



TYNDALE

• UNIVERSITY COLLEGE & SEMINARY •

Tyndale Research Ethics Policy Manual

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INTRODUCTION

Tri-Council Policy for Research in Canada

The 3rd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) was first completed in August 2010 and revised in 2014 and 2018.¹ It is the official guideline for ethics for the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). Any research funded by these agencies is subject to the TCPS 2 (as it may be modified from time to time). At Tyndale University College & Seminary faculty receive research funding from these agencies. In addition, Tyndale promotes an ethical approach to research consonant with our theology and values (as found at www.tyndale.ca). Therefore Tyndale University College and Seminary (Tyndale) has adopted TCPS 2 as the core of its research ethics policy.

This document mirrors TCPS 2 in its outline and is designed as a supplement rather than as a replacement for TCPS 2. As such, it has gaps where the reader should refer exclusively to the current version of the TCPS 2. All Tyndale researchers should be familiar with both this document and TCPS 2. This document provides additional detail on conducting research ethically within the context of Tyndale. It supplements TCPS 2 where TCPS 2 requires additional detail, allows for multiple options, or does not address issues of specific concern to Tyndale. However, as TCPS 2 reminds us, “No single document can provide definitive answers to all ethical issues that may arise in an undertaking as complex as research involving humans.” (TCPS 2, Introduction).²

Research Requiring Ethical Review

All faculty, staff, and student research at or under the auspices of Tyndale that involves, as participants, living individuals requires review and approval by the REB in accordance with this policy (Article 2.1).

Some research conducted for internal evaluative purposes is exempt from review (see Article 2.5 for details).

Authority of Tyndale’s Research Ethics Board

Tyndale’s Research Ethics Board (REB) is accountable to the Tyndale Senate and Tyndale’s Research Officer. The Research Officer is not a member of the REB.

The REB is mandated to evaluate, approve, reject, propose modifications to, or terminate, in accordance with this Policy, any proposed or ongoing research involving human participants that is conducted within the facilities or under the jurisdiction of Tyndale. This includes students, faculty, staff or others (including visiting researchers) at Tyndale whether on the Tyndale campus or elsewhere and irrespective of the source of financial support (if any) (Article 1.2). This responsibility extends to research carried out in

¹ TCPS 2 can be found online at http://pre.ethics.gc.ca/eng/nr-cp_2019-06-05.html.

Interpretations of the current version of TCPS 2 can be found here, http://www.pre.ethics.gc.ca/eng/policy-politique_interpretations.html.

² Unless otherwise noted all subsequent references are to TCPS 2 and will omit this reference.

collaboration with researchers from other institutions, and to researchers from outside the Tyndale community who access resources or research participants at Tyndale.

For all such research involving human participants an ethics application must be submitted to the REB. The research can only proceed after the REB has granted approval.

Chapter 1 - ETHICS FRAMEWORK

The first chapter of TCPS 2 outlines the importance of research ethics (Ch. 1, A), the core principles of research ethics, and explains how TCPS 2 should be applied. This section identifies the core principles of TCPS 2 (Article 1.1), applies this to research ethics at Tyndale, and explains how this manual should be used.

A. Importance of Research and Research Ethics

See TCPS 2 Ch. 1, A.

B. Core Principles:

TCPS 2's policy guidelines are based on three core principles: respect for persons, concern for welfare, and justice. These principles are consonant with Tyndale's values as a Christian institution. For example, we respect persons and are concerned for their welfare because we believe all people are made in God's image and we are concerned for justice because justice and righteousness are an intrinsic part of God's character and actions in Scripture.

These three principles impact the way we do our recruitment, the importance of seeking permission from human participants before using their data for our research purposes, how careful we are in preserving their anonymity, how we treat our participants during the research, and how we treat everyone equitably and fairly, and so on. Tyndale's Mission Statement applies to research ethics as much as it applies to everything we do as an institution:

Tyndale is dedicated to the pursuit of truth, to excellence in teaching, learning and research, for the enriching of mind, heart and character, to serve the church and the world for the glory of God.

C. How to Apply this Policy

Tyndale researchers should begin by familiarizing themselves with TCPS 2. Following a careful reading of that document, they should come to this REB Policy document for specific applications of the policies of TCPS 2 to research conducted at Tyndale—returning to TCPS 2 as necessary to fill in details.

TCPS 2 emphasizes the need for the researcher to take into consideration the particular perspective of the participant and the social, economic, and cultural context that shapes the participant's life (Ch. 1, C). Tyndale is a Christian institution within a Canadian evangelical tradition. Some participants in research conducted at Tyndale or by Tyndale researchers will have perspectives and life contexts that prioritize a Christian worldview. These different contexts can lead to worldviews that differ from the worldviews of participants commonly involved in research at public institutions in Canada. Tyndale researchers need to take this unique context into account.

All forms referenced in this document are available on the Tyndale REB website (www.tyndale.ca/REB). Questions can be addressed to the REB using reb@tyndale.ca.

Chapter 2 - SCOPE AND APPROACH

TCPS 2 explains that,

While all research shall be reviewed in light of the core principles of this Policy, the proportionate approach to REB review is intended to direct the most intensive scrutiny, time and resources, and correspondingly, the most protection, to the most ethically challenging research. (Article 2.9)

Tyndale takes a proportionate approach to REB Review. Thus, the researcher needs to put more time and effort into designing and implementing research projects having more risk to participants than in reviewing those projects having minimal risk to participants. TCPS 2 defines minimal risk research as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.” (Glossary). This is also the principle the REB uses to evaluate the level of review applied to a submitted research ethics review.

A. Scope of Research Ethics Review

TCPS 2 identifies what qualifies as research, who a participant is, different approaches for identifiable as compared to non-identifiable data and how one should use secondary data (Article 2.1). It also describes which research and activities are exempt from REB review, the role of the scholarly review, and the continuing monitoring of research by the REB. This section highlights several areas of specific interest for the Tyndale community.

Research and activities that do not normally require an ethical review

Research that does not normally require an ethical review includes research that “relies exclusively on publicly available information,” involves either the public observation of people or people who are not specifically identified, and research which “relies exclusively on secondary use of anonymous information” (Articles 2.2 to 2.5). Unless required by the teaching objectives of the course the Tyndale REB recommends that course-based research use these kinds of data or publicly available sources of data (e.g., Statistics Canada).

Internal evaluations are also activities which do not require ethical review. TCPS 2 explains,

Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review. (Article 2.5)

Researchers should consult TCPS 2 for additional details about research that does not normally require an ethical review (Articles 2.2 to 2.6). See section on course-based research below for additional details on which course activities require review.

Scholarly Review of Research

The Tyndale REB may require a scholar review of research to aid the REB in their judgment of the “ethical implications of the methods and design of the research” (TCPS 2, 20). The Tyndale REB requires an external scholarly review under any of the following circumstances: funding is being requested from an external source which requires scholarly review, or the REB judges that its expertise is not sufficient to evaluate the methods and design of the research. Scholarly review, when required, is to be completed by a peer in the same discipline in which the research is conducted. If Tyndale does not have the expertise to provide the scholarly review this peer can be from an academic or research institution external to Tyndale.

Student research is general exempt from the requirement for peer review because the faculty supervisor, project advisor, or thesis advisor is judged to be providing the scholarly review. The Tyndale REB reserves the right to request additional scholarly reviews as necessary to address any concerns that arise.

REB Review Shall be Continuing

Following initial REB review and approval, research ethics review shall continue throughout the life of the project ensuring that all stages of a research project are ethically acceptable and addressing any unanticipated issues that arise and are reported by the researcher to the REB (Article 2.8).

Researchers must submit an annual report on any continuing research. The REB chair will review the report(s) and contact the researcher if there are any concerns. The REB reserves the right to request additional information from the researcher and may require additional review of the program of research.

B. Approach to Research Ethics Board Review – Benefits and Risks

In accordance with the principle of proportional review (Article 2.9), the Tyndale REB sets its level of scrutiny according to the level of risk of the research. To be ethically acceptable the benefits of the research must outweigh the risks of the research. When reviewing risks the REB will consider “the magnitude or seriousness of the harm, and the probability that it will occur” (Ch. 2, B).

Judgment about the relative risks and benefits of research is affected by “the role of the culture, values and beliefs of the populations to be studied.” (Ch. 2, B). At Tyndale certain types of research may have a different judgment of the relative benefits and risks of research than students and faculty at institutions that do not share our value or worldview.

Chapter 3 - THE CONSENT PROCESS

TCPS 2 Chapter 3 describes general principles of consent necessary for including participants in research, possible departures from the general principles, issues of participant capacity, and documentations of consent.

Consent must be given voluntarily, can be withdrawn at any time, and the data already submitted by the participant can be requested to be withdrawn without consequence to the participant. Article 3.2 includes a list of information to consider when obtaining consent.

Ministry-based research, pastor/researchers, and faculty, carrying out research with students or church members must give particular concern to voluntary consent because of their position of authority over participants. Generally, such research should be minimal risk if participants are not anonymous to the researcher.

In all cases, requests for ethical review must include information on how the research will mitigate the risks of power imbalances.³ Consult TCPS 2 and the Tyndale REB for examples of appropriate levels of consent.

A. General Principles

When obtaining consent to conduct research, researchers shall provide all information necessary to make informed decisions (Article 3.2). Consent must be ongoing and shall generally precede data collection (Article 3.3). Researchers have an obligation to disclose to the participant any “material incidental findings” made in the course of research (Article 3.4) and must make participants aware of any known risks associated with the research.

B. Departures from General Principles of Consent

Under certain conditions research may proceed before obtaining participant’s consent (See Article 3.7 for details). This situation may come up, for example, with research involving partial disclosure or deception where informing participants of the true purpose of the research would invalidate results, or in action research where the full scope of the research is not known until after the research is conducted. In all cases the principles of informed consent continue to apply.

C. Capacity

TCPS 2 defines capacity as “the ability of prospective or actual participants to understand relevant information presented about a research project and to appreciate the potential consequences of their decision to participate or not participate” (Ch. 3, C). TCPS 2 outlines the conditions that must be met prior to beginning research involving individuals who do not have the capacity to give consent (Article 3.9), the conditions that must be met in order for an authorized third party to give consent for an individual who lacks legal capacity, and their right to dissent and refuse to participate (Article 3.10) and the process that must be followed when individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity (Article 3.11).

³ Examples of how to minimize risk in course-based research include: make the assignment about the experience of the researcher rather than a report on the data collected from the research participants, if the researcher is the teacher of the class they should consider collecting the data anonymously until all evaluations have been submitted, and if the research is in a ministry context they should consider community-based and action research approaches to data collection.

D. Consent Shall be Documented

Tyndale will accept all forms of consent allowed by TCPS 2 (Article 3.12). However, this consent must be documented and researchers must have provision to store this record of consent in a secure location according to the requirements of the research (e.g., isolated from the researcher if perpetual anonymity is required).

Chapter 4 – FAIRNESS AND EQUITY IN RESEARCH PARTICIPATION

This chapter addresses the fair inclusion of groups of participants who may have been unjustly excluded historically in research (Articles 4.1 to 4.7). This includes women in general, women who are pregnant or breast-feeding, children, the elderly, individuals lacking capacity, and vulnerable participants or groups. Tyndale has additional theological and ethical reasons to support these fairness and equity policies and the ethical distribution of research results.

Chapter 5 - PRIVACY AND CONFIDENTIALITY

Key concepts addressed by TCPS 2 in this chapter include privacy, confidentiality, security, and identifiable information. It discusses how to ethically handle different types of information and how to safe guard the sensitivity of the information in different settings (Ch. 5, A).

Researchers have an ethical obligation to safeguard all information entrusted to them and not misuse it and must describe how they will do this to the Tyndale REB (Article 5.1 and 5.2). They need to safeguard all information (including being aware of and describing institutional security safeguards). This ethical obligation extends to secondary use of identifiable information (Ch. 5, D) and data linkage (Ch. 5, E).

Chapter 6 - GOVERNANCE OF RESEARCH ETHICS REVIEW

This chapter describes the specifics of the governance of research ethics review at Tyndale University College & Seminary.

A. Establishment of Research Ethics Boards

The Tyndale REB is established by “the highest body within an institution” (Articles 6.1 and 6.2) which is the Tyndale Senate and it has oversight of the REB. Conversely, the REB is independent in its decision-making about the ethics of research but is accountable to the Senate (Article 6.2). Through the Chair of the Senate the Tyndale REB is supported administratively and financially. The REB’s mandate is to review the ethical acceptability of research at the institution (Article 6.3).

The Tyndale REB will be composed of at least five members with expertise directed by the guidelines in TCPS 2 (Article 6.4). Requirements for the composition of the REB include familiarity with the research under review, knowledge of ethics, and at least one REB member from the larger community. The REB will identify potential REB members and

consult with the appropriate Academic Dean to verify availability of potential members for service on the REB. Potential REB members identified by REB and available for service will be recommended to the Senate for appointment. External members do not need input from the Academic Deans before recommendation to the Senate.

REB members shall serve for a three-year term which may be renewed three times (total of nine years) upon the approval of the Senate. Continuity of membership shall be taken into account at all times. After nine years the member must sit off one year before being eligible for reappointment. In special circumstances appointments may be extended for up to an additional term with the permission of the Senate to maintain continuity (Article 6.6). In making appointments to the REB, the Senate shall consult with the Tyndale community, especially with faculty members whose research is likely to require REB approval (Article 6.7). The chair(s) of the REB is responsible to ensure that the review process corresponds to this policy (Article 6.8). The institution is responsible to establish quorum rules for the REB (Article 6.9). For Tyndale, motions of the REB will be considered to pass on the vote of a simple majority of the current REB members.

The REB shall meet several times a year, normally face to face, to discharge responsibilities and review research proposals as required (Article 6.10). The chair(s) of the REB are chosen internally by the REB.

Additional Expertise

The REB, in the exercise of its powers and discharge of its responsibilities, may, from time to time and in consultation with the Chair of the Senate, retain outside legal counsel to provide legal advice to the REB on matters before it. Hiring of independent legal counsel services shall be done according to Tyndale's policies pertaining to the authority and process for incurring expenses and the selection of experts. Neither such outside legal counsel nor Tyndale's regular legal counsel shall serve as a member of the REB. If a member of the REB is a lawyer, the role of that individual is to alert the REB to legal issues and their implications, neither to provide formal legal opinions nor to serve as legal counsel for the REB.

If a project under review requires specific community or research subject representation, or is a project that requires expertise not available from its regular members, the REB Chair, in consultation with the Chair of the Senate, shall nominate appropriate *ad hoc* members for the duration of that particular review (Article 6.5). Should the appointment of such *ad hoc* members become a regular requirement, membership of the REB may, with the approval of the Senate, be modified to include the required representation.

The Senate shall appoint up to two substitute REB members to serve on the REB in the event of sickness or other unforeseen eventualities that keep a regular REB member from fulfilling their duties. This member should meet all regular requirements of REB membership.

Indemnity

In the event of litigation, Tyndale shall, at its sole discretion, determine the course and strategy of the case and whether to pursue litigation or settle the matter before trial, including at the appeal process.

Within the context of a claim (or the threat of a claim or legal action), for their own protection and that of Tyndale, REB members, personally and collectively, shall not respond/speak to the claim or threat thereof. REB members shall immediately advise Tyndale's President of the situation and cease all communication with the claiming party. In the management of the situation, REB members shall collaborate with Tyndale's administration and act solely upon instructions from Tyndale's senior leaders or its legal counsel.

In the event of litigation against any or all REB members, providing that said member(s) acted in an ethical and honest manner as per the "reasonable peer standard"⁴, Tyndale will hold harmless, represent and defend against any claim or litigation instigated by third parties for matters within the boundaries and jurisdiction of the REB. This shall be at no cost to REB members.

This section shall not be interpreted as a duty upon Tyndale to instigate a legal action on behalf of any or all REB members but rather it is limited solely to a duty to defend. This coverage shall continue to protect REB members after they have been succeeded or stepped down from the Board and shall endure to the benefit of their heirs, successors or estates.

B. Procedures for Research Ethics Board Review

This section outlines the review procedures for regular review, review of student assignments, and delegated review. Researchers should submit their proposals for approval prior to the start of recruitment of participants or access to data (Article 6.11). The level of REB Review is in proportion to the risks involved. The Tyndale REB accepts three types of review: full REB review, course-based research review and delegated REB review (Article 6.12). To qualify for course-based or delegate review research must be minimal risk.

Full REB Review at Tyndale

When a researcher submits a request for ethical review the following procedures are to be followed:

- (a) Applications for ethical review are received three times per year (August 1, November 1, and April 30.)
- (b) Application should be sent to the REB Administrative Assistant (AA) via REB@tyndale.ca

⁴ "Reasonable peer standard" is defined and understood as being a comparative standard established to measure what would be the behaviour and judgement of a typical member of that profession, exercising average care and skill when faced with the same circumstances. (This is the same definition as the legal definition of the "reasonable person under the law" - historically stated as the "reasonable man").

- (c) When the form is received the REB the AA will distribute it to all committee members.
- (d) Each committee member will review the application and fill out Form I – Ethics Review Form and return the completed form to the REB AA
- (e) When the REB AA has received completed forms from all REB members the AA will forward them to the REB Chair for review
- (f) The REB Chair will bring the application to a scheduled REB meeting for review
- (g) The REB will make one of four decisions:
 - a. The research is unethical and cannot be conducted
 - b. The research is unethical but can be made ethical with specific named revisions
 - c. The research is ethical but requires procedural changes
 - d. The research is ethical and can proceed. This is known as approval.
- (h) Board members will reach a consensus on the decision regarding the application. That discussion will be communicated to the applicant in writing by the chair or the REB AA. At the discretion of the REB the applicant may receive non-binding comments from individual REB members.
- (i) On approval of an ethical review application the Chair will complete Form J – Certificate of Ethics Review Clearance and notify the REB AA of approval
- (j) The REB AA will forward the approval form to the applicant(s) along with a copy of Form C – Annual REB Review or Final REB Report

Course-based Research Review

Courses at Tyndale may include assignments designed to help students develop research skills. While these assignments may not fit the standard definitions of research the potential risk to participants requires ethical review.

REB review is not required if there is no human research component. Professional skill development conducted for the purpose of information gathering is also not subject to research review but must adhere to the professional standards of codes of conduct of that discipline. Student activities are classified as professional skill development when the objective of data collection is to:

- develop skills which are standard practice within a profession
- gather information that is part of the normal relationship between students and participants (e.g., classroom teacher and students, minister and parishioner)
- conduct learning exercises not intended to generate data for research purposes

Student activities are classified as research when the objective of data collection is to:

- teach students about research processes and expand theoretical or conceptual knowledge
- compare techniques, practices, and/or programs to identify which is more effective
- have something written up in a manner that would be acceptable for an academic presentation or journal article

- have primary data collected, organized, and analyzed for distribution (e.g., systematically collecting information which is intended to be used to produce a research paper or presentation)

Departmental review is normally not acceptable, except for the review of minimal-risk research within course requirement. Such a study must be part of a course requirement and aim to improve knowledge of the study area or research methods. Criteria to qualify for this level of review include:

- research must be no more than minimal risk
- participants must be members of the general population capable of providing free and informed consent themselves
- there should be a small number of participants
- projects must be non-controversial (e.g., they should not collect personal, sensitive or incriminating data)
- methods of data collection must be non-invasive
- projects cannot include deception

If course-based research meets all these criteria then the responsibility for review, on behalf of the REB and in compliance with the Tri-Council Policy Statement, lies within the office of the Academic Dean in which the course occurs. All departments need to review all syllabi in their department to assure that research assignments meet ethical standards. However, instructors have the responsibility of submitting appropriate documentation, as outlined below, and for reviewing the proposed project with the appropriate Academic Dean's office of Tyndale. The Academic Dean's office has the responsibility of forwarding copies of appropriate documentation and for reporting results of such reviews to the REB as they are given.

Student research deemed to be beyond minimal risk must receive a full REB review (See TCPS 2, Glossary for a definition of Minimal risk research). In the case of non-minimal risk research instructors must submit their REB assignment approval forms before the course begins to ensure that the REB Committee will have enough time to review the proposed project/assignment. Students will need to apply for full REB review and receive approval before beginning their research. If students are conducting research as part of an instructor's research project they should be identified as research participants on the instructor's application to the REB.

Any uncertainty concerning the level of risk shall be referred to the REB Chair. Should the REB Chair question the appropriateness of a departmental review, he or she may request that the REB undertake a full review.

Course-based research review research will keep to the following procedure:

- (a) The professor responsible for the assignment shall complete and submit the Form G – Request for Departmental Approval of Course Syllabi and Assignments to the appropriate Academic Dean's office.
 - a. Research should be required by an assignment recorded in the course syllabus. The syllabus will be included with the application.
 - b. Students cannot begin the assignment until approval has been received.

- c. Assignments must meet the criteria for course-based research review (See above)
 - d. The consent form or oral script to be used by students will be included in the application
- (b) The Academic Dean's office reviews and reports approved requests and submits the signed form to the REB Administrative Assistant
- a. The Academic Dean's office shall be satisfied that the research conforms to TCPS 2, the Tyndale Research Ethics Policy, and meets the criteria for course-based research review
 - b. The Academic Dean's office should consult the REB about any questions or concerns related to the research or research ethics policy
 - c. Research not approved by the Academic Dean's office cannot proceed
- (c) Students review, complete and submit Form F- Student Research Information and Checklist to the professor responsible for the assignment
- a. The instructor shall be satisfied that the project complies with the guidelines set by TCPS 2, the Tyndale Research Ethics Policy, and meets the criteria for course-based research review
 - b. The instructor shall collect and retain signed consent forms from participants for three years after the research project is complete
 - c. The instructor shall forward a list of these approved studies to the appropriate Academic Dean's office and the REB Chair(s) prior to initiation of research by the student
 - d. In the event of uncertainty about the ethical appropriateness of the research, instructors have the responsibility for directing students to submit *Form A – Application for Ethics Review* to the REB.
- (d) In all cases students shall not proceed with their research until they have received ethical approval.

Course based research does not have to be re-reviewed the next time the course is offered if the syllabus is substantially the same and the research assignment is unchanged. However, the instructor must continue to follow the guidelines for course-based review above including providing a list of the approved research projects to the appropriate Academic Dean's office and the REB Chair(s) prior to initiation of research by the student.

Delegated Review

The REB may delegate review responsibilities of Minimal Risk research to a sub-committee to expedite review and reduce committee workload. This committee should include a member of the full REB. Departmental review (see above) is a form of delegate review. Minimal risk undergraduate or graduate research is not eligible for departmental review but may be eligible for delegated review at the discretion of the REB Chair. The TCPS2 requires full review for thesis research. Delegated review committees may also be developed for departments with specialized review needs (e.g., expertise beyond that of the sitting REB). In all cases these delegated review committees will report all decisions to the full REB, and follow the principles of review in TCPS 2 and this document. Research shall not extend beyond the completion of the course or project requirements without additional review. The Tyndale REB retains oversight over all research review and may require research to be submitted to the full REB.

Collaborations with other Academic institutions or Research Centres

Tyndale requires a full ethical review even if it is a collaborative project. A complete submission of Tyndale's REB application is not required for joint research if one of the other institutions' REB, is TCPS 2 compliant, and has already approved the project. However, Tyndale reserves the right to review the full ethical review forms from those institutions should it be deemed necessary. In addition, a copy of the full application and record of approval must be submitted to the Tyndale REB.

Continuing Research Ethics Review

Researchers are responsible for submitting annual progress reports and final reports to the REB Administrative Assistant on the annual anniversary of having received ethical approval to conduct their research (Article 6.14) using *Form C. REB Annual Progress Report or Final Report*. Researchers may also request an extension to continue the research. If the research includes no changes in protocol and is for follow-up with existing participants. They only need chair approval to continue. The chair will report the approval at the next REB meeting. If there are changes to the protocol the research must complete and follow the requirements of *Form E - Request for Change (Amendment)*.

Final reports should be submitted after final contact with research participants. This should include completion of any commitments made to participants at time of initial contact (e.g., provision of feedback to participants, destruction of all identifiable data). When the REB reviews and accepts the final report their oversight of the research is considered complete. If the researcher(s) would like to continue the research at a later point an addition *Form A – Application for Ethics Review* must be submitted to the REB.

Unanticipated Issues and Requests for Changes to Approved Research

If unanticipated issues arise in the research that necessitated extension, revision or cancellation of a research project the researcher should complete and submit *Form E - Request for Change (Amendment)* within 30 days of becoming aware of the issue (Article 6.15).

Requests for “substantive changes” to originally approved research shall be submitted in a timely matter and will be reviewed by the Tyndale REB in accordance with a “proportional approach” (Article 6. 16). Researchers should review TCPS 2 for guidelines on how to determine what changes need to be reported to the Tyndale REB.

Record Keeping

An administrative assistant for the REB will be appointed by the Chair of the Senate (see Article 6.17). The administrative assistant shall keep records of all review requests, committee decisions, REB membership details, and related reports. The administrative assistant shall also provide general administrative support to the REB and will fulfill other duties as needed.

Minutes of all REB meetings shall be prepared and maintained by the administrative assistant. The minutes shall clearly document the decisions of the REB, along with the reasons for them (including the dissents of any members of the REB). The minutes will be stored electronically and will be made accessible to authorized representatives of the institution, researchers, and funding agencies (Article 1.8).

Minutes and records of research applications submitted and reviewed shall be kept indefinitely. Research review applications will be kept indefinitely in electronic form.

All paper files pertaining to the REB shall be kept in a locked cabinet or room until they are scanned for electronic record keeping. After scanning all paper records are to be shredded. The decision to destroy paper records should take into account continued interest in the area of research, participant confidentiality, and available storage resources.

Researchers should indicate how long their research data will be kept and plans for adequate storage in their request for review.

C. Reconsideration and Appeals

Researchers have the right to appeal the decision of the REB (Article 6.18). Appeals of REB decisions must be submitted to the REB Administrative Assistant within 30 days of receiving the decision of the REB. Appeals should include the following components (and be no more than five double-spaced pages in length):

- (a) A one page explanation of why the applicant disagrees with the REB decision.
- (b) Reference to precedent literature that establishes that similar research was conducted in a similar manner and received approval from a TCPS 2 adherent institution
- (c) A description of changes to the research project, if any. This should include a revised REB ethics review application
- (d) If desired an applicant can provide documentation from an outside review of the exact documents received by the Tyndale REB. If provided the applicant should provide contact information for the external review body and is responsible for any costs associated with that review.

On receipt of the request for appeal the chair(s) of the REB will review the request and determine if the application should be returned to the REB committee. A decision on the appeal will be provided within 60 days.

When the REB rejects such appeals the researcher can appeal to the Senate. The Senate will appoint a committee with similar expertise to the REB. This committee is subject to the regular requirements of TCPS 2 and this policy. This committee shall not include any members of the REB whose decision is under appeal. This committee “may approve, reject, or request modifications to the research proposal” (Article 6.20). The decision of this institutional appeal committee will be final (Article 6.20).

D. Research Ethics Review during Publicly Declared Emergencies

Tyndale does not have the resources at this time to review and supervise research during publicly declared emergencies. If a researcher thinks this is a possible avenue of research they should find a collaborator at an institution that can accommodate this type of research (Articles 6.21 to 6.23).

Chapter 7 - CONFLICTS OF INTEREST

Conflict of interest arises when research interest conflict or appear to conflict with the personal or corporate interests of the researcher(s) (See Ch. 7). Such conflicts need to be disclosed, managed, and minimized. If this cannot be accomplished to the satisfaction of the Tyndale REB the research may not go forward.

A. Key Concepts

Areas of potential conflict of interest include: institutional, REB Member, and researcher conflict of interest. This section describes REB member and research conflict of interest as it relates to Tyndale.

B. Institutions and Conflicts of Interest

Research taking place at Tyndale must abide by Tyndale's relevant conflict of interest guidelines. Such guidelines should be publicly available to all people affected by the research (e.g., participants, REB members, researchers, administrators, research sponsors).

The REB while overseen by the Senate shall act independently from Tyndale's management and Board of Governors. It is the policy of Tyndale to respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfil its primary duties. To maintain high ethical standards, the public trust, and integrity of the research process, the REB maintains a relationship with Tyndale University College & Seminary to avoid and/or manage any real or apparent conflicts of interest.

C. REB Members and Conflicts of Interest

Tyndale REB members are in a conflict of interest when their research is under review and cannot vote in judgments related to their any research in which they are involved (e.g., conducting, participating in, supervising).

If the REB is reviewing research in which a member of the REB has a personal interest in the research under review they shall not be present when the REB is discussing or making its decision. REB members are responsible to disclose when their relationship with other members of the organization puts them in a conflict situation when reviewing research. If this threatens quorum, the REB will ensure that a substitute member is available. Due to the potential of conflict of interest, senior administrators at Tyndale should not serve on the REB (Article 7.3).

The REB member may disclose and explain the conflict of interest and offer evidence to the REB that the conflict of interest is not an impediment to the research.

If the REB rejects a research proposal for reasons of conflict of interest the applicant who proposed the research has the right to hear the evidence and to offer a rebuttal. Any questions concerning a conflict of interest should be directed to the REB Chair(s). Members of the REB should err on the side of caution when determining whether or not they have a conflict of interest.

D. Researchers and Conflicts of Interest

Tyndale requires that all real or perceived conflict of interest be reported to the REB and, if the research is approved, disclosed to the participant(s). In order to assess financial conflicts of interest researchers shall submit "all kinds and amounts of payment (financial or in-kind)" associated with their research to the REB (Article 7.4).

In ministry-based-research, and research conducted by faculty, particular attention to conflict of interest is needed because of the added level of trust and the power dynamics inherent in those relationships. Researchers in these contexts should not use their authority to influence the willingness of those over whom they have power to participate in

the research. Researchers shall pay specific attention to power and dual role relationships, shall take steps to mitigate their influence, disclose it to participant(s), and will report all such relationships and the actions taken to the REB—even if they arise after an approved research ethics review.

Tyndale researchers should consider TCPS 2 Chapter 9 for a model of research that minimizes dual-role conflicts.

E. Research Incentives

TCPS2 defines incentives as "anything offered to participants, monetary or otherwise, for participation in research" (Article A.3.1). Researchers should familiarize themselves with the TCPS2 discussions of the effect of incentives on risks, voluntariness, appropriateness, etc.

Normally, incentives cannot be withdrawn for lack of participation. The existence of incentives, what they are, and how they are administered should be included in the research consent form. Special care must be taken when offering incentives to vulnerable populations (See Article 4.7) and when incentives have the potential to lead to conflict of interest (Chapter 7).

In the special case of research with current students, participation in research studies cannot be required for completion of a course / program. If extra credit is offered for research participation, extra credit must also be available to students in a manner that does not involve participation in research but which involves an equivalent time commitment and level of work. Extra credit should be small enough that it does not alter the participant's behaviour in the study. Normally, extra credit will be no greater than 3% of the course grade. Extra credit is only to be awarded for research participation related to the course of study for which the extra credit is offered (i.e., the research can be reasonably understood as contributing to course learning).

Chapter 8 - MULTI-JURISDICTIONAL RESEARCH

This chapter discusses the implications of collaborative or multi-jurisdictional research.

A. Review Mechanisms for Research Involving Multiple Institutions and/or Multiple REBs

When a TCPS 2 compliant REB at another institution has approved research, the Tyndale REB may choose to approve the research based on that external review. However, the Tyndale REB is still responsible for the ethical acceptability of the research and conduct of the researchers and reserves the right to subject the research to additional review (Article 8.1). In order for research to qualify for this alternative form of review it must meet the following criteria:

- (a) All involved institutions must agree to follow TCPS 2
- (b) The agreement to accept external review should be formalized and documented
- (c) The Tyndale Senate is advised of the arrangement
- (d) Copies of the ethical review, agreements and supporting documentation be provided to the Tyndale REB for their records

B. Ethics Review of Research Conducted outside the Institution

Tyndale researchers working outside of Tyndale, or outside of Canada (Article 8.3), shall apply the same ethical standards as here in Canada in addition to any relevant standards of the context or country in which the research takes place. Researchers shall obtain approval for their research at “the local site” where the research is taking place, if such an approval body exists, and/or from the local institution with whom they are collaborating, if that is the case, as well as from the REB of their home institution. Article 8.4 provides more detail about the information that researchers need to provide to their home REB.

Chapter 9 - RESEARCH INVOLVING THE FIRST NATIONS, INUIT AND MÉTIS PEOPLES OF CANADA

TCPS 2 recommends a community-based approach to research with Indigenous peoples in Canada. See TCPS 2 for details. The Tyndale REB will take the recommendations in this chapter into account when reviewing research that involves First Nation, Inuit and Métis peoples. This chapter will be of value to anyone engaged in community-based or participatory action research approaches to research. This chapter should be reviewed by anyone conducting community-based research (e.g., counsellors, spiritual directors, ministers and other religious workers, teachers, social workers).

Chapter 10 - QUALITATIVE RESEARCH

Researchers conducting qualitative research should be familiar with this chapter.

A. Nature of Qualitative Research

This section summarizes “the general approach, as well as methodological requirements and practices” of qualitative research under nine headings: Inductive Understanding; Diversity of Approaches; Dynamic, Reflective and Continuous Research; Diverse, Multiple, and Often Evolving concepts; Data Collection and Sample Size; Research Goals and Objectives; Dynamic, Negotiated, and ongoing Consent Process; Research Partnerships; and Research Results.

B. Research Ethics Review of Qualitative Research

Qualitative research proposals shall generally be presented to the REB before recruiting participants. However, qualitative research may have an initial exploratory phase intended to discuss “the feasibility of the research, establish research partnerships, or design of a research project” (Article 10.1). In qualitative research it is sometimes difficult to determine the beginning or end of a research project. Furthermore, contact often has to be made with the particular community before research plans can be drawn up. Nevertheless researchers still need to explain in their proposal what procedures they will use for seeking consent and how they will document that consent (Article 10.2).

When the research involves observation of people in natural environments or virtual settings, where people reasonably expect privacy, “the researcher shall explain the need for exception to the general requirement for consent” (Article 10.3). If such research

is non-obtrusive and does not allow for identification of persons in the results, it will normally be regarded as minimum risk (Article 10.3).

When researchers plan to disclose the identity of participants in publications, etc., they shall obtain consent from the participants (Article 10.4).

Some qualitative studies have emergent designs. In this case, researchers shall give the REB all the available information, and if, during the research, changes to data collection procedures may have ethical implications, they shall consult with the REB (Article 10.5).

Chapter 11 – CLINICAL TRIALS

The Tyndale REB does not currently have the expertise to review this type of research.

Chapter 12 - HUMAN BIOLOGICAL MATERIALS INCLUDING MATERIALS RELATED TO HUMAN REPRODUCTION

The Tyndale REB does not currently have the expertise to review this type of research.

Chapter 13 - HUMAN GENETIC RESEARCH

The Tyndale REB does not currently have the expertise to review this type of research.

APPENDIX A – LIST OF TYNDALE REB FORMS (available separately)

Form A – Application for Ethics Review

Form B – Peer Review Form for Scientific Merit

Form C – Annual REB Review or Final REB Report

Form D – Request for Ethics Clearance for Research Based on Secondary Use of Data

Form E – Request for Change (Amendment)

Form F – Student Research information and Checklist

Form G – Request for Departmental Approval of Course Syllabi and Assignments

Form H – Checklist of Documents

Form I – Ethics Review Form for the REB

Form J – Certificate of Ethics Review Clearance