University of Windsor

Guidelines for Research Involving Humans

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TABLE OF CONTENTS

RESEARCH AT THE UNIVERSITY OF WINDSOR 5
CORE PRINCIPLES 5
Respect for Persons 6
Concern for Welfare 6
Justice 6
RESEARCH ETHICS AND LAW 6
UNIVERSITY OF WINDSOR RESEARCH ETHICS BOARD 7
Mandate 7
RESPONSIBILITIES FOR PROTECTING RESEARCH PARTICIPANTS 8
Members of the research team 8
The Principal Investigator 8
University of Windsor Students as Principal Investigators 8
Co-investigators, collaborators, consultants, research team 9
The University Administration 9
The University of Windsor Research Ethics Board (REB) 10
Membership and Terms 10
REB Composition 11
Recordkeeping 11
TYPES OF RESEARCH THAT REQUIRE REVIEW 12
Relationship between Research Ethics Review and Scholarly Review 12
EXEMPTIONS TO THE REVIEW PROCESS 13
Publicly available information 13
Observation in public places 13
Secondary use of anonymous information 14
ACTIVITIES NOT REQUIRING REB REVIEW 14
Creative Practices 14
CRITERIA USED BY THE BOARD FOR REVIEW 15
LEVELS OF REVIEW 16
The Principle of Proportionate Review 16
Full Board Review 16
The Principal of Minimal Risk 17
Delegated Expedited Review 17
Course-Based Research and Research Activities within Courses 18
Executive Review 18

Decision Making by the REB 18
Appeals of REB Decisions 19
MULTI-CENTERED AND INTER-INSTITUTIONAL REVIEW 20
Research in other jurisdictions or external to the University of Windsor or the University premises 20
Approval by other research boards 20
Initiating ethical review for multi-jurisdictional research 20
Multi-Institutional Research 21
Institutional agreements between REBs 21
CONTINUING REVIEW 21
UNANTICIPATED ISSUES AND ADVERSE EVENTS 22
REQUESTS FOR CHANGES TO APPROVED RESEARCH 22
NON-COMPLIANCE 22
THE PRINCIPLES OF REVIEW 23
Risks and Benefits 23
Risks 23
Benefits 23
Risk Assessment 24
Participant Recruitment 24
Recruitment of students, employees, colleagues and subordinates 24
Fairness and Equity in Research Participation 24
Research Involving Women 25
Research Involving Children 25
Research Involving the Elderly 25
Research Involving First Nations, Métis, Inuit 25
Research Involving Participants Lacking Decision-Making Capacity 25
Participants' Vulnerability and Research 25
Research with Specific Populations 26
Research involving Children and Young People 25
Age of Consent 26
Research involving Persons who are mentally incompetent 26
Research involving First Nations, Métis, Inuit Peoples 26
Informed Consent 26
Overview of the elements of Informed Consent 26
Consent Shall Be Given Voluntarily 27
Consent Shall Be Informed 27
Consent Shall Be an Ongoing Process 28

Incidental findings 28
Consent Shall Precede Collection of, or Access to, Research Data 29
Consent and critical inquiry 29
Departures from General Principles of Consent 29
Consent for Research in Individual Medical Emergencies 30
Consent and Decision-Making Capacity 30
Broad Consent for the Storage of Data and Human Biological Materials for Future Unspecified Research 32
Principle of Assent 33
Research directives 34
Consent shall be documented 34
Consent and Disclosure of Information 35
Voluntariness of consent 35
Exceptions and alterations to normal consent requirements 36
Deception 36
Privacy and Confidentiality 36
Ethical duty of confidentiality 38
Group Research Events and the Limits of Confidentiality 38
Disclosure of Results 39
Equitable Distribution of Research Benefits 39
Conflict of Interest 40
Conflicts of interest involving researchers 40
Management of multiple roles 40
Conflicts of interest by REB members 41
Institutional conflict of interest 41
SPECIFIC RESEARCH METHODOLOGIES AND DOMAINS 41
Qualitative research 41
Clinical trials 41
Human biological materials and genetic research 42
Naturalistic observation 42
Secondary use of data 42
Right to provide permission for secondary use 43
Data linkage 44
SUBMITTING RESEARCH FOR REVIEW: APPLICATION PROCESS 44
What to submit 44
Other items to include in applications 44
REQUIREMENTS FOR ADDITIONAL CERTIFICATIONS AND APPROVALS 45

RESEARCH AT THE UNIVERSITY OF WINDSOR

Research is an essential component of the mission of the University of Windsor, and the University is justifiably proud of the contributions to society and to the advancement of knowledge that have resulted from the research of its academic community.

When research involves human participants, their data and/or human biological materials (TCPS 2.1), the University shares with researchers the responsibility that the research is conducted in accordance with the highest ethical standards. In Canada, a common policy of ethical conduct for research has been developed by the Social Sciences and Humanities Research Council of Canada (SSHRC), the Natural Sciences and Engineering Research Council of Canada (NSERC) and what was then the Medical Research Council (MRC). As of 1998, the *Tri-Council Policy Statement*: *Ethical Conduct for Research Involving Humans* (*TCPS*) sets out the interdependent duties to research participants, that are shared by researchers, institutions and Research Ethics Boards (REBs). This policy has been revised four times, and the version at the time of preparation of these revised guidelines is the TCPS2 (2022). “TCPS” refers to this version throughout these guidelines, unless otherwise indicated.

As well as a condition of funding, the *TCPS* sets out, as a minimum, what is expected of researchers and their institutions as ethical standards. It is intended to harmonize the ethics review process involving researchers from different disciplines or institutions. *The University of Windsor Guidelines for Research involving Humans (2023)* are consistent with and reflect the adoption by the University of the *TCPS, TCPS2,* and the current *TCPS2 (2022)* by the University. Some statements of the University of Windsor *Guidelines* are verbatim adoptions of the *TCPS2 (2022).*

CORE PRINCIPLES

Respect for human dignity has been an underlying value of the *TCPS* since its inception. Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. In this Policy, respect for human dignity is expressed through three core principles – Respect for Persons, Concern for Welfare, and Justice. These core principles transcend disciplinary boundaries and, therefore, are relevant to the full range of research covered by this Policy (*TCPS2*, 2022, Chap. 1B).

The guidelines set out in the *TCPS* and in the *University of Windsor Policy on Research Involving Humans* are based on the following three core principles:

Respect for Persons

The principle 'Respect for Persons' recognizes the intrinsic value of human beings and the respect and consideration that they are due. From this principle flows respect for autonomy; and the need to seek free, informed and ongoing consent.

Concern for Welfare

The principle 'Concern for Welfare' refers to the quality of that person's experience of life in all its aspects. From this principle flows the need to protect the welfare of participants, and in some cases to promote welfare. The welfare of groups of individuals may also be affected by research and must be considered. Generally, risks must be outweighed by benefits in the ethical analysis.

Justice

The principle of 'Justice' is the obligation to treat people fairly and equitably. From this principle flows the need to consider equity in recruitment and inclusion practices; and to manage imbalance of power between members of research teams and research participants.

RESEARCH ETHICS AND LAW

Researchers are responsible for ascertaining and complying with all applicable legal and regulatory requirements with respect to consent and the protection of the privacy of participants. Legal and regulatory requirements may vary depending on the jurisdiction in Canada in which the research is being conducted, and who is funding and/or conducting the research, and they may comprise constitutional, statutory, regulatory, common law, and/or international or legal requirements of jurisdictions outside of Canada. Where research is considered to be a governmental activity, for example, standards for protecting privacy flowing from the *Canadian Charter of Rights and Freedoms*, federal privacy legislation and regulatory requirements would apply (*TCPS2*, 2022, Chap 1C).

The law affects and regulates the standards and conduct of research involving humans in a variety of areas, including, but not limited to privacy, confidentiality, intellectual property and the decision-making capacity of participants. In addition, human rights legislation and most documents on research ethics prohibit discrimination on a variety of grounds and recognize equal treatment as fundamental. REBs and researchers should also respect the spirit of the *Canadian Charter of Rights and Freedoms*, particularly the sections addressing life, liberty and security of the person, as well as those involving equality and

discrimination (*TCPS2*, 2022, Chap 1C).

UNIVERSITY OF WINDSOR RESEARCH ETHICS BOARD

The authority of the University of Windsor REB is established by Senate of the University of Windsor. The REB reports to the Senate annually.

This authority of the REB includes the mandate to SOLELY determine when review is required for any activity that potentially meets the definition of research, and to provide clearance for, reject, propose modifications to, or terminate any proposed or ongoing research involving research participants which is conducted within, or by members of, the institution, using considerations set forth in the most current *TCPS* as a minimum standard.

Mandate

The mandate of the REB is:

a. To keep current on ethical issues related to research involving human participants; to educate the University community on these issues and to formulate policies on these matters;
b. To act as an intermediary, advocate, and provide resources for research participants;
c. To determine the scope of activities that require REB oversight. The REB is the sole body that can determine whether an activity constitutes research, and whether review and oversight is required;
d. To review, approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants conducted at University of Windsor or by members of University of Windsor, including anyone affiliated with the University conducting such research at or under the auspices of University of Windsor;
e. To assess and limit the risks to participants in research involving humans; and where there is more than minimal risk identified, the REB shall engage in the deliberations necessary to be satisfied that the design of a research project is capable of addressing the questions being asked in the research;
f. To conduct the continuing review of research projects and to determine guidelines for the review and clearance of ongoing research projects and guidelines for reviewing requests for changes in previously approved research;
g. To develop policies and procedures for assessing and approving undergraduate student research;
h. To develop policies and procedures for determining scope of review, assessing and providing clearance for teaching activities that involve the collection of data from or about human participants;

i. To act as the Appeal Board for appeals of decisions rendered regarding undergraduate student research;
j. To proactively educate, communicate, advise and serve as a resource to the research community, on guidelines, procedures and other matters relating to the conduct of research with humans;
k. To meet regularly to discharge the responsibilities of the REB and to keep and maintain minutes of such meetings; with the documentation being accessible to researchers, as it pertains to their application;
l. To inform the institution regarding structure and procedures followed by the REB and to engage in activities to review the processes and procedures of the REB;
m. To maintain strict confidentiality of applications and deliberations about actions, so as to protect the intellectual rights of researchers; excepting when permission is provided by a researcher to breach confidentiality, or to manage academic misconduct or adverse events;
n. To implement and monitor the final decision of the Appeal Board on behalf of the Research Ethics Appeal Board;
o. To establish informal or formal agreements with REBs (or other designated ethical review bodies) at other institutions and organizations regarding shared responsibility for research ethics oversight.

RESPONSIBILITIES FOR PROTECTING RESEARCH PARTICIPANTS

Members of the research team

The Principal Investigator

As the individual responsible for the scientific and ethical oversight of the research and the implementation of the research project, the Principal investigator (PI) bears direct responsibility for ensuring the protection of every research participant. The responsibility starts with project design, which must minimize risks to participants while maximizing research benefits. The Principal Investigator must ensure that all members of the research team comply with the requirements of the *University of Windsor Guidelines* and the *TCPS.* The Principal Investigate will be required to present a certificate of successful completion of the *TCPS On-Line Tutorial*.

University of Windsor Students as Principal Investigators

The University of Windsor REB recognizes undergraduate and graduate students as Principal Investigators, but all student protocols must have a faculty supervisor who serves as the de facto PI with responsibility for the conduct of the research. Final responsibility for the ethical conduct of the research lies with the supervisor.

Co-investigators, Collaborators, Consultants, Research Team

Other individuals affiliated with a research project are responsible for working with the PI to implement the research in accordance with the protocol as cleared by the REB. Such individuals will seek to understand the plan for the ethical conduct of research as appropriate to the role that they hold with the project.

All members of the research team share in the responsibility for the ethical conduct of the research and are expected to communicate any ethical concerns about the research to the PI in a timely manner. Further, all members of the research team who will interact with participants or have access to their data must complete appropriate training regarding the requirements of conducting and overseeing research (TCPS2 CORE-2022 Course on Research Ethics or an equivalent) and should have sufficient expertise in the discipline and methods of the proposed research.

The University Administration

The TCPS2 (2022) states that the highest body within an institution shall: establish the REB or REBs, define an appropriate reporting relationship with the REBs, and ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfil their duties (*TCPS2*, 2022, 6.2).

The President of the University of Windsor is responsible for establishing and resourcing the REB. This includes the allocation of resources to support the mandates of the REB listed above, REB coordination, support in policy development and interpretation, record keeping, communication and education functions as well as the provision of research ethics training opportunities to REB members, researchers and students. Research ethics administration staff should also have the necessary qualifications, as well as initial and continuing training, to appropriately perform their roles and responsibilities (*TCSP2,* 2022, 6.2).

The President may delegate their responsibilities to a designate from the senior administrative level who has authority and oversight regarding academic or research matters. At the time of the revision of this policy, the responsibilities are designated to the Vice President Research and Innovation, which satisfies this provision. There shall be no further delegation of responsibility.

THE REB IS independent in its decision making. The Administration recognizes that the REB operates at arms-length to the University of Windsor (TCPS2, 2022, 6.2).

The institution recognizes the mandate of the REB to review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the institution (*TCPS2*, 2022, 6.3).

The University will establish and maintain policies and procedures related to the responsible conduct of research, for example including: conflict of interest, obtaining and using funds, collaboration with other researchers and other institutions. The University shall include the REB in discussions of activities that involve the collection of information from human participants and any area of activity that fall under the jurisdiction of the REB or which may impact the effective functioning of the REB (*TCPS2,* 2022, 6.2).

Academic administrators, such as Deans, Directors and Department Chairs or Heads, have a responsibility for the ethical conduct of research carried out within their jurisdiction. Additionally, they have a duty to create a climate for ethical practice of such research by promoting awareness of this policy and the requirement for ethics review to researchers. Where students are engaged in research, this responsibility should extend to ensuring that students are adequately instructed in the principles and implementation of research ethics, and that the appropriate review mechanisms are in place at the local level.

The qualifications and expertise that the REB needs shall be considered when appointing and renewing REB chairs and members. The University of Windsor shall provide REB members with support to obtain the necessary training to effectively review the ethical issues raised by research proposals that fall within the mandate of the REB (*TCPS2*, 2022, 6.7).

The University of Windsor Research Ethics Board (REB)

The University of Windsor REB is formally constituted to review and monitor all research involving research participants conducted under the auspices of the University. The Board is an autonomous entity whose primary responsibility is ensuring the safety and well-being of all research participants involved in research programs carried out by the University of Windsor researchers.

The REB is responsible for the overall administration and documentation of the ethics review process.

Membership and Terms

The University of Windsor REB shall consist of at least 5 members, including both men and women, appointed by the President, or designate, and in consultation with the current REB Chair. The members of the REB are appointed for three-year terms; terms should be staggered among the REB members. The appointments are renewable. The REB Chair shall be appointed

by the President and shall serve, normally, a term of three years, which is renewable (*TCPS2*, 2022, 6.6).

REB Composition

The REB will seek to maintain broad representation across the disciplines, faculties, and diverse modes of inquiry.

The membership of the REB shall consist of at minimum (*TCPS2*, 2022, 6.4):

a. At least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
b. At least one member is knowledgeable in ethics;
c. At least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
d. At least one community member who has no affiliation with the institution.
e. The REB shall endeavor to ensure that each member be appointed to formally fulfil the requirements of only one of the above categories.
f. To ensure the independence of REB decision making, senior administrators, including but not limited to Board of Governors, Deans, Associate Deans, or any other individuals with a conflict of interest regarding the independence of the REB, shall not serve on the REB.

The REB will seek the consultation of ad hoc advisors in the event that it requires additional expertise or knowledge to review the ethical acceptability of a research proposal competently. The Chair may seek additional members to advise on the particular project, or consult externally, in confidence (*TCPS2*, 2022, 6.5).

Recordkeeping

The REB maintains comprehensive records, including all documentation related to the projects submitted to the REB for review, attendance at all REB meetings, and minutes reflecting REB decisions. Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision (TCPS2, 2022, 6.13).

Communications with the REB are treated as confidential. The contents of REB files are closed. Only members of the REB and its administrative staff have access to records, and only on a need to know basis. The REB shall maintain a privacy policy to ensure protection of REB records.

The REB Chair has the discretion to breach confidentiality in cases of potential academic misconduct, noncompliance, and for reasons of participant protection. The REB Chair will restrict the information that is released to the scope of the issue that is under consideration.

TYPES OF RESEARCH THAT REQUIRE REVIEW

The following requires ethics review and clearance by the REB before the research commences (*TCPS2*, 2022, 2.1):

- research involving living human participants;
- research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Research is defined by the *TCPS* as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (*TCPS2*, 2022, 2.1).

Human research participant is defined by the *TCPS* as those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question (*TCPS2*, 2022, 2.1).

Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses is subject to review by the REB (*TCPS2*, 2022, 2.1).

Research requiring review includes any research that:

- is conducted by University of Windsor faculty, staff or students;
- is performed on the premises of the University of Windsor;
- is performed with or involves the use of resources, facilities or equipment belonging to the University;
- involves University students, staff or faculty;
- satisfies a requirement imposed by the University for a degree program or for completion of a course of study;
- is conducted by or under the direction of any employee or agent of the University of Windsor in connection with his or her institutional responsibilities.

When in doubt about the applicability of this Policy to a particular project, the researcher shall seek the opinion of the REB. The REB makes the final decision on exemption from research ethics review as well as the level of proportionate review.

Relationship between Research Ethics Review and Scholarly Review

To be ethical, research must have potential value (also referred to as scientific merit). Per the guidance in the TCPS, REBs will evaluate the scholarly merit of research (*TCPS2*, 2022, 2.7). The REB will begin this process by considering the argument for merit provided in the application. The REB will seek to understand

the potential value of research within disciplinary scholarly standards. Should the REB determine that additional review beyond the information provided by an applicant is required, the REB will determine when it shall seek ad-hoc independent guidance.

In conducting reviews, the REB must remain impartial and should not reject proposals because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups.

EXEMPTIONS TO THE REVIEW PROCESS

The following areas are identified by the *TCPS (2022)* as normally being exempt from review and approval by a REB. To obtain an exemption, researchers must consult with the REB, which will issue an exemption letter under the appropriate category. Researchers engaging in activities falling under the descriptions below must consult with the REB to determine if they are exempt from review. If the criteria are met, the REB will issue an exemption letter under the relevant category.

Even though review by the REB is not required, the board encourages researchers to treat those who participate in research projects in a manner consistent with the guidelines set out in the Tri-Council Policy Statement, Second Edition. This includes, for example, seeking consent from individuals to gather information, making clear to individuals how their information will be used, providing confidentiality where appropriate, and using the information gathered in a manner that is respectful to those who contributed.

Publicly available information

Research that relies exclusively on publicly available information does not require REB review when:

a. The information is legally accessible to the public and appropriately protected by law; or
b. The information is publicly accessible and there is no reasonable expectation of privacy.

Exemption from REB review is based on the information being accessible in the public domain, and that the individuals to whom the information refers have no reasonable expectation of privacy. Information contained in publicly accessible material may, however, be subject to copyright and/or intellectual property rights protections or dissemination restrictions imposed by the legal entity controlling the information (*TCPS2*, 2022, 2.2).

Observation in public places

REB review is not required for research involving the observation of people in public places where:

a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups.
b. Individuals or groups targeted for observation have no reasonable expectation of privacy; and
c. Any dissemination of research results does not allow identification of specific individuals (*TPS2*, 2022, 2.3).

Secondary use of anonymous information

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information (*TCPS2*, 2022, 2.4).

ACTIVITIES NOT REQUIRING REB REVIEW

Researchers engaging in activities falling under the description must consult with the REB to determine if they are exempt from review. If the criteria are met, the REB will issue an exemption letter under the relevant category.

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. These activities refer to assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training. Those activities are normally administered in the ordinary course of the operation of an organization where participation is required, for example, as a condition of employment in the case of staff performance reviews, or an evaluation in the course of academic or professional training (*TCPS2*, 2022, 2.5).

Researchers engaging in activities falling under the above description must consult with the REB to determine if they are exempt from review. If the criteria are met, the REB will issue an exemption letter under the relevant category.

Creative Practices

Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain information from

participants to answer a research question is subject to REB review (*TCPS2*, 2022, 2.6).

CRITERIA USED BY THE BOARD FOR REVIEW

The following criteria will be considered by the REB when reviewing an application to involve human participants in research:

- **Risk and risk management**
  - the overall level of risk to research participants;
  - whether the risks to participants are minimized by using procedures or methods that are consistent with sound research design, but which do not expose participants to unnecessary harm;
  - whether the risks are reasonable (balanced) in relation to the anticipated benefits to the participants;
  - appropriate provisions are made for the on-going monitoring or continuing review of the participant's welfare;
  - whether any potential bystander risks to those who have not been consented to participate in the research have been mitigated;
  - whether the potential benefits outweigh the potential risks;
- **Consent**
  - whether the protocol has a consent process which provides for free and informed consent, including providing for withdrawal from the research;
  - whether the purpose of the study is fully outlined;
  - if deception is part of the study that it is necessary and justified;
  - whether those recruited for the research are competent to provide consent, or if alternative consent will be used;
  - whether rights to withdrawal are provided and are reasonable;
- **Privacy and confidentiality**
  - whether there is adequate protection of the privacy of the participants and the confidentiality of the information/data being obtained (prior to, during, and following the completion of the research) and in the data management plan throughout the data life cycle.
- **Fair inclusion**
  - whether the selection and recruitment of the participants is inclusive and appropriate in relation to the research participants and to the research;
- **Conflict of interest, multiple roles, and undue influence**
  - whether there is any conflict of interest which should be considered, and if so, whether appropriate mechanisms for handling the conflict have been put into place;
  - whether there are any multiple roles between researchers and

participants, or between individuals involved in the research, and if so if multiple roles are sufficiently acknowledged and managed;
- whether there is a potential for undue influence between any individuals during the conduct of the research.

The REB may consider additional criteria where it is appropriate and in keeping with their mandate.

LEVELS OF REVIEW

The Principle of Proportionate Review

The REB shall adopt a proportionate approach to research ethics review based upon the general principle that the more invasive and risky the research, the greater should be the care in assessing the research (*TCPS2*, 2022, Chap. 1C). As a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (Delegated Review); the higher the level of risk, the higher the level of scrutiny (Full Board review). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research (*TCPS2*, 2022, 2.9).

Given that the REB is tasked with assessing risk for a wide range of research activities and must maintain sufficient expertise, specialized review sub-boards may be tasked with reviewing specific classes of research. The REB may designate aspects of a research project to multiple review committees or may seek expert input from a specialized review board at another site for all or a part of a project.

Based upon the principle of proportionate review, the REB reviews applications for research involving research participants at the following four different levels:
- Full REB Review;
- Delegated Review;
- Delegated External Review by a specialized committee formally designated by the REB;
- Executive Review.

Full Board Review

Review by the fully convened University of Windsor REB (Full Board) is the default requirement for all research involving human participants, unless the proposed research meets the criteria for delegated expedited review or review by a formally delegated review committee. Research that requires Full REB review includes:

- All research which involves greater than minimal risk to individuals or a specific community will be reviewed by the Full Board at a regularly constituted meeting;
- Research involving new or unfamiliar methodologies that have greater than minimal risk will be reviewed by the Full Board;
- Issues specific to biomedical research are discussed below.

The Principal of Minimal Risk

The standard of minimal risk is defined as follows:

"Minimal risk" research is defined 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 those aspects of their everyday life that relate to the research (TCPS2, 2022, Chap. 2).

More-than minimal risk in research projects is assessed through the following methods:

a. The Chair of the University of Windsor REB or the Chair's designate reviews the projects and assesses whether participants will incur greater-than-minimal risk;
b. A Delegated internal review board, in the process of reviewing an application, determines that the level of review should be increased in consultation with the Chair of the REB;
c. A Delegated external board reviews a project or course and the committee identifies factors within the research project which indicate the potential of greater than minimal risk (Delegated boards are expected to consult regularly with the REB regarding this threshold); or
d. If a researcher requests a Full Board review based on their assessment that the project could incur greater-than-minimal risk.

Delegated Expedited Review

The term "expedited" refers to specific categories of research that may be approved outside a meeting of the Full REB and does not indicate the timing or promptness with which the project is considered and approved.

Research projects meet the criteria for delegated expedited review where:

- The project involves no more than minimal risk;
- The project is a replication of a previously approved protocol with significant revisions, provided it meets the criterion of minimal risk.

Projects which are conducted by expedited review are assessed by the following method: Where the project involves no more than minimal risk or involves significant revisions it will be sent to two REB members and the REB Chair for review and the reviewers will provide a written assessment of the level of risk

and any other ethical issues arising from their review.

Designated external review committees have been established at the University of Windsor. The authority of the external review committee is delegated by the Full REB. The external committee reviews research related to the specific mandate for which the committee is established. All external review committees will operate within written guidelines that have been reviewed and cleared by the Full Board.

Course-Based Research and Research Activities within Courses

Undergraduate and graduate courses which include class projects and activities designed to develop research skills involving research participants require review by the REB. Course activities that involve the collection of information from or about other people require review. A Delegated external specialized committee may include reviewing course-based research skills in their guidelines.

Executive Review

Research projects meet the criteria for executive review, by the Chair of the REB or designate, where:

a. The project has previously been approved by another Research Ethics Board or other formally constituted ethical review committee;
b. The project is an application for approval "in principle" to allow for activities not involving human participants, in accordance with the Tri-Council *Memorandum of Understanding*;
c. The project is a replication or extension of a previously approved protocol without significant changes to the risks associated with the project;
d. The project only involves secondary use of existing data;
e. If the original protocol had notable associated risks, the REB Chair or designate will determine if executive review of the subsequent protocol changes is sufficient.

Decision Making by the REB

Projects for review of research involving research participants may be:

a. Approved without questions or request for modification;
b. Approved subject to clarification and/or modifications;
c. Deferred, pending receipt of additional information or major revisions;
d. Disapproved

Please note, the reference to "approval" outlines a number of appropriate meanings according to the TCPS 2 and other guiding resources. This language

remains in these Guidelines for compliance. In relationship to the term "clearance", the University of Windsor Research Ethics Board (REB) defines "ethical clearance" as the process set by an institution and presided over by the REB to holistically regulate research projects to ensure their design and execution plan are ethically sound and will render anticipated result with the outcome being approval.

The REB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. The REB will seek to make decisions on the ethical acceptability of research in an efficient and timely manner, and shall communicate all approvals and refusals in formal correspondence to researchers.

The University of Windsor REB will strive to reach consensus of all members in respect to its decisions concerning applications for review. In the event that consensus cannot be reached, a vote may be taken. The decision of the majority of the REB shall prevail.

The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals. The REB may also invite researchers to attend an REB meeting to provide further information about their proposal. In either case, the researchers shall not be present when the REB is making its decision.

When the REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Appeals of REB Decisions

Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project (*TCPS2*, 2022, 6.18). Such requests can only be launched for procedural or substantive reasons. The onus is on the researchers to justify the grounds on which they request an appeal and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by the TCPS2 (TCPS2, 2022, 6.20).

The President or designate will, in consultation with the Chair of the REB, designate an Appeal Board Chair and four Appeal Board members. The Appeal Board Chair is a voting member of the Appeal Board. The Chair of REB may not serve on an Appeal Board reviewing an REB decision.

The Appeal Board shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final. The Appeal Board will conduct a review of the application and associated documentation, which may include the original ethics application, the original REB decision, all

subsequent written communications, documents and records, including REB minutes pertaining to the submission, a copy of a research project for funding of the proposed research, if applicable, relevant references or copies of pertinent guidelines, internal and external policies and legislation.

The Appeal Board will render a final and binding decision by majority vote, which may either

a. Uphold the original decision;
b. Modify the original decision; or
c. Impose specific conditions for approval of the project.

In the event a majority vote is not rendered, the Chair of the Appeal Board shall cast the deciding vote. The Appeal Board will communicate its decision in writing, with reasons, to the researcher, the Chair of the REB and to all members of the Appeal Board. The Appeal Board will provide advice to the REB in the event of the modification of the original decision of the Board, or in the event of the imposition of specific conditions for approval of the project.

Appeals from a decision of a delegated external review committee shall be made to the University of Windsor REB, and the decision of the University of Windsor REB when rendered, shall be final.

MULTI-CENTERED AND INTER-INSTITUTIONAL REVIEW

Research in other jurisdictions or external to the University of Windsor or the University premises

All research conducted by or involving University of Windsor faculty, students or employees or agents, conducted in other jurisdictions or away from the University premises, must comply with the research ethics policy at the University of Windsor, and at the ethics board or through the equivalent board, committee or process at the additional location or institution, provided that there is such a process reasonably available.

Approval by other research boards

Research projects which have been reviewed and approved by research ethics boards other than the University of Windsor REB, will be subject to review, by the Chair of the REB. The REB Chair may seek review by the internal delegated review committee or the Full REB.

Initiating ethical review for multi-jurisdictional research

The ethical review process typically commences with the REB at the institution at which the primary PI is located. In cases where the PI is at another institution, the University of Windsor REB agrees to receive the initial

submission on the other institution's application forms. The REB may request additional information, or ask for the application to be submitted on its form. If the primary PI is from the University of Windsor, the ethics review process should be initiated at the University of Windsor, unless otherwise determined with the Chair of the REB. The University of Windsor REB is the REB of record for its faculty, staff, students, employees or agents.

Multi-Institutional Research

The REB shall be advised as to whether the same project has been reviewed by another REB, including reviews conducted outside of Canada. University of Windsor retains accountability for the research within its institution and by its faculty, staff, students, employees or agents.

Multi-centre research may include:

- A research project conducted at more than one institution or organization either by the same or different researchers;
- A research project conducted jointly by researchers affiliated with different institutions.

Institutional agreements between REBs

The REB may establish formal or informal agreements with other REBs regarding the handling of REB applications between the institutions. Such agreements may be made for individual research projects, or for all research that is jointly conducted between the institutions. Formal agreements must be agreed to by the signatories of both institutions.

CONTINUING REVIEW

The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. The proportionate approach means the higher risk, the greater the scrutiny of the continuing review process (*TCPS2*, 2022, 6.14).

Following initial REB review and approval, research ethics review shall continue throughout the life of the project. This includes risks that may remain to participants following the completion of data collection, in the subsequent retention and sharing of data (*TCPS2*, 2022, 2.8).

A progress report will be required at minimum on an annual basis for each project.

Projects that are classified as minimal risk will require an annual status report and a final report upon completion, unless otherwise determined by the REB.

All approved projects may be subject to further review and monitoring by the

REB.

UNANTICIPATED ISSUES AND ADVERSE EVENTS

Researchers, including faculty supervisors and co-investigators, shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare (*TCPS2*, 2022, 6.15). Reports should be directed to the Chair of the REB and submitted according to guidelines on the REB website. Unanticipated issues and adverse events should be reported to the REB no later than 3 days of their occurrence. Serious adverse events should be reported within 24 hours.

Reports of unanticipated issues, adverse and serious adverse events will be investigated by the REB Chair, or their designate, and the results will be communicated to the researcher. Upon report of an unanticipated issue, adverse or serious adverse event; The Chair of the REB may take one or more the following actions until the event is resolved:

a. Call for a suspension of recruitment for a component or some or all of the research project;
b. Call for a suspension of activities for some components or all of the research project;
c. Request additional documentation, REB review or other reports from the research team;
d. Other action as relevant to addressing the event.

REQUESTS FOR CHANGES TO APPROVED RESEARCH

Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review.

Researchers are advised to consult with the REB if uncertain whether a change is sufficiently minor to not require reporting.

In general, it is not the scope of the change that dictates the ethics review process, but rather the ethical implications and risk associated with the proposed change.

Changes that substantially alter the nature of the approved research may be assessed as a new research project and require a new REB review (*TCPS2*, 2022, 6.16).

NON-COMPLIANCE

All research involving human research participants must be submitted for

review and receive clearance from the REB before being initiated. The Office of Research Ethics (ethics@uwindsor.ca) and the website www.uwindsor.ca/reb/ make these *Guidelines* and the *TCPS* available to researchers.

Researchers should be aware that failure to comply with these *Guidelines* constitute misconduct in research. Allegations of non-compliance can have disciplinary implications. Please refer to the Collective Agreement (Article 60 - Ethical Conduct of Research) *Investigation of Allegation(s) of Fraud and/or Misconduct in Academic Research* and the *Policy on Research Integrity and the Responsible Conduct of Research* (2013) found on the Office of Research Services website.

THE PRINCIPLES OF REVIEW

Risks and Benefits

The REB will determine whether the risks of the research are reasonable in relation to the anticipated benefits (if any) to the research participants and the importance of the knowledge that may reasonably be expected to result. Foreseeable harms should not outweigh anticipated benefits (TCPS2, 2022, Section C).

Risks

Research participants must not be subject to unnecessary risks of harm, and their participation in research must be essential to achieving scientific and societal important aims.

The REB is concerned about risks of:
- Physical harm;
- Psychological and social harm;
- Injury to reputation or privacy; and
- Breach of any relevant law.

The REB is concerned about risks to:
- The participants involved;
- Bystanders to the research;
- Clearly identifiable third parties;
- The researcher personally and any staff involved; and
- Broader cultural, ethnic and national interests.

Benefits

In all research involving research participants, there is a duty not only to benefit others, but to maximize the net benefits of the research. Potential benefits include:

- Specific advantages to participants or to third parties or to society;
- Any general increase in human knowledge;
- Increased knowledge of the researcher, especially for student researchers.

Risk Assessment

The REB must determine that risks to participants in all research are minimized by the use of procedures that are consistent with sound research design and which will not expose the participants to unnecessary risks. In keeping with this principle, the REB will examine the research plan, including the research design, debriefing where appropriate, methodology and the data management plan. Research that is poorly designed or is lacking in statistical power such that meaningful results cannot be obtained is ethically problematic because it may erode the public trust in the research process by subjecting research participants to unnecessary risk or by wasting their time.

The REB will also consider the professional qualifications and resources of the research team in its assessment of risk.

Participant Recruitment

Research benefits and burdens should be distributed fairly. Researchers must justify any exclusions based on sex or gender, race, or ethnicity, and exceptions should be made only when there is adequate scientific justification for exclusion.

Recruitment of students, employees, colleagues and subordinates

Researchers should avoid using their own students or employees, colleagues or subordinates as research participants, as both explicit and subtle undue influence or coercion can occur in these cases.

If there is good scientific reason for including students, researchers should provide a rationale addressing the following issues:

a. Ensure that students are confident that their participation will not influence class standing, grades, or other benefits under the control of the researcher;
b. Limit the use of extra credit points as a reward for participating;
c. Keep financial rewards commensurate with the risks of participation;
d. Inform students who might participate about the review process, the rationale for the study, the process of data collection and the researcher's interest;
e. Seek to recruit from a broad base of students.

Fairness and Equity in Research Participation

Appropriate Inclusion. Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the

basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion (*TCPS2*, 2022, 4.1).

Inappropriate Exclusion

Research Involving Women

Women shall not be inappropriately excluded from research solely on the basis of gender or sex. Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding (*TCPS2*, 2022, 4.2, 4.3).

Research Involving Children

Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage (*TCPS2*, 2022, 4.4).

Research Involving the Elderly

Elderly people shall not be inappropriately excluded from research solely on the basis of their age (*TCPS2*, 2022, 4.5).

Research Involving First Nations, Métis, Inuit

Chapter 9 of the TCPS2 (2022) provides detailed guidance regarding working with individuals and communities.

Research Involving Participants Lacking Decision-Making Capacity

Subject to applicable legal requirements, individuals who lack capacity to decide whether or not to participate in research shall not be inappropriately excluded from research (TCPS2, 2022, 4.6). Where a researcher seeks to involve individuals in research who do not have decision-making capacity, the researcher shall, in addition to fulfilling the conditions in Articles 3.9 and 3.10, satisfy the REB that:

a. The research question can be addressed only with participants within the identified group;
b. The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
c. Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

Participants' Vulnerability and Research

Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances (*TCPS2*, 2022, 4.7).

Research with Specific Populations

Research involving Children and Young People

Research involving children and young people should only be conducted where:

a. The research question posed is important to the health and well-being of the children;
b. The participation of children is indispensable to the purpose of the research;
c. The study method is appropriate for children and young people;
d. The circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person; and
e. An authorized legal representative cannot consent to research that is not in the best interests of the person they represent.

Age of Consent

There are no clear legal requirements about children's abilities to consent to, or to refuse participation in a research project. A young person's consent or a child's consent can be given whenever that person or child has sufficient competence to make a decision about participating in the research. Similarly, a young person or child can withdraw consent or refuse to participate.

Researchers must consider the competence of children relative to the tasks that they will be asked to undertake. In cases that children are thought to be not competent to consent, children will be asked for their assent. Guidelines AND OR POLICIES regarding consent and assent of children may vary depending on the location where the research will take place (e.g., recruiting or administering research within a school board or health care setting).

Research involving Persons who are mentally incompetent

Researchers should consider that those who are not competent to consent for themselves should not be automatically excluded from research which could potentially benefit them as individuals or the group that they represent.

An incompetent participant's withdrawal of consent must be respected, whether or not the participant was competent at the time of the withdrawal.

Research involving First Nations, Métis, Inuit Peoples

The REB will review all research with these groups using the guidance provided in Chapter 9 of the TCPS2 (2022) and subsequent versions of the guidance.

Informed Consent

Overview of the elements of Informed Consent

Informed consent is a process whereby a choice is made:

- by a competent person;
- on the basis of adequate information concerning the nature of the research to be conducted and foreseeable consequences;
- without undue influence or coercion (*TCPS2*, 2022, 3.1).

The informed consent process is different from getting a research participant to sign the consent form. Researchers should strive to convey information to participants, not merely disclose it to them. In the case of translations, the researcher must satisfy the REB that the translation is accurate and appropriate.

Consent Shall Be Given Voluntarily

- Consent shall be given voluntarily.
- Consent can be withdrawn at any time.
- If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

Consent Shall Be Informed

Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project (*TCPS2*, 2022, 3.2).

The information generally required for free and informed consent includes:

- Contact information and identification of the researchers;
- Information that the individual is being invited to participate in a research project;
- A statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
- A plain language and accessible description of all reasonably foreseeable benefits;
- A plain language and accessible description of foreseeable risks both to the participants and in general, that may arise from research participation;
- An assurance that prospective participants:
  - are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
  - will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and

    - will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;
- Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
- The measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
- The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
- The identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
- An indication of what information will be collected about participants and for what purposes;
- An indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected (see Article 5.2);
- A description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;
- Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
- A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
- A statement informing participants of their rights as research participants and the contact information for the Research Ethics Board Office;
- In clinical trials, information on stopping rules and when researchers may remove participants from trial.

Consent Shall Be an Ongoing Process

Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research. Consent encompasses a process that begins with the initial contact (e.g., recruitment) and carries through to the end of participants' involvement in the project (TCPS2, 2022, 3.3).

Change in participant capacity is an important element of ongoing consent. Rather than an age-based approach to consent, this Policy advocates an approach based on decision-making capacity as long as it does not conflict with any laws governing research participation. This includes those whose decision-making capacity is in the process of development, those whose decision-making capacity is diminishing or fluctuating, and those whose decision-making capacity

remains only partially developed (Application of Article 3.10) (TCPS2, 2022, 3.3).

Incidental Findings

Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research (*TCPS2*, 2022, 3.4).

Consent Shall Precede Collection of, or Access to, Research Data

Research shall begin only after the participants, or their authorized third parties, have provided their consent (*TCPS2*, 2022, 3.5).

Consent and Critical Inquiry

Research in the form of critical inquiry, that is, the analysis of social structures or activities, public policies, or other social phenomena, requires an adjustment in the assessment of consent. In critical inquiry, permission is not required from an institution, organization or other group in order to conduct research on them. If a researcher engages the participation of members of any such group without the group's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation. Specific requirements pertain to aboriginal and indigenous organizations.

Departures from General Principles of Consent

The REB may approve research that involves an alteration to the requirements for consent set out above if the REB is satisfied, and documents, that all of the following apply (*TCPS2,* 2022, 3.7A/B):

a. The research involves no more than minimal risk to the participants;
b. The alteration to consent requirements is unlikely to adversely affect the welfare of participants;
c. It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
d. In the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
e. The plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials.

Debriefing must be a part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate.

Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable and appropriate.

There may be circumstances in which debriefing is impossible, impracticable or inappropriate in research involving alterations to consent requirements. Note that "impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience. The onus is on researchers to satisfy the REB that their research involves circumstances that make it impossible, impracticable or inappropriate to offer a debriefing.

All research involving intentional deception will be evaluated by the REB Chair using guidelines established by the Full Board to determine the level of review required. The nature, extent, associated risks, and degree to which the deception can be corrected must be considered. The default for research involving deception absent such review is review by the Full Board.

Consent for Research in Individual Medical Emergencies

Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:

a. A serious threat to the prospective participant requires immediate intervention;
b. Either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care;
c. Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant;
d. The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project;
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.

When a previously incapacitated participant regains decision-making capacity, or when an authorized third party is found, consent shall be sought promptly for continuation in the project, and for subsequent examinations or tests related to the research project.

It is the responsibility of researchers to justify to the REB the need for this exception.

Consent and Decision-Making Capacity

Competence means that a person is capable of making a morally and legally

valid choice to participate in research. In the context of research, it means the capacity to understand the nature and consequences of one's acts. Competence is determined by both the situation and the person's understanding of it. A prospective research participant may be incompetent in certain situations but competent in others (*TCPS2*, 2022, Chap. 3C).

To be considered competent to make a valid choice, prospective research participants should be able to understand and appreciate:

- the nature and purpose of the research in question;
- why they, as opposed to others, are being selected and asked to participate;
- the fact that the suggested intervention is for research purposes;
- the relevant elements of uncertainty about the project;
- what participation in the particular research protocol means for the participant;
- whether or not the intervention may provide any direct personal benefit to them;
- how the consequences of a decision to participate or not to participate will affect their own current and future circumstances;
- that they will be free to withdraw from participation at any time during the course of the protocol;
- that a decision not to participate or to withdraw from participation will not adversely affect their care;
- any conflict of interest on the part of the person recruiting the participants or conducting the study;
- the confidentiality of any records that identify the participant;
- research that involves physical contact or physical activity and, whether compensation or social and psychological support will be available if the participant is harmed and where to get further information about this;
- who can answer questions about the research, including the principal investigator and a neutral third party who can explain the rights of research participants.

Decision-making capacity refers to 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.

Assessing decision-making capacity is a question of determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it.

One may therefore have diminished capacity in some respects but still be able to decide whether to participate in certain types of research. Researchers should be aware of all applicable legal and regulatory requirements with respect to

decision-making capacity and/or consent. These may vary among jurisdictions. Authorized third parties who are asked to make a consent decision on behalf of a prospective participant should also be aware of their legal responsibilities.

Those who lack the capacity to decide on their own behalf must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of decision-making capacity be used to inappropriately include them 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: (*TCPS2*, 2022, 3.9).

a. The researcher involves participants who lack the capacity to decide on their own behalf to the greatest extent possible in the decision-making process;
b. The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
c. The authorized third party is not the researcher or any other member of the research team;
d. The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and
e. When authorization for participation was granted by an authorized third party, and a participant acquires or regains decision-making capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

Broad Consent for the Storage of Data and Human Biological Materials for Future Unspecified Research

Broad consent is defined as consent for future unspecified research (subject to applicable law). Unlike blanket consent, which is typically unrestricted, broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry). Broad consent applies to the storage and secondary use of participants' data and human biological materials collected for research purposes. The use of broad consent is in the context of future research using data and human biological materials with no direct contact or intervention with participants at that time. While blanket consent is not permitted under the TCPS, broad consent is permitted (TCPS2, 2022, 3.13).

When seeking consent for a specific research project at the same time as seeking

consent for storage of data and human biological materials for future unspecified research, prospective participants must be provided with an option to consent to each separately.

To seek broad consent for the storage and future unspecified use of data and human biological materials, researchers shall provide prospective participants, or authorized third parties, with applicable information as set out in Articles 3.2 and 12.2 in the TCPS as well as the following details, as appropriate to the particular research project:

a. the type, identifiability, and amount of data and human biological materials being collected and stored for re-use, and for what potential purpose;
b. the voluntariness of the participant's consent, including any limitations on the feasibility of withdrawal;
c. a general description of the nature and types of future research that may be conducted, including whether the research might be conducted outside of Canada (if known);
d. the risks and potential benefits of storage of data and human biological materials, and of their use in future unspecified research, including areas of uncertainty where risks cannot be estimated;
e. access to a general description of the repository and its governance;
f. a statement regarding participants' preference to being re-contacted for additional future research;
g. whether the data or human biological materials could be shared with researchers who are not subject to the TCPS;
h. whether the research will (if known) or might include whole genome sequencing or similar technologies that may pose a substantial risk of re-identification of the participant or identification of material incidental findings (when appropriate);
i. whether linkage of data gathered in the research or derived from human biological materials with other data about participants – either contained in public or personal records – is anticipated (Article 5.3); and
j. separate options for consenting to participate in a specific research project and for consenting to the storage of data and human biological materials for future unspecified research.

Principle of Assent

Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation (*TCPS2*, 2014, 3.10).

Many individuals who lack legal capacity to make decisions may still be able to express their wishes in a meaningful way, even if such expression may not fulfil

all of the requirements for consent. Prospective participants may be capable of verbally or physically assenting to, or dissenting from, participation in research.

Those who may be capable of assent or dissent include:

- those whose decision-making capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing;
- those who once were capable of making an autonomous decision regarding consent but whose decision-making capacity is diminishing or fluctuating; and
- those whose decision-making capacity remains only partially developed, such as those living with permanent cognitive impairment.

While the assent of individuals who lack legal capacity to make decisions would not be sufficient to permit them to participate in the absence of consent by an authorized third party, their expression of dissent or signs suggesting they do not wish to participate must be respected.

Research directives

Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process (TCPS2, 2014, 3.11).

Consent shall be documented

Evidence of consent shall be contained either in a signed consent form or by the researcher utilizing another appropriate means of consent, which shall be documented (TCPS2, 2014, 3.12). The researcher shall bear the onus to comply with the REB guidelines and standards for free and informed consent and must satisfy the REB that all elements of consent have been addressed.

Written consent in a signed statement from the participant is a common means of demonstrating consent, and in some instances, is mandatory. However, written documentation of consent is not required. Where consent is not documented in a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes and other strategies, for documenting the consent process. Consent may also be demonstrated solely by the actions of the participant (e.g., through the return of a completed questionnaire).

Where individual written consent is inappropriate, either because of the nature of the research or the characteristics or culture of the proposed research participants, an alternative process for consent should be developed by the researcher and details of the alternative process should be submitted to the REB for review and approval.

Whether or not a consent form is signed, it may be advisable to leave a written

statement of the information conveyed in the consent process with the participant. For participants, it is evidence that they have agreed to participate in a particular research project. It may serve as a reminder to participants of the terms of the research project. It may also facilitate the ability of participants to consider and reconsider their involvement as the research proceeds. However, researchers should not leave any documentation with participants if it may compromise their safety or confidentiality. Additionally, in some cases it may not be appropriate to leave a written statement, such as in cultural settings where such written documentation is contrary to prevailing norms.

Consent and Disclosure of Information

Informed consent means a choice based upon all relevant information concerning the proposed research. The researcher must provide information concerning the purpose and nature of the research, the potential harms and benefits, and the process of research participation as outlined above in *Consent Shall Be Informed.*

Information must be provided to the participant in a way that meets the following requirements:

- in the prospective research participant's preferred language;
- in lay terms that avoid the overuse of technical terms;
- preferably in the first or second person (e.g., "you" or "your child");
- at an appropriate level for the person's age and educational level; and
- with descriptive accounts of relevant information.

Voluntariness of consent

For consent to be voluntary, free and genuine, an individual must have the opportunity to choose between consent and refusal, without undue interference, fear, constraint, compulsion or undue inducement. Undue influence includes physical duress; fraudulent misrepresentation, or promises of companionship, or affection; economic incentives; emphasis on benefits over risks or burdens; or appeals to emotional weaknesses, loyalty to professional care givers, or family solidarity.

Particular care must be taken in cases where the prospective research participants are students, or employees, or are dependent upon family or other care-givers, or where the prospective participants are in long-term care facilities and other institutional settings.

Payments or incentives to participate must be reasonable and must not place undue pressure on research participants either to join or remain within a research project.

Potential research participants should not feel rushed or coerced and they should have the time to consult with others.

Exceptions and alterations to normal consent requirements

The REB may approve a consent procedure which does not include, or which alters some or all of the elements of the normal requirements for informed consent, or waive the requirement to obtain informed consent, provided that the REB can be offered a rationale that:

a. The research involves no more than minimal risk to the participants;
b. The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
c. The research could not be practicably carried out without the waiver alteration;
d. Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
e. The waiver or altered consent does not involve a therapeutic intervention.

When in doubt about an issue involving free and informed consent, researchers should consult the REB.

Deception

Prospective participants normally must be fully informed about the purpose of the study before being asked to agree to participate. There may be legitimate reasons, however, for needing to withhold specific details about a study. In this situation, it is the researcher's responsibility to provide sufficient detail on the application form about the nature of the deception as well as a rationale for why it is necessary.

Research participants involving deception must be involved in a debriefing session at the end of their participation. This debriefing session serves as an opportunity to provide participants with an explanation for why deception was required to answer any questions in regard to the use of deception. In cases where the research may have impacted upon the psychological health or well-being of the participant, it may be appropriate to provide additional follow-up or to offer counseling or other types of assistance.

The REB requests that researchers seek written consent from participants to use the data obtained in the research that employed the deception. Once the deception is revealed, participants should be given a contact on the REB if they have any concerns about the conduct of the research.

Privacy and Confidentiality

Privacy. Privacy refers to an individual's right to be free from intrusion or

interference by others. It is a fundamental right in a free and democratic society. Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy. An important aspect of privacy is the right to control information about oneself (*TCPS2*, 2022, Chap. 5A).

The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information.

Confidentiality. The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft (*TCPS2*, 2022, Chap. 5A).

Security. Security refers to measures used to protect information. It includes physical, administrative and technical safeguards.

Identifiable Information. Where researchers seek to collect, use, share and access different types of information or data about participants, they are expected to determine whether the information or data proposed in research may reasonably be expected to identify an individual. Information is identifiable if it may reasonably be expected to identify an individual, when used alone or combined with other available information. Information is non-identifiable if it does not identify an individual, for all practical purposes, when used alone or combined with other available information. The assessment of whether information is identifiable is made in the context of a specific research project. Researchers and REBs shall consider whether information proposed for use in research is identifiable. The following categories provide guidance for assessing the extent to which information could be used to identify an individual:

- Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
- Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-

identification of individuals from remaining indirect identifiers is low or very low.
- Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Ethical duty of confidentiality

Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality (*TCPS2*, 2022, 5.1).

Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements in application materials they submit to the REB; and during the consent process with prospective participants (*TCPS2*, 2022, 5.2).

Researchers shall provide details to the REB regarding their proposed measures and data management plan throughout the data life cycle for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal (*TCPS2*, 2022, 5.3).

Institutions or organizations where research data are held have a responsibility to establish appropriate institutional security safeguards.

Research participants have a right to privacy and researchers have a corresponding duty to treat private information in a respectful and confidential manner. When reviewing applications for approval, the REB must balance the need for research against infringements of privacy; invasions of privacy must be minimized as much as possible. The value of privacy of research participants is not absolute, some public interests such as protection of health, life and safety may require infringement of the right to privacy, as may the type of research being conducted; without access to personal information, it would be difficult if not impossible to conduct important societal research in such fields as epidemiology, history, genetics and politics.

Different cultures will value privacy in different ways and these values must be respected. The issue of privacy must be looked at from the cultural perspective of the participant, not the researcher. As a general guide, the best protection of the confidentiality of personal information and records will be achieved through anonymity. Researchers are responsible for ensuring the confidentiality of data on research participants by maintaining such data in secure storage and by limiting access to data to authorized individuals.

The REB is required to review research projects in adherence to both provincial and federal privacy laws.

Group Research Events and the Limits of Confidentiality

When information is gathered in a group setting (including focus groups) for research, the following statement or a statement of a similar nature needs to be included in the confidentiality section of the Letter of Information and the Consent Form:

"The focus group is a group event. This means that while confidentiality of all the information given by the participants will be protected by the researchers themselves, this information will be heard by all the participants and therefore will not be strictly confidential."

Researchers must discuss how they plan to manage the inherent risks to confidentiality that are present in group research events.

Disclosure of Results

In all cases, where data have been obtained, research participants have the right to request and receive the results and interpretation of grouped data within a reasonable period of time. The investigator has the responsibility to present individual data, accurately, sensitively, and in a language comprehensible by the participant. Researchers may also articulate an intention to select information that will be reviewed and then communicated to participants under certain circumstances as part of the research plan.

Immediate full disclosure of results may not be feasible in all cases, for example where data has been collected over an extended period of time. Disclosure of results may have to be deferred until the end of the project. In some cases, it may be more appropriate to disclose the results to the parents, guardians or authorized third parties, or the entire family or community.

Equitable Distribution of Research Benefits

Researchers should consider ways to ensure the equitable distribution of any benefits of participation in research.

Researchers should also be sensitive to the expectations and opinions of participants regarding potential benefits of the research. Prior to the commencement of the research, researchers should formally or informally discuss these expectations with individuals and/or groups, and outline the scope and nature of potential benefits that may accrue to participants during and after the research. REBs should be vigilant to ensure that the proposed distribution of benefits is fair, without imposing undue burdens on the researcher that would make it too difficult or costly to complete research (TCPS2, 2022, Chap. 4).

Researchers should normally provide copies of publications, or other research reports or products, arising from the research to the institution or organization – normally the host institution – that is best suited to act as a repository and disseminator of the results within the participating communities. In general, researchers should ensure that participating individuals, groups and communities are informed of how to access the results of the research. Results of the research should be made available to them in a culturally appropriate and meaningful format, such as reports in plain language in addition to technical reports.

Conflict of Interest

Researchers and REB members must disclose actual, perceived or potential conflicts of interest.

Conflicts of interest involving researchers

Conflicts of interest most often arise out of the structural features of relationships or practices. In many situations it is impossible to eliminate conflicts of interest, however, they must be identified so that steps can be taken to disclose them openly and to control their impact. Conflicts of interest may or may not involve financial or monetary interests. The central issue is that individuals may be drawn in two directions at once in such a manner that their judgment may be affected, or their motives may be open to question (*TCPS2*, 2022, 7.4).

To identify and address conflicts properly, researchers must advise the REB on budgets, commercial interests, consultative relationships and any other relevant information, if requested. When a significant real or apparent conflict of interest is apparent, the REB may require the researcher to disclose this conflict to the prospective participants during the informed consent process.

The REB should seek to ensure that financial considerations do not serve to diminish respect for the principles of this Policy or the scientific validity and transparency of research procedures (TCPS2, 2022, Chap. 7).

To assess the likelihood of a real or an apparent conflict of interest which must be disclosed, researchers should consider:

- Whether an outside observer would question the ability of the individual to make a proper decision despite possible considerations of private or personal interests;
- Whether the public would believe that the trust relationship between the relevant parties are a conflict of interest.

Management of multiple roles

Multiple roles of researchers and their associated obligations (e.g., acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue

influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures (e.g., consent of participants). To preserve and not abuse the trust on which many professional relationships rest, researchers should be fully cognizant of conflicts of interest that may arise from their dual or multiple roles, their rights and responsibilities, and how they can manage the conflict. When acting in dual or multiple roles, the researcher shall disclose the nature of the conflict to the participant in the consent process (TCPS2, 2022, Chap. 7).

Conflicts of interest by REB members

If the REB is reviewing research in which a member of the Board 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.

No member of an REB should review research in which he or she has any conflict of interest, including any personal involvement or participation in the research, financial interest in the outcome, involvement in competing research, or an interest as a supervisor of a student researcher, for the purpose of carrying out the research project.

Institutional conflict of interest

The REB maintains an arms-length relationship with the University and is an autonomous board with a mandate to ensure that all research involving human participants are in compliance with the current version of the *TCPS*, including avoiding and managing real and apparent conflicts of interest between the institution and human research participants (*TCPS2*, 2022, 7.1).

Conflicts of interest will be managed per the guidance in the TCPS2 (2022), subsequent guidance, and the University of Windsor Conflict of Interest Policy.

SPECIFIC RESEARCH METHODOLOGIES AND DOMAINS

Qualitative research

Issues regarding the ethical conduct of research using qualitative methods are discussed in detail in Chapter 10 of the TCPS2 (2022).

Qualitative research may pose special ethical issues around gaining access, building rapport, using data and publishing results. Researchers and REBs should consider issues of consent, confidentiality and privacy, and relationships between researchers and participants in the design, review and conduct of the research. Some of these may be identified in the design phase. Others will arise during the research itself, which will require the exercise of discretion, sound judgment and

flexibility commensurate with the level of risk and potential benefit arising from the research, and considering the welfare of the participants, individually or collectively.

Clinical trials

Detailed information about ethical considerations when conducting clinical trials is provided in Chapter 11 of the TCPS2 (2022).

Human biological materials and genetic research

Detailed information about ethical considerations when conducting research with human biological materials and genetic research is provided in Chapters 12 and 13 of the TCPS2 (2022).

Naturalistic observation

Ethics review is normally required for research involving naturalistic observation. Naturalistic observation which does not allow for the identification of the participants and that is not staged should normally be regarded as of minimal risk and eligible for expedited review.

REB review is not required for research involving the observation of people in public places where (*TCPS2*, 2022, 2.3):

a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
b. Individuals or groups targeted for observation have no reasonable expectation of privacy; and
c. Any dissemination of research results does not allow identification of specific individuals.

Projects involving the use of naturalistic observation where it is clear that the participants are seeking public visibility (for example at political rallies, demonstrations or public meetings) and where participant confidentiality and anonymity are ensured do not require ethics review.

Secondary use of data

Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose.

Secondary use of data is the use in research of data contained in records collected for a purpose other than the research itself, such as patient or school records, or records from previously conducted research.

Reasons to conduct secondary analyses of data include: avoidance of duplication in primary collection and the associated reduction of burdens on

participants; corroboration or criticism of the conclusions of the original project; comparison of change in a research sample over time; application of new tests of hypotheses that were not available at the time of original data collection; and confirmation that the data are authentic.

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information (*TCPS2*, 2022, 2.4).

If the participants were anonymous or the information collected was completely anonymized under a prior REB clearance, then REB review is not required for subsequent use.

Privacy concerns and questions about the need to seek consent arise when information provided for secondary use in research can be linked to individuals, and when the possibility exists that individuals can be identified in published reports, or through data linkage. Privacy legislation recognizes these concerns and permits secondary use of identifiable information under certain circumstances (TCPS2, 2022, Chap. 5D).

Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied the REB that (*TCPS2*, 2022, 5.5A):

a) identifiable information is essential to the research;
b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

In the case of secondary use of identifiable information, researchers must obtain consent unless the researcher satisfies requirements a through f listed above.

"Impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.

Right to provide permission for secondary use

At the time of initial collection, individuals may have had an opportunity to express preferences about future uses of information, including research uses. Data stewards have an obligation to respect the individual's expressed preferences. For example, where an individual does not want information used for future research, data stewards shall remove this information from any datasets used or made available for research.

Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information, where the data have been anonymized and it is not possible to identify any specific participant or their data.

When secondary use of identifiable information without the requirement to seek consent has been approved, researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact (TCPS2, 2022, 5.6).

Data linkage

Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage (*TCPS2*, 2022, 5.7).

Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that: the data linkage is essential to the research; and appropriate security measures will be implemented to safeguard information.

SUBMITTING RESEARCH FOR REVIEW: APPLICATION PROCESS

What to submit

All forms that researchers must file with the REB are available on the REB website (https://www.uwindsor.ca/research-ethics-board/).

The Office of Research Ethics can assist researchers with the completion of the application and with any questions relating to the ethics review process (519-253-3000 x3948; ethics@uwindsor.ca).

Other items to include in applications

One digital copy of the application form and all accompanying material must be

submitted including an original, signed signature page to the Office of Research Ethics.

Applications should be accompanied by: (where applicable)

- a copy of all questionnaires or test instruments;
- a copy of any recruitment notices, e-mails, advertisements or any other material to be used to solicit participation;
- a description of any verbal explanation to be given to participants before they are asked to consent to participate in the study;
- a transcript of any script(s) to be used;
- a copy of any consent form(s) to be completed;
- a copy of any debriefing script/research summary sheet or materials to be provided to the participants;
- copies of all contracts relevant to the conduct of the research
- copies of all letters of permission required to gain access to sites, participants, information, secondary data, etc.;
- any other material relevant to the REB decision.

REQUIREMENTS FOR ADDITIONAL CERTIFICATIONS AND APPROVALS

Researchers are responsible for obtaining any additional certifications or approvals that are required prior to conducting the research, and submitting copies of approvals to the REB. Such certifications may be internal to the University of Windsor, or from an external agency or authority.

REB clearance does not provide certification in any of the following areas, each of which requires review by another committee at the University, including but not limited to:

- Biosafety
- Radiation
- Chemical Control
- Animal Care

In addition, research involving human pluripotent or human totipotent stem cells that have been derived from an embryonic source, and/or that will be grafted or transferred in any other form into humans or non-human animals requires review and approval by the Stem Cell Oversight Committee (SCOC) as well as the REB. The researcher shall provide evidence of SCOC approval to the REB. SCOC reviews research involving human pluripotent and human totipotent stem cells that:

- have been derived from an embryonic source; and/or
- will be transferred into humans or non-human animals.

SCOC does not review research involving human pluripotent stem cells that come

from somatic (non-embryonic) tissue and that are not going to be transferred into humans or non-human animals (TCPS2, 2022, 12.10).