

Policy Title: Research Ethics with Human Participants

Parent Policy: None

Policy Administrator: Co-chairs of the Human Research Ethics Board

Approval History: University Senate, April 28, 2020; Senate Motion #2019/20–055
University Senate, May 2, 2017; Senate Motion#2016/17–075
University Senate, December 4, 2012; Motion#2012/13-012
May 13, 2009; October 29, 2008; June 13, 2007; April 9, 2006;
February 2, 2004; July 2003; January 22, 2002; 2000

Purpose:

The objectives of this policy are:

- See the introductory paragraph in the attached policy and procedures

Scope of this Policy: See the Preamble in the attached policy and procedures

Policy Statement: See below

Definitions: Contained within the attached policy and procedures

Child Policies: None

Monitoring Data: The policy administrator(s) will provide Senate with a compliance report each fall semester for the preceding FA, SP, SU semesters on the responsibilities stated in section 1.1 of the Terms of Reference.

As a member of the academic and research community, Trinity Western University endorses the principles set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) 2018, http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-epts2_2018.html, and this document describes how TWU will apply Tri-Council policy. These ethical standards include respect for human dignity, respect for free and informed consent, respect for vulnerable persons, provision for privacy and confidentiality (for both participants and researchers), respect for justice and inclusiveness, balancing harms and benefits, and minimizing potential harms and maximizing potential benefits to participants. Trinity Western University recognizes its responsibility to promote the highest ethical standards in compliance with the Tri-Council Policy Statement in the conduct of research involving human participants. The mandate of the Human Research Ethics Board (HREB) is to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants as to compliance with Tri-Council policy. The purpose of ethical review is to ensure that individual or collective rights of human participants are protected, and that participants in research are not exposed to emotional or moral harms or inappropriate physical harms and that the standards of the Tri-Council are maintained.

For more specific ethical guidelines and principles, please read the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

Preamble

“Research” for the purposes of the Human Research Ethics Board is defined as intended to extend knowledge through disciplined inquiry and/or systematic investigation. Disciplined inquiry is inquiry conducted in such a way as to be able to withstand the scrutiny of the relevant research community.

An ethics review is required when research data is derived from: a) information which is collected through intervention or interaction with a living individual(s), b) identifiable private information about an individual(s) whether involving the use of primary or secondary sources of data, c) human remains, organs, tissues, body fluids, cadavers, embryos, fetuses, human DNA or RNA and/or d) graphic, written or recorded information including video or audio recordings derived from individually identifiable human participants. An ethics review is not required when research data are derived from a) a public data base where aggregated data which cannot be associated with any one individual or group of individuals is obtained, b) observations of behaviour within a public gathering which cannot be associated with any specific individual, organization or self-identified group of individuals, and/or c) information already in the public domain (e.g. autobiographies, diaries or public archives). Quality assurance, performance review and testing are also excepted unless they are also being used for other purposes such as thesis research, publications or conference presentation.

This policy requires that all research projects involving human participants undertaken by members of the university community including all faculty, staff and students, including students carrying out research as part of class assignments fall within the jurisdiction of the HREB, irrespective of the source of financial support (if any) and irrespective of the location of the project, if in the latter case, the investigator represents the work as TWU research or the investigator identifies his or her affiliation as with TWU. Researchers from outside the

community who access resources or participants at TWU are also required to undergo review.

1.0 Terms of Reference

1.1 Responsibilities

The Human Research Ethics Board (HREB) of Trinity Western University is responsible to the Vice Provost of Research and Graduate Studies for:

- Developing policies regarding ethical issues relating to the use of human participants, as noted below under section 3.1, in research and experimental teaching protocols;
- Reviewing all protocols requiring the participation of human participants as to compliance with the Tri-Council Policy Statement;
- Reviewing policies, procedures and practices biannually to ensure that ethical review is both expeditious and effective;
- Establishing procedures for expedited review (section 3.6) and designating those types of proposals or projects suitable for each type of review;
- Maintaining up-to-date records of all ethical reviews carried out under its jurisdiction; Maintaining an internet website containing relevant policies, procedures, applications, checklists and sample consent forms, as well as links to granting agency resources;
- Submitting an annual report to the Senate and the Vice Provost of Research and Graduate Studies.

The policies and practices adopted by the HREB will be consistent with the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

1.2 Composition of the HREB

(a) The HREB shall be made up of no less than five voting members, including both men and women, and include:

- One community representative with no formal affiliation with the University;
- At least two university members with broad expertise in the methods or areas of research covered by the HREB (research involving human participants or the use of human tissue);
- At least one university member with broad knowledge in ethics or experience in the evaluation of ethical implications of research involving human participants;
- At least one member with knowledge in the law;

(b) The HREB membership shall be the responsibility of the Vice Provost of Research and Graduate Studies of Trinity Western University. The selection of members will be in accordance with Tri-Council Policy.

(c) At times the university's legal counsel may be consulted, but when deemed appropriate by the HREB chair an independent counsel may be consulted.

(d) The Vice Provost of Research and Graduate Studies shall appoint the Chair and determine the length of term for the Chair.

(e) With the exception of the Chair, committee members shall serve for staggered three-year terms, which normally may be renewed once. The continuity of membership shall be taken into account when members are being changed.

In order that meetings are able to proceed with the necessary quorum, the HREB Chair may, from time to time, in consultation with the Vice Provost of Research and Graduate Studies appoint an alternate HREB member who is familiar with the policy and procedures of the HREB to replace a member unable to attend a meeting.

1.3 Authority

The University endorses the ethical principles cited in the Tri-Council Policy Statement and has mandated its HREB to ensure that all research investigations involving human participants as outlined in Article 2.1 of the TCPS 2 (2018) are in compliance with the Statement.

The HREB will have jurisdiction over all research involving human participants, which is conducted within or by members of Trinity Western University. All research involving human participants will only proceed after ethical approval has been granted by the HREB. The HREB has the authority to deny permission to open research accounts or to access funding for projects that have failed to receive ethical approval. The HREB also has authority to propose modifications to research undergoing review or to terminate ongoing research using the considerations consistent with Tri-Council Policy Statement.

1.4 Indemnification

Trinity Western University agrees to indemnify and save harmless members of the Human Research Ethics Board from any and all liability associated with the exercise of the members' duties while serving on the Board, provided that the Board member is not guilty of infamous or unlawful conduct. In this regard Trinity Western University agrees to pay invoices for legal fees and disbursements which may be rendered to the HREB member from time to time during the course of any litigation commenced against the member, provided however that the University retains the right to require the said HREB member to tax the account of the legal counsel rendering the invoices or otherwise ensure that the legal costs being paid by the University are fair and reasonable under all of the circumstances.

2.0 University Support

The Vice Provost of Research and Graduate Studies shall make available adequate resources to support the administrative processes and to allow HREB members to attend from time to time educational activities provided by the annual CAREB conference so that the University as a whole remains in compliance with Tri-Council policy.

The Vice Provost of Research and Graduate Studies shall insure that faculty members are informed each year about the need to comply with the Tri-Council Policy Statement and facilitate ongoing faculty education regarding compliance with ethical review standards, as well as the consequences of non-compliance.

3.0 Guidelines for Review of a Research Proposal

3.1 HREB Interim Approval

Interim approval may be granted by the HREB Chair when a researcher needs agency consent for carrying out a research project with the understanding that the project cannot commence without the completion of the review process and formal approval of the HREB. Similarly, researchers who need ethical review of their projects in order to obtain research funds from granting agencies may also ask for interim approval.

3.2 Review of Multi-Centred Research

All research to be carried out at TWU or by members of the TWU community must be approved by the TWU HREB. Where the researcher holds ethics approval for the proposed research from another institution, the TWU HREB will perform an expedited review of that application. To facilitate coordination of research carried out at several institutions and reviewed by several HREB's, the researcher may wish to distinguish between core elements of the research which could not be altered without invalidating the pooling of data from the various institutions and those elements that could be altered to comply with local requirements. The researcher shall provide information about the ethics committees of any other institutions that will consider the project so that the HREB may coordinate review or communicate any concerns.

In a multi-site study, the lead PI is responsible for communicating any changes to the study, new information, and/or unanticipated events to the HREB, to the sponsor (if any), and to local site PIs. PIs must inform their local HREBs in situations where no alternative review model for research involving multiple institutions has been established.

3.3 Review of Research in Other Jurisdictions, Countries, or Communities

Research to be performed outside the jurisdiction of TWU or outside of Canada shall undergo prospective ethics review both by the HREB of TWU and by the ethics committee, where such exists, with the legal responsibility and equivalent procedural safeguards in the jurisdiction where the research is to take place.

Researchers should provide copies of publications or other research reports to the appropriate institution in the host country.

Where researchers intend to conduct research involving humans that addresses community identities or the status of various people groups, researchers should consider relevant guidance in Chapter 9: *Research involving the First Nations, Inuit and Métis Peoples of Canada*, when appropriate.

4.0 Decisions of the Human Research Ethics Board

4.1 Reconsideration

When the HREB is considering a decision to disallow a research project, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply in writing before making a final decision. If consensus still exists to disallow the research project, researchers then have the right to request, and the HREB has an obligation to provide, reconsideration of decisions before the full HREB as in section 3.5 (i). During such a meeting of the full HREB, the researcher shall have the opportunity to be personally present and enter into discussion with the HREB, but shall not be present when the HREB makes its final decision.

Neither individual departments nor members of the administration may override negative HREB decisions reached on grounds of ethics without a formal appeal as described in section 4.3.

4.2 Appeal

Researchers must apply to the Vice Provost of Research and Graduate Studies to appeal a final negative HREB decision within two months of the date of the decision. A copy of the appeal letter should also be sent to the HREB Chair.

Non-compliance with the substance of the Tri-Council Policy Statement is a reason for refusing to grant an appeal. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the Tri-Council Policy Statement. An appeal shall proceed only if the Vice Provost of Research and Graduate Studies agrees the appeal is not frivolous; or there was at least one dissenting member of the HREB.

Trinity Western University has entered into a formal written agreement with The King's University in Edmonton for the Research Ethics Committee of that institution to act as a standing Appeal Board. The decision of the Appeal HREB shall be final and binding.

5.0 HREB Conflict of Interest

Researchers shall disclose in research proposals they submit to the HREB any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest or community conflicts of interest of which they are aware that may have an impact on their research. Upon discussion with the researcher, the HREB shall determine the appropriate steps to manage the conflict of interest.

If the HREB is reviewing research in which a member of the HREB has a personal interest (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the HREB is discussing or making its decision. In cases of disagreement over conflicts of interest, both the HREB member in alleged conflict and the researcher may present evidence and offer a rebuttal concerning the nature of the conflict of interest. The other members of the HREB should make a final decision regarding how to proceed.

6.0 Clinical Trials

All research involving clinical trials shall conform to the Good Clinical Practices as described in the International Conference on Harmonization Guidance document. Researchers should consult TCPS 2 (2018) Chapter 11: *Clinical Trials* for detailed instructions. Links to both documents are found on our website.

7.0 First Nations Research

Research involving Indigenous Peoples will follow the guidelines set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018), Chapter 9: *Research Involving the First Nations, Inuit and Métis Peoples of Canada*. A link to this document is found on our website.

8.0 Definitions

Third party consent: Informed consent given by someone other than the patient or research subject.

Lead principal investigator (lead PI): designated PI who is responsible for the ethical conduct of the study for all sites, when research is being conducted at more than one location.

9.0 Dissemination of research

Researchers shall disseminate, through publication or otherwise, the analysis of data and interpretation of research results, including those that do not support the research hypotheses. The dissemination shall take place in a timely manner without undue restriction. Minimal threshold for publication is deposit of a research report in the TWU repository, TWUSpace.

10.0 Acknowledgement

In preparation of this document, the Research Ethics Committee wishes to acknowledge their reliance on the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. We also wish to acknowledge our reliance on the Research Ethics Policies used at the University of British Columbia, Queen's University, the University of the Fraser Valley, and Simon Fraser University.