

[ ]  Yes [ ]  No

**If yes, indicate for how long.**

**If you intend to keep the data indefinitely, provide justification and describe how anonymity or ongoing confidentiality will be ensured.**

## G. Debriefing and Dissemination

### 1. Participants should be debriefed at the end of their participation in the entire project. If the study has involved deception or intentional non-disclosure, participants must be made aware of this in the debriefing process.

**(a) Describe plans for adequate and timely debriefing. Attach any written documents or a script of the basic debriefing that will be given to participants/communities at the completion of their participation.**

**(b) Will participants/communities be given the option of withdrawing their data following debriefing?**

[ ]  Yes [ ]  No

**If no, explain why.**

### 2. Describe plans for informing participants of the results of the research project after completion.

## H. Submission Checklist – Required

**These items are to be submitted with your application. Incomplete applications will not be reviewed. Items with an asterisk (\*) must be included with all applications. Please write N/A for items that are not applicable.**

[ ]  \* Letter of initial contact, advertisement, or other recruitment documents, or script of verbal recruitment.

[ ]  \* Participant and/or parental consent form or oral script.

[ ]  Script for obtaining assent (required when there is a parent/guardian giving consent).

[ ]  Agency permission letter(s).

[ ]  Copy of questionnaire(s), test(s).

[ ]  Explanatory letter with questionnaire(s), test(s).

[ ]  Sample questions for interview(s).

[ ]  Sample questions for focus group(s).

[ ]  \* Debriefing document and/or oral script.

[ ]  Other documents required by study procedures (e.g. confidentiality agreements).
Please specify:

## I. Submission

Please submit one original signed application with all required attachments, and one copy of this application with all required attachments to Elizabeth Kreiter, HREB Coordinator, Suite 101, Fosmark Centre.

## J. Signatures

Your signature indicates that you agree to abide by all policies, procedures, regulations, and laws governing the ethical conduct of research on humans. Guidelines may be found on the TWU website. Any changes in protocol, procedures, or consent forms made after HREB approval will be submitted to the Human Research Ethics Board for review prior to implementation.

Principal Investigator Date

The signature of the supervisor below indicates that the supervisory committee has reviewed and approved the student’s proposal and attests to the scientific and scholarly merit of the project. It also indicates that the supervisor has assisted the student in the preparation of this application.

Student/Research Fellow’s Supervisor Date

The signature of the administrator indicates that adequate infrastructure is available to conduct this research. (Please note, if the Chair or Director is also the Principal Investigator, a Co-Investigator, or the supervisor of the student applying, he/she cannot sign as Chair/Director as well. An alternate administrative signature must be provided.)

Chair/Director Date

## For HREB use only

❒ *Approved with no modifications required* ❒ *Approved pending minor modification* ❒ *Not approved, or deferred pending major modification*

Signature of HREB Chair or alternate: Date of review:

Date of final approval with all required modifications: