

# Trinity Western University Policy Template

**Policy Title:** Research Ethics with Human Participants

**Parent Policy:** None

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

**Approving Body:** Senate

**Approval History:** 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 attached policy and procedures.

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, 2014) [http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf), 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 Research Ethics Board (REB) 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 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 REB, 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 Research Ethics Board (REB) 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 REB will be consistent with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (current version).

### 1.2 Composition of the REB

(a) The REB 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 REB (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 REB 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 REB 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.

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

### 1.3 Meetings

(a) The REB shall meet at least twice each semester for education, reporting and review of policy and procedures.

(b) The REB will hold additional formal meetings each semester as needed to review all projects that involve greater than minimal risk.

(c) In the event of a tie vote, the matter under consideration will be deemed to have not passed.

(d) The REB shall require a quorum of at least two thirds of its members at all meetings concerned with the ethical approval of research proposals. Decisions requiring full review shall be adopted only if members attending the meeting possess the range of background expertise stipulated in 1.2.

(e) Minutes shall be taken at all meetings clearly documenting the REBs decisions and any dissents and the reasons for them. The minutes shall be available for review in the presence of a committee member.

### 1.4 Authority

The University endorses the ethical principles cited in the Tri-Council Policy Statement and has mandated its REB to ensure that all research investigations involving human participants as defined in section 3.1 are in compliance with the Statement.

The REB 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 REB. The REB has the authority to deny permission to open research accounts or to access funding for projects that have failed to receive ethical approval. The REB also has authority to propose modifications to research undergoing review or to terminate ongoing research using the considerations consistent with Tri-Council Policy Statement.

### 1.5 Indemnification

Trinity Western University agrees to indemnify and save harmless members of the 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 REB 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 REB 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 REB 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 Procedural Guidelines for Review of a Research Proposal

### 3.1 Ethics Review

(a) All research that involves information that is collected through intervention or interaction with human participants, including interviews, naturalistic research, and the use of focus groups requires review and approval by the REB in accordance with this policy, before the research is started, except as stipulated below. This includes all research undertaken by members of the university community including all faculty, visiting researchers, students, and staff irrespective of the source of financial support (if any) and irrespective of the location of the project.

(b) Research that is derived from identifiable private information from human participants is subject to REB review. This includes the secondary analysis of data collected for other purposes e.g. medical records or data collected for other purposes including research previously approved by the REB.

(c) Research involving human remains, organs, tissues, body fluids, cadavers, embryos, fetuses, or human DNA should also be reviewed by the REB. Review by the REB is also necessary for such materials taken in routine situations but which are later used for educational purposes.

(d) Research involving graphic, written or recorded information including video or audio recordings derived from identifiable human participants is also subject to REB review.

(e) Research involving culturally sensitive objects, including but not limited to the clothing and personal effects of the dead, should also obtain REB approval. Researchers are expected to acquire the requisite knowledge about the beliefs and behaviours of cultural groups with which they are not familiar, in order to ensure that their research is conducted so as to exhibit respect for those cultures.

(f) Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the participant is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols.

(g) Quality assurance studies, performance reviews or testing within normal educational

requirements are excepted unless they contain elements of research and the findings will be published or presented at a conference.

### 3.2 Scholarly Standards

(a) The REB shall satisfy itself that all projects requiring REB approval have both scholarly value and validity and are capable of addressing the questions being asked in that research project. Under some circumstances and depending on the level of risk, the REB may request that an internal or external peer review be conducted as a condition of approval.

(b) The extent of scholarly review for biomedical research that does not involve more than minimal risk shall depend on the expertise of the REB reviewers in the discipline involved. Peer reviews conducted by granting agencies shall be considered acceptable forms of external peer review.

(c) Normally research that does not involve more than minimal risk shall not be required to undergo discipline-specific peer review of research design.

(d) Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts, or on organizations. Such research is not to be blocked by harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, in extremes, through action in the courts for libel.

### 3.3 Principle of Proportionate Review

The REB shall use a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research. The more potentially invasive or harmful the proposed research, the greater the scrutiny that will be given in its review. Potential harm is to be assessed in terms of the magnitude of the harm and the probability of its occurrence.

In accordance with the principle of proportionality, the REB shall implement three different levels of review: full REB review as described in section 3.5, expedited review as described in 3.6, and departmental review of projects carried out within formal course requirements as described in 3.7.

### 3.4 Submissions to the REB

(a) All requests for ethical review must be made on the Request for Ethical Review Form and submitted to the REB Coordinator. ~~Nine~~ Eleven copies must be submitted for full REB review. In the case of expedited review, as described in section 3.6, two copies must be submitted. Researchers are advised to retain a copy for themselves. Forms may be obtained from the Office of Research website, or the REB Coordinator.

(b) The REB shall keep an open file of each application for ethical approval. The file shall be opened by the REB Coordinator when sufficient information has been submitted by the researcher to start the review process. The original application, descriptions of research and methodology, correspondence, relevant documents, review forms, revised materials, and any

comments from the public or other information relevant to the research project shall be kept in the file. It is the responsibility of the researcher to address all the recommendations made by the REB and keep the file complete and up to date at all times. All revisions in consent letters or protocols must be filed with the REB. When the research project is finished, the researcher(s) is to submit the Final Project Report form to the REB Coordinator and the files shall be closed and kept as records demonstrating compliance with the Tri-Council Policy Statement. The files remain the property of TWU and may not be removed by the researchers. These files shall be subject to audit by authorized representatives of TWU (research administrators), members of appeal boards, and funding agencies.

(c) All research receiving ethical approval, whether through the normal or expedited process, as well as that receiving departmental level review shall require a proper file showing compliance with the Tri-Council Policy Statement. Insufficient information in the file is grounds for refusing or delaying ethical approval.

### 3.5 Review Procedure

(a) All proposals and projects received for review or referral will be examined initially by the REB Coordinator to ensure that documentation is complete.

(b) Where the Chair determines that the proposal or project is suitable for expedited review, the application will be reviewed by the Chair and one other member of the REB as described in section 3.6. All other projects, including any research that involves the slightest potential of violating the rights of human participants or which involves more than minimal risk, will be reviewed by the entire REB. In addition, the Chair reserves the right to refer any study for full board review for any reason. Projects involving the collection of tissue/DNA for the purpose of creating or adding to a tissue/DNA bank or for genetic research must also be submitted for full board review. Projects of researchers from other institutions for which a research ethics review has been completed will be reviewed by the REB chair only.

(c) Where a review is to be conducted by the entire REB, the researcher shall make available 11 copies of the relevant material no less than 14 days prior to a formal meeting.

(d) The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but such researchers may not be present when the REB makes its decision. Discussion between the REB and the researcher may result in a deferral of the REB's decision until the researcher has considered the discussions and possibly modified the project.

(e) Before group discussion, each REB member will complete a Review Form listing any ethical concerns and suggested changes. The Chair or designate will provide the researcher with a summary of the consensus of the REB. The researcher shall have the opportunity to reply in writing.

(f) Where a consensus of the REB exists for approval or for approval subject to minor modifications, the Chair or designate will communicate in writing or by email with the researcher and upon completion of any minor modifications grant ethical approval.

(g) Where an REB consensus reveals ethical problems such that ethical approval cannot be granted, the Chair or designate will first communicate in writing with the applicant to see if the problems can be addressed satisfactorily and the researcher shall respond in writing point by point. The Chair shall then circulate the modifications proposed by the researcher and determine whether a consensus exists on the acceptability of those modifications.

(h) Where no consensus exists for granting ethical approval, or if any member of the REB present so requires, a resolution may be put to a formal vote; but no project shall be approved on such a vote unless at least two-thirds of those members present vote in favour of approval, and only if members attending the meeting possess the range of expertise stipulated in section 1.2.

(i) Where no REB consensus exists for granting ethical approval and the researcher's attempts to address the ethical problems satisfactorily are unsuccessful, the Chair may disallow or suspend research on ethical grounds.

(j) Where a proposal or project has been disallowed or suspended, the applicant may request that a second formal meeting of the full REB be held upon reasonable notice. The researcher shall have the opportunity to be present for discussion with the REB in order to determine if a solution acceptable to the REB may be found. If a consensus of the REB exists against granting approval after the second formal meeting, the research will be terminated, but the researcher has the right of appeal as in section 4.3.

### 3.6 Expedited Review

(a) Expedited review does not require face-to-face meetings of the REB members, but the Chair must report requests for expedited review and results of such reviews to other members of the REB at the next REB meeting. Expedited review is review by the Chair of the REB (or designate) and one other member, rather than the full REB. It is available only in cases that obviously involve no more than minimal risk (as defined in the Tri-Council Policy Statement, page 22: if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk).

(b) The applicant for ethical review is responsible for an acknowledgement of minimal risk to the REB, however, at the discretion of the Chair the REB may classify research involving participants under 19 years of age, or participants not able to give fully informed consent, or research involving deception or sensitive topics that could cause distress to the participant as constituting greater than minimal risk and therefore not eligible for expedited review.

(c) The Chair (or designate) and second reviewer shall complete written Review Forms as in section 3.5 above indicating any areas of concern and detailing suggested changes. The Chair (or designate) will provide the researcher with a summary of the consensus of the two reviewers and the researcher shall respond in writing or by email with any necessary changes. The REB authorizes the Chair to grant approval when the Chair deems that the conditions of both reviewers have been met as stipulated in sections 4.1.b and c.



(d) In cases where approval has been denied on the basis of expedited review, the researcher may request a full review of the proposal at the next formal meeting of the REB.

### 3.7 Review of Course Projects

This policy requires that all thesis research (including honours theses) and major projects must be submitted to the REB using the normal REB application form posted on the website.

In addition to the above the following requirements apply:

(a) Class projects using fellow students enrolled in that particular course as participants:

Instructors shall obtain the general approval of the REB for class projects that occur on a continuing basis until the instructor changes the nature or scope of the assignment.

Instructors shall also indicate in the syllabus that students are encouraged but not required to serve as participants in class projects. TWU students who are not enrolled in that particular course should use the form referred to in item b. REB approval of the project shall be for three years unless changes are made in the protocol, or the instructor of the course changes, in which case a new application must be submitted. Instructors must retain the signed consent forms and/or oral scripts for three years.

(b) Class projects involving participants who are not enrolled in that particular course:

Instructors shall first obtain the approval of the REB for such projects using the form provided on the website. A copy of the consent form or oral script to be used by students must be included with the instructor's application. The REB will accept generic applications for class projects within the same course provided that they have similar procedures. REB approval of the project shall be for three years unless changes are made in the protocol, or the instructor of the course changes, in which case a new application must be submitted. Instructors must retain the signed consent forms and/or oral scripts for three years.

(c) Class projects involving interviews only:

When students are required to conduct interviews of participants not enrolled in the same course, and the interviews are all on similar, previously arranged topics, and do not involve students interviewing participants in subordinate positions (e.g. employees), the instructor shall first obtain REB approval by submitting the appropriate form and either a letter of consent or a script to be used to obtain verbal consent. A verbal consent script must comply with the principles set out in section 7 below. Instructors shall provide students with copies of the approved letter of consent or an approved script to be used for obtaining verbal consent. Upon completion of the interviews, students will return to the instructor a signed copy of the letter of consent or the script indicating student compliance with the procedures and the informed verbal consent of their interviewees. Instructors must keep these signed forms on file for at least three years. REB approval of the project shall be for three years unless changes are made in the protocol, or the instructor of the course changes, in which case a new application must be submitted. Instructors must retain the signed consent forms and/or oral scripts for three years.

(d) Class projects for individual or group research

Where individual students or groups of students are required to (or wish to) carry out their own human participant research projects, they must submit the Request for Ethical Review of Research form and follow the standard protocols for ethics review.

### 3.8 Continuing Ethics Review

(a) Ongoing research shall be participant to continuing ethics review. The rigour of the review shall be based on the level of risk and the scope of the research project. The principal investigator must immediately notify the REB Chair of any ethical/safety problems or any substantial change to the research plan or research protocol. All changes in letters of consent must also be filed with the REB before use.

(b) Ethical approval may be issued for one year from date of initial approval for research involving no more than minimal risk, although the REB may decide to limit approval to a shorter period. If the project continues after the period for which it has been approved, the researcher must submit a completed Annual Renewal and Amendment Form to the REB including details of any safety/ethical problems. If no ethical or safety problems have occurred and no substantial change has been made to the research plan or protocol, the REB Chair may issue a one-year extension. If, in the opinion of the REB Chair, the research plan or research protocol has been substantially changed or problems have arisen, re-submission and review by the REB is required. Application for renewal may be given twice for a total of three years. At the end of three years a new application must be submitted.

(c) In the case of research involving more than minimal risk, the researcher shall propose to the REB, as part of the application process, the continuing review process deemed appropriate for that project. The REB will notify the researcher of any modifications it deems necessary in the review plan. At predetermined intervals the researcher shall submit reports to the REB assessing how closely the researcher and research team have complied with the ethical safeguards proposed in the initial application.

(d) In the case of research involving greater than minimal risk, or in the case where serious ethical or safety problems have arisen, the Chair shall present the application for renewal to a meeting of the full REB.

(e) The researcher shall promptly notify the REB when the project concludes, using the Final Project Report form. Upon receipt by the Research Ethics Board of this form, a chair of the Research Ethics Board will sign the researcher's statement, declaring Research Ethics Board oversight to be concluded.

### 3.9 Turn-around Time

The turn-around time upon receipt of completed submissions that receive expedited review by a subcommittee is generally within four (4) to six (6) weeks. The turn-around time for submissions that require review by the entire REB is generally between six (6) to eight (8) weeks. To ensure that every needed item is included in the submission, a checklist is provided with the Request for Ethical Review Form.

### 3.10 Interim Approval

Interim approval may be granted by the REB 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 REB. Similarly, researchers who need ethical review of their projects in order to obtain research funds from granting agencies may also ask for interim approval.

### 3.11 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 REB regardless of approval by any other institutional REB. To facilitate coordination of research carried out at several institutions and reviewed by several REB'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 REB may coordinate review or communicate any concerns.

### 3.12 Review of Research in Other Jurisdictions or Countries

Research to be performed outside the jurisdiction of TWU or outside of Canada shall undergo prospective ethics review both by the REB 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.

## 4.0 Decisions of the Research Ethics Board

### 4.1 Decision-making

(a) The outcome of the first review of an application through either full REB or expedited review shall be one of the following: approved, approved with minor modifications, deferred pending major modifications or clarification, and not approved.

(b) Where approval is granted subject to minor modifications, the REB authorizes the Chair to grant approval when the Chair deems that all concerns have been addressed.

(c) Where approval is deferred pending major modifications the Chair shall circulate the researcher's changes or clarifications among the reviewers. The Chair shall determine whether consensus then exists either for approval to refer the matter back to the applicant for further modifications. If no consensus for approval or modifications exists the Chair shall put the matter to a vote.

(d) Upon final approval by the REB a certificate of approval shall be issued by the REB Coordinator.

### 4.2 Reconsideration

When the REB 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 REB has an obligation to provide, reconsideration of decisions before the full REB as in section 3.5 (i). During such a meeting of the full REB, the researcher shall have the opportunity to be personally present and enter into discussion with the REB, but shall not be present when the REB makes its final decision.

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

#### 4.3 Appeal

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

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

#### 5.0 REB Conflict of Interest

If the REB is reviewing research in which a member of the REB 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 REB is discussing or making its decision. In cases of disagreement over conflicts of interest, both the REB 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 REB should make a final decision regarding how to proceed.

#### 6.0 Sanctions

The REB Chair shall have the sanction of refusing permission to open a research account or to access university controlled funds for researchers who do not comply with the Tri-Council Policy Statement.

The REB will report to the Vice Provost of Research and Graduate Studies any cases that undermine Trinity Western University's compliance with the Tri-Council Policy Statement, and the President and Vice Provost of Research and Graduate Studies shall together decide what sanctions or penalties to impose on the researcher(s).

#### 7.0 Free and Informed Consent

##### 7.1 Requirement for Free and Informed Consent

(a) Research governed by this Policy may begin only if (1) prospective participants, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained

throughout their participation in the research. Exceptions to this requirement are noted below in sections d and e and in section 7.5.

(b) Evidence of free and informed consent by the participant or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented and described in the application.

(c) Sample consent forms and a checklist of required information shall be maintained on the website.

(d) The REB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

(i) The research involves no more than minimal risk to the participants;

(ii) The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;

(iii) The research could not practicably be carried out without the waiver or alteration;

(iv) The participants must be given a debriefing if such debriefing is possible, practical and appropriate. The debriefing must include an opportunity to refuse consent or withdraw data whenever possible, practicable and appropriate.

(v) The waived or altered consent does not involve a therapeutic intervention.

(e) Naturalistic observations of unstaged events whose participants are not able to be subsequently identified in research records require REB approval, but do not require signed consent forms.

(i) Whether such research is considered minimal risk will depend upon the nature of the activity observed and extent to which regard is taken for maintaining the dignity of participants.

(ii) Naturalistic observations involving staged events will be considered greater than minimal risk research.

(iii) Photographs, videos and audio recordings of participants are to be considered identifiable information, whether collected in naturalistic research or any other research setting.

(f) Part of the process of informed consent consists of informing the research participant about any subsequent use of the collected data. This is of particular concern when research takes the form of interviews, or when participants can be otherwise identified by name, personal information, photographs, video or audio recordings. Participants should be informed in the letter of consent about who specifically will have access to such identifiable information (e.g. co-workers, supervisors, agencies), whether information will be stored in anonymous or identifiable form and what will happen to the data at the conclusion of the study. For example at the end of the research project transcripts might be made of interviews with all identifying information removed, names replaced with pseudonyms and audio or video recordings destroyed.

(g) Further REB approval must be obtained before researchers engage in secondary use of data

that would involve possible personal identification of participants. Approval would depend upon whether participants had been informed that data would be retained for additional use, as well as the extent to which the researcher has minimized the potential for harm. Participant consent is not normally required for use of data that has been previously collected and stored in an anonymous form. It is the responsibility of the researcher to satisfy the Research Ethics Board that the data is non-identifiable, recognizing that the context of the data collection and use must be considered in determining whether or not it is identifiable.

(h) Depending on the nature of the information collected, participants should also be told if mandatory reporting of certain behaviours is required (e.g. child abuse, homicidal or suicidal intent, or reportable communicable disease).

(i) In situations where there is an attempt to compel disclosure of confidential participant information by legal means, Trinity Western University will provide researchers with financial and other support to obtain the independent legal advice which permits the researcher to make an informed decision as to whether disclosure or resistance is warranted. If resistance is warranted, institutional support includes the independent legal advice which makes that resistance possible, or ensuring that such support is provided. It is recognized, however, that the personnel and financial resources of the institution are limited. Support levels for cases calling for resistance will be determined by consultation among the researcher, university administration and the REB. In cases where independent legal counsel determines that resistance is not warranted, the university will not provide support to pursue resistance.

## 7.2 Voluntariness

Free and informed consent must be given voluntarily, without manipulation, undue influence or coercion. Care is needed to ensure the voluntary nature of informed consent especially in situations in which the researcher is in a position of authority or influence over the research participant, e.g. health-care practitioner and patient, teacher and student, employer and employee, counsellor and client. It is incumbent on the researcher to provide the REB with explanations of special care to be taken to eliminate coercion in obtaining informed consent.

## 7.3 Letter of consent

For each participant two letters of informed consent should be prepared. One copy of the signed consent should be retained by the researcher and one copy given to the participant. The letter of consent must contain:

(a) A statement that the study comprises a research project;

(b) A clear statement of the purpose of the research in a manner appropriate to the participant's culture, the identities of the researchers including departmental affiliation and phone numbers, the expected duration and nature of participation, and a description of the procedures;

(c) A statement of the reasonably foreseeable harms that may arise from participation, including risks, inconveniences, possible financial, emotional, psychological, or social harms such as social stigmatization or threats to reputation;

(d) A statement of the expected benefits to the individual participant and society in general. If no benefit to the individual is expected then this must be clearly stated;

(e) An assurance that the individual is free to not participate and has the right to withdraw at any time without harmful consequences or prejudice;

(f) Any research involving more than minimal risk must provide participants with the name, phone number and email address of the REB Coordinator and a statement that ethical concerns may be addressed to her or him. All graduate student researchers must include the name and telephone number of their supervisor so that participants may contact them with concerns;

(g) The possibility of commercialization of research findings, and the presence of any potential conflict of interest on the part of the researchers, their sponsors or TWU.

(h) The measures to be taken in disseminating results, and whether or not participants will be identified directly or indirectly.

(i) An indication of what information will be collected about participants and for what purposes, an indication of who will have access to that information and how confidentiality will be protected, a description of anticipated use of the data, and indication of who might have the duty to disclose the information collected and to whom such disclosures could be made.

(k) A statement indicating that, by consenting, participants have not waived any right to legal recourse in the event of research-related harm.

#### 7.4 Decision Making Capacity

(a) While participants in research should normally have Decision Making Capacity (or autonomy, that is, full capacity to consent to the research procedure), it is possible for participants with diminished capacity to participate in research. For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

(i) the researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;

(ii) the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;

(iii) the authorized third party is not the researcher or any other member of the research team;

(b) Competence (capacity to consent) is defined here as the ability of prospective participants to give informed consent in accord with their own fundamental values. It involves the ability to understand and to appreciate the potential consequences of a decision... (TCPS, page 2.9). Competence involves the ability to understand the nature of the research and the consequences of one's decision, as well as having an adequately developed capacity for forming and revising personal values.

(c) As a minimum the following safeguards must be met to protect the dignity, interests and integrity of individuals who lack competence:

- (i) The researcher must state how free and informed consent will be sought from the authorized third party and how the incompetent participant's best interests will be protected.
- (ii) The authorized third party may not be the researcher or any member of the research team.
- (iii) The continued free and informed consent of the authorized third party will be required to continue the participation of a legally incompetent participant, as long as the participant remains incompetent.
- (iv) When a participant who began participation in a project through third party authorization becomes legally competent during the project, his or her informed consent shall be required for participation to continue.
- (v) In situations where a participant who began participation in a research project as a competent individual becomes incompetent during the course of a project, informed consent must be sought from her or his authorized third party for participation in the research to continue.

(d) The Tri-Council Policy Statement requires researchers to ascertain the willingness of individuals to participate in research if they are legally incompetent but can nevertheless understand the nature and consequences of the research. These individuals will normally be required to give assent to participation before they can participate in research. The assent may be written in the case of adults and older children, or verbal or physical in the case of younger children or those with permanent cognitive impairment. These requirements apply even though free and informed consent has been obtained, or is available, from an authorized third party. Regardless of competency due to age or ability, and in spite of authorized third party consent, the potential participant's dissent shall preclude his or her participation.

(e) Participants under the age of majority should not be excluded from research unless there is a valid reason for exclusion. The Research Ethics Board must consider the level of development of such participants in order to determine their capacity for informed consent. Where such capacity is seen to be absent, researchers must seek consent from an authorized third party.

(f) Written parental consent is normally required for research in the schools and an opportunity must be presented either verbally or in writing to the potential participant to refuse to participate or withdraw at any time. The letter of assent or verbal script presented to the potential participant must be submitted to the REB for review.

## 7.5 Incidental Findings

(a) Researchers are obliged to disclose to the participant any material incidental findings (unanticipated findings made during the course of research but not part of the research goals) discovered in the course of research. Such findings are material in that they are liable to have significant health, psychological or social implications for the participant. When material incidental findings are likely, the researcher's application to the REB should include a plan indicating how such findings will be disclosed to participants. When researchers are in doubt as to when or how to disclose material incidental findings, they should consult with colleagues and/or the REB.



(b) Researchers should be cautious in disclosure of incidental findings to avoid causing needless concern to participants. When necessary, researchers should direct participants to a qualified professional to discuss the possible implications of the incidental findings for their welfare. In some cases, incidental findings may trigger legal reporting obligations and researchers should be aware of these obligations.

#### 7.6 Research in Emergency Health Situations

A limited class of psychosocial research which takes place in emergency situations may be carried out without obtaining free and informed consent providing the research has already obtained REB approval. TCPS article 2.8 states that such research is subject to all legislative and regulatory requirements and to criteria established in advance of the research by the REB. In addition ALL of the following criteria set out in TCPS article 2.8 must apply:

- (a) A serious threat to the prospective participant requires immediate intervention; and
- (b) Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care; and
- (c) Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant; and
- (d) The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
- (e) Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- (f) No relevant prior directive by the participant is known to exist.

As soon as the participant regains capacity or an authorized third party is found, free and informed consent must be sought for the research to continue.

#### 8.0 Clinical Trials

All research involving clinical trials shall conform to the Good Clinical Practices as described in the International Conference on Harmonization Guidance document. A link to this document is found on the ethics website.

#### 9.0 First Nations Research

Research involving First Nations (including Inuit and Métis) persons, will follow the guidelines set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans ([TCPS 2, 2010, http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf)), Chapter 9.

#### 10.0 Definitions

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

## 11.0 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 Prince Edward Island, the University of Calgary, Queens University, McMaster University and the University of British Columbia.