

INTRODUCTION

The purpose of the ethical standards embodied in this policy is to promote and facilitate the conduct of all research in ways that respect the dignity and preserve the well-being of human research subjects, the researcher and the institution without limiting acceptable research activities. The TRU Standards for the Protection of Human Research Participants (TRU Standards), throughout its evolution, has consistently presented a set of ethical principles and ethics review procedures that reflect the commitment of TRU and its members to national and international norms that have developed across a wide variety of fields, including the humanities, the arts and natural, medical and social sciences. It is our aim to ensure safeguards for the subject and the researcher and protect the integrity of the institution.

1.1.1 Definitions, Purview of the TRU Standards

The term researcher when used in the TRU Standards includes:

- a. any member who conducts or advances research in that capacity or who accesses Thompson Rivers University students or staff as human research participants;
- b. any other person who conducts or advances research as connected with TRU; and
- c. any person who conducts research using TRU resources (whether research space, materials, equipment or human resources)

The term member when used in the TRU Standards includes faculty, emeritus faculty, staff, sessional instructors, administrators, students, visiting or adjunct scholars, fellows and chairs, paid and unpaid research associates and assistants and any person in a like position.

The TRU Standards apply to each person who meets the above stated definition of researcher whether acting as a principal investigator, a junior collaborator or in some other capacity. Thus, a junior collaborator who meets the definition of researcher must conform to the TRU Standards even if the principal investigator for the research does not meet the definition of researcher and accordingly does not fall under the purview of the TRU Standards.

1.2 ADOPTION AND INCORPORATION OF ETHICAL PRINCIPLES AND ARTICLES OF THE TRI-COUNCIL POLICY

The Medical Research Council, the Social Sciences and Humanities Research Council of Canada and the Natural Sciences and Engineering Council jointly issued a national human research ethics policy in 1998 entitled Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (that policy as revised or amended from time-to-time by the three Councils is referred to here as the Tri-Council Policy). The TRU Standards are consistent with, and reflect the adoption by TRU of, the Ethical Principles and requirements of the Articles of the Tri-Council Policy. All members, researchers and all other persons responsible for the development and implementation of the TRU Standards, whether as Research Ethics Committee – Human Subjects(REC-HS) members or administrators, shall implement those ethical principles and articles as adopted in the TRU

Standards. From time-to-time as the Ethical Principles and/or requirements of the Articles of the Tri-Council Policy are revised or amended any such revision or amendment shall be deemed to be an amendment and revision to corresponding sections of the TRU Standards.

1.3 GUIDING ETHICAL PRINCIPLES

Researchers contribute to human welfare by acquiring knowledge and applying it to human problems. They simultaneously consider two types of obligations in the design and conduct of research. One of these obligations is to conduct research as capably as their knowledge permits, and another is to protect the dignity and preserve the well being of human research participants.

1.3.1 Respect for Human Dignity

The cardinal principle of modern research ethics is respect for human dignity. Such respect requires that researchers protect the multiple and interdependent interests of the person - from bodily to psychological to cultural integrity - as they may be affected by the research. This principle forms the basis of the remaining ethical principles described in the following subsections.

Conflicts may sometimes arise from the application of these principles in isolation from one another. Researchers and REC-HS must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

1.3.2 Respect for Free and Informed Consent

Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research participant.

1.3.3 Respect for Vulnerable Persons

Respect for human dignity entails high ethical obligations towards vulnerable persons—to those whose lack of competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

1.3.4 Respect for Privacy and Confidentiality

Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying privacy, confidentiality and anonymity respected.

1.3.5 Respect for Justice and Inclusiveness

Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research proposals, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly

burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

1.3.6 Balancing Harms and Benefits

The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance—that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefit analysis thus affects the welfare and rights of research participants, the informed assumption of harms and benefits, and the ethical justification for competing research paths.

This is not to say that harm may not result from research. In some areas of research such as political science, economics or modern history, there may be occasions in which research ethically results in harm to the reputations of organizations or individuals in public life.

There is often uncertainty about the magnitude and kind of benefits or harms that may result from proposed research and a resultant uncertainty about the balance of benefits and harms. This uncertainty imposes an obligation to conduct research at a high level of competency in order to maximize the potential benefits of the research.

1.3.7 Minimizing Harm

A principle related to achieving a favorable harms-benefit balance is that of non-maleficence, or the duty to avoid, prevent or minimize harm. Research procedures which might cause serious or lasting harm to a participant must not be used unless their absence would expose the participant to a risk of even greater harm. Research participants must not be subjected to unnecessary risks of harm. Their participation must be essential to achieving scientifically and societally important aims that cannot otherwise be realized. Minimization of harm also requires that research involve the smallest number of human participants and the smallest number of tests on them that shall ensure scientifically valid data. Should adverse effects result from research procedures, the researcher has an obligation to assist the participant in reducing or eliminating those effects.

1.3.8 Maximizing Benefit

Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize benefits. The principle has particular relevance for researchers in areas such as social work, education, health care and applied psychology. Benefits of research may accrue to the research participants themselves, to other individuals or to society as a whole, or to the advancement of knowledge. In most research, the primary benefits are for society and for the advancement of knowledge.

1.3.9 Methodology

If there is more than minimal risk in the research proposal, methodology will be examined by the Research Ethics Committee – Human Subjects because if it is bad methodology then there is no benefit in doing the research and thus any risk to the subject outweighs the lack of benefits.

1.3.10 Minimal risk

Risk of harm is no greater than what the subject encounters in everyday life. This is to be determined from the point of view of the subject. Researchers must be careful not to exploit the

subjects whose lives are considered to involve daily high levels of risk-taking (e.g. prisoners, homeless teenagers, etc.)

Risk and harm are to be determined by considering:

- magnitude of harm
 - probability of harm
- The subject-centred perspective must be adopted when considering these

elements. Harm may be:

physical
psychological
social
legal
economic
affronts to dignity

1.4 RESEARCH REQUIRING ETHICS REVIEW

1.4.1 Research

For the purpose of the TRU Standards, research involves a systematic investigation to establish facts, principles or generalizable knowledge.

1.4.2 Research that Must Receive Ethics Review

All research that involves living human participants or involves human remains, cadavers, tissues, biological fluids, embryos or foetuses (except as stipulated in this 1.4.2) requires review and approval by an REC-HS before the research is started regardless of:

- a. whether it is funded (eg, by grant, award, fellowship, contract) or is non-funded;
- b. whether funding is internal (ie, University) or is from an external source (including domestic and foreign public, governmental, and private sources);
- c. whether participants are drawn from University sources or from any other sources (eg, workplaces, residences, public places, day care centres, non-University hospitals, other universities, the military, public/private/separate schools);
- d. whether participants are paid or unpaid;
- e. whether it is conducted inside or outside Canada;
- f. whether it is conducted on University property or at any other location;
- g. whether it is conducted in a laboratory or in the field;
- h. whether it is conducted in person or by some other means (eg, mail, telephone, computer link);
- i. whether information is collected via direct observation, apparatus, questionnaire, interview, or review of records or other materials not normally available to the public;
- j. whether it is experimental, correlational, qualitative, or descriptive in nature;
- k. whether it is conducted to acquire basic or applied knowledge (eg, safety and function assessments of equipment and materials, product development assessments, personnel selection, consumer preferences, and product evaluation);

- l. whether the information collected has as its focus the human participant or some aspect of the environment with which the human participant interacts;
- m. whether the research is a pilot study or a fully developed project;
- n. whether it is primarily for teaching or demonstration purposes or whether the primary purpose is the acquisition of new knowledge;
- o. whether or not it is intended for publication or other public presentation.

Research about living persons, including persons in public life and artists, based on information contained in publicly available materials is not subject to REC-HS review unless the subject, or a third-party, is approached directly for interviews or for access to private papers or other materials, and then only to ensure that such approaches are conducted according to professional protocols. Note that research involving the observation, assessment, or recording of public behavior normally does require REC-HS review. However, research involving observation of participants in, for example, political rallies, demonstrations, public meetings or similar activities does not require REC-HS review since it can be expected that the participants are seeking public visibility and therefore observation and possible recording.

Quality assurance studies, performance reviews of an organization, or its employees or students within the mandate of the organization, or testing within normal educational requirements, are not subject to REC-HS review unless they contain an element of research in addition to assessment. Researchers shall seek the advice of their REC-HSs whenever there is any ambiguity or doubt about the applicability of the TRU Standards to a particular project.

Procedures and practices exclusively used for pedagogic purposes (eg, classroom discussion, practicum observation), without a research component are not subject to REC-HS review. Such procedures and practices do require attention to other professional standards of ethical conduct.

1.4.3 Student Honours Projects

In order to be eligible for graduation, students who are doing research as part of their honours projects must submit evidence that their project has been approved by the appropriate D/SERC. The honours student's supervisor is requested to include the official signed REC-HS approval form with the thesis copy that is retained by Thompson Rivers University.

1.5 AUTHORITY, MANDATE AND MEMBERSHIP OF REC-HS 1.5.1 Authority

Authority for ethics review is this policy as approved by Education Council of Thompson Rivers University, with the Office of the Vice-President Academic responsible for implementation of the TRU Standards as well adherence to the Tri-Council policy. Authority is also established under The Integrity in Research and Scholarship policy ED-15-2 policy as well as the Undergraduate Student Research policy.

1.5.2 Mandate

Thompson Rivers University REC-HS is mandated to approve, reject, propose modifications to, or terminate any proposed or ongoing research which is subject to REC-HS review pursuant to the TRU Standards. A decision of the REC-HS to allow research on ethical grounds is final. A decision of the REC-HS to disallow research on ethical grounds, unless reversed by that REC-HS on a reconsideration pursuant to the TRU Standards, may be reversed only through the appeal process

described in this policy.

The REC-HS shall suspend any ongoing research under its purview that it deems to pose an unacceptable risk of harm to participants

Research that has not been submitted to and approved by the REC-HS as required pursuant to the TRU Standards cannot be undertaken. Non-compliance with this provision may constitute misconduct under TRU Integrity in Research and Scholarship Policy ED-15

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1.5.3 Membership of REC-HS and Qualifications of Members

Composition

Ethicist from TRU Faculty
Faculty Member from each Division or School
Faculty member from Psychology
Faculty member from Social Sciences
Administrator
Coordinator, Research Services
Counsellor
Williams Lake Representative
Community Representative
Lawyer (volunteer)

- Student A quorum will consist of a simple majority of voting members. The chair is to be chosen from among the membership. Members are to serve a two-year term. The student member is to serve a one-year term.

1.6 REC-HS ASSESSMENT, DECISION-MAKING AND PROCEDURES

1.6.1 Proportionate Approach to Ethics Assessment

Thompson Rivers University uses a proportionate approach to ethics assessment as recommended in the Tri-Council Policy. The more potentially harmful the research is to participants, the greater shall be the ethical scrutiny to which the research is subjected.

Except as permitted here, any ethics review required by the TRU Standards shall be a full REC-HS assessment at a meeting as provided in the TRU Standards. The TRU Standards provide for an RECHS to establish an expedited review process by the REC-HS Chair or a member or members of the REC-HS designated by the Chair where the research subject to the review is deemed to pose no more than minimal risk. The TRU Standards also provide for Divisions to adopt procedures by which research to be conducted by undergraduate students as part of their course work can be reviewed by specially constituted Divisional/School ethics review boards who report annually to the REC-HS, provided the research poses no more than minimal risk.

1.6.2 Ethics Proposals and Determination of Review Level Required

The REC-HS shall establish and publicize a regular schedule of meetings and notify researchers in its constituency about submission dates for proposals prior to the meetings. Frequency of meetings should reasonably reflect the needs of researchers.

Undergraduate courses are a significant source of proposals for human ethics review. Proposals may be for

classroom or laboratory demonstration of human research procedures or result from the assignment to students of research projects that are conducted outside the classroom. Because the underlying principle is that of protection of human participants, all such procedures must be reviewed. In order to assist instructors of such courses, special procedures for course instructors should be developed. For example, instructors might be able to propose several projects within a single application for their courses. When the same procedures and projects are used from year to year in a course, continuing approval may be granted by the REC-HS for a fixed number of years, at the conclusion of which a renewal of the approval may be requested. Divisional/School Ethics Review Committees might arrange meeting dates that coincide with the timing of course research assignments.

Ethics review pursuant to the TRU Standards shall be based upon fully detailed research proposals. Undergraduate researchers shall submit their proposals for ethics assessment in the format prescribed to either the Divisional/School Ethical Review Board Chair or such person designated by the Chair to assess the level of review required. The Chair or designate shall determine whether the proposal poses greater than minimal risk and therefore must receive full REC-HS review at a meeting of the REC-HS or poses no more than minimal risk and therefore may receive Divisional/School ethical review.

The standard of minimal risk is commonly defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects. There is a similar threshold regarding undue or excessive offers of benefit. As an offer of payment in relation to research participation exceeds the normal range of benefits open to the research subject, it is increasingly likely to amount to an undue incentive for participation. (*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans ICI*) The work of the REC-HS should be unconstrained by the implications of their decisions for research funding. For this reason, ethics review of research funding proposals normally shall be reviewed prior to submission of proposals to the funding agencies, even if the funding agency accepts post-submission ethics review results. If a full review cannot be completed prior to funding application submission, however, REC-HS Chairs are authorized to conduct a preliminary review and when appropriate issue a provisional ethics approval for the project. Final approval shall be contingent on complete review of the proposal at a meeting of the REC-HS, or where permitted and appropriate, through the REC-HS expedited review procedure.

Funding organizations sometimes require or accept proposals written at a general level of description (ie, the proposals are not fully detailed). In such cases, ethics assessment and approval shall apply only to the funding proposal. Researchers subsequently must submit fully detailed proposals to their REC-HS for review prior to commencement of the research.

1.6.3 Scholarly Review

The REC-HS shall satisfy itself that the research design and methods of projects that pose more than minimal risk are capable of addressing the questions being asked in the research.

REC-HS shall base its judgement about scholarly value on a global assessment of the degree to which the research might further the understanding of a problem, issue or phenomenon; it shall not be based on methodological biases or a preference for particular procedures or on the judgement that another approach is possible. REC-HS shall recognise that theoretical or methodological preferences are often open to debate and take this into account to ensure fair judgement. The committee may consult outside experts, if necessary.

There is no such thing as a definitive study; the significance of any individual study, even when viewed in retrospect, is not always immediately apparent and can be trivialised. Accordingly, the benefit of a particular research project should often be judged within the context of a research program, taking into account the expertise and experience of the researchers. An integral part of some research programs is the pilot study, the results of which may be only suggestive but which can provide important indications of how to proceed with the research. The value of pilot studies is often indirect and may be better evaluated in the broader context of

a research program; otherwise, pilot studies are evaluated under the normal ethical guidelines

Research in the humanities and social sciences which poses, at most, minimal risks shall not normally be required by the REC-HS to be peer reviewed in order to determine capacity to address the questions being asked.

Certain types of research, often from social science and humanities disciplines, may legitimately have negative effects on public figures or on organizations. Such research should not be disallowed automatically because of a negative imbalance of benefits and harms. The safeguard for those in the public arena is through public debate and discourse and through action in the courts.

1.6.4 Decision-Making Standards and Review Procedures

The TRU Standards form the basis of decision-making by REC-HS. REC-HS shall be familiar with the commentary contained in the Tri-Council Policy and shall refer, where appropriate, to other external policies and commentaries (eg, the Canadian Code of Ethics for Psychologists of the Canadian Psychological Association; Ethical Principles for the Conduct of Research in the North of the Association of Canadian Universities for Northern Studies.)

REC-HS meetings at which full reviews of proposals are conducted shall be face-to-face.

The REC-HS shall invite researchers to participate in discussions of their proposals, but the researchers cannot be present when the REC-HS make its decisions.

The REC-HS shall develop procedures to ensure the impartiality and fairness of the review processes and to avoid conflicts of interest. Members shall not be present during REC-HS discussions of research with which they are associated, whether the proposal is from a student, faculty member, or external researcher.

Decisions of REC-HS shall be reached by consensus wherever possible. If the REC-HS cannot achieve consensus, however, the decision shall be based on majority vote.

For expedited reviews (e.g., during the summer when quorum may be impossible), the decision to approve must be made by consensus if two or more REC-HS members conduct the review. Lack of consensus in such cases shall automatically result in referral of the proposal for full REC-HS assessment unless the applicant chooses to withdraw the proposal.

When an REC-HS identifies factors that may jeopardize the well-being of human participants, such issues should be resolved cooperatively by the REC-HS and the researcher. When the REC-HS considers a negative decision, it shall provide the researcher with all reasons for doing so and give the researcher an opportunity to reply before making a decision.

When an REC-HS decides to deny an application or makes approval contingent on changes to the proposal, researchers have a right to request, and REC-HS has an obligation to provide, reconsideration based on the researcher's rebuttal to the concerns identified by the REC-HS.

The REC-HS does not consider granting retroactive approval of already initiated or completed research projects. Even in cases where no harm has occurred to the participants, the veracity of the research process, and the role responsibility of the research ethics committee has been negatively impinged upon.

When a REC-HS decides to deny an application or makes approval contingent on changes to the proposal, it shall provide the researcher with written grounds for the decision.

See also: Guidelines for Research and Other Studies involving Human Subjects

1.6.5 Record Keeping

Minutes of all REC-HS meetings shall be prepared and maintained by the REC-HS. The minutes shall clearly document the REC-HS's decisions and any dissents, and the reasons for them. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes must be accessible to authorized representatives of the institution, researchers, and funding agencies.

The REC-HS shall maintain one copy of each research proposal it considers, either during face-to-face meetings or through expedited review, as part of its records.

The REC-HS may establish additional requirements for record-keeping relevant to granting agency requirements, and to legislative requirements (eg, the Province of British Columbia Freedom of Information and Protection of Privacy Act). The minimum amount of time that REC-HS records shall be kept is three years beyond the completion of the specific approved project.

1.6.6 Review Procedures for Ongoing Research

Ongoing research shall be subject to continuing ethics review. The rigour of the review shall be in accordance with the proportionate approach to ethics assessment.

As part of each research proposal submitted for REC-HS review, the researcher shall propose to the REC-HS the continuing review process deemed appropriate for that project. The REC-HS shall determine the nature of the continuing review process, including the intervals at which the researcher must submit materials, if any, for review. Normally, continuing review shall consist of at least the submission of a succinct annual status report to the REC-HS.

Researchers are required to report to the REC-HS any changes in research design, procedures, sample characteristics, and so forth that are contemplated after REC-HS approval has been granted. The REC-HS through full or expedited review, depending on the nature of the proposed changes, must approve the changes before the modified research can proceed or continue.

Researchers are required to notify the REC-HS immediately if an untoward or adverse event occurs during their research or if data analysis or other review reveals undesirable outcomes for participants.

1.7 APPEALS OF REC-HS DECISIONS

An exterior University Research Ethics Committee shall serve as the Research Ethics – Human Subjects Appeal Board (*pending agreement*). A researcher who continues to dispute an RECHS decision following reconsideration by the Appeal Board may appeal that decision too. However, because ethics review and the observance of research ethics at Thompson Rivers University is based on the collegial relations between REC-HS and researchers, a request for appeal must be the last resort. The Appeal Board must be satisfied that all reasonable attempts to resolve disagreements cooperatively by the researcher and the REC-HS must have been exhausted before an appeal shall be heard by the Appeal Board. Bases for appeal are restricted to claims of procedural irregularity, lack of due process, and exceptions to precepts of natural justice such as bias. If such appeal grounds are substantiated, the Appeal Board shall in the first instance attempt to remedy the problem in the original REC-HS's procedures and direct that REC-HS to rehear the case. If a substantiated problem cannot be remedied, the Appeal Board shall hear the case de novo. Arguments based on the facts of the case are suitable for reconsideration by the original REC-HS, not for appeal to the Appeal Board. Decisions by the Appeal Board on appeal matters are final.

1.8 REVIEW OF OFF-CAMPUS RESEARCH

The jurisdiction of TRU to prohibit one of its members from conducting research which is subject to the ethics review process contained in the TRU Standards is not diminished by the fact that the research project shall be conducted outside the campus of TRU, whether in British Columbia, in Canada or elsewhere. Such research shall be subject to prospective ethics review both by the researcher's REC-HS, and by the applicable ethics board or process, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards where the research is to be conducted.

1.9 FREE AND INFORMED CONSENT

1.9.1 Normal Requirements

Research, except as otherwise permitted in Section 1.9.3, may begin only if prospective participants, or authorized third parties, have been provided the opportunity to give free and informed consent about participation, and their free and informed consent has been given and maintained throughout their participation in the research.

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion. Participants have given free and informed consent when they have freely agreed to serve in the study on the basis of well-understood information about the objectives of the research. They must be fully informed of all risks and possible benefits of their participation. The participants must have an opportunity to evaluate the relative weight of any risks and benefits of the proposed research that concerns them. Continuing voluntary participation requires that participants be assured that at any time their withdrawal consent to the research shall not result in penalty or harm or loss of promised benefits that are not inherently contingent on completion of participation.

The investigator must establish a fair agreement with the participant which clearly expresses the participant's respective obligations and responsibilities before the participant decides whether or not to participate. The researcher must inform the participant of all aspects of the research that could reasonably be expected to influence the participant's willingness to participate, and the researcher must explain all other aspects of the research that concern the participant, including aspects that involve financial gain.

Any incentive offered to participants must not be so large as to become an undue inducement that would undermine the voluntariness of their participation. Captive populations (such as prisoners and those involuntarily committed to mental institutions) must not be offered inducements that would unduly improve their situation or influence their relation to others. If the participants are students and are involved in research as part of their education, they must be given an opportunity to obtain equivalent experiences through alternative procedures. All monetary reimbursements and other incentives used to solicit participation must be clearly agreed to in writing. The investigator must honour all promises and commitments included in the agreement.

Special problems of consent and voluntariness arise when, in addition to being a research participant, there is a second relationship between research subject and a researcher. This may be of the nature of relationship between patient and physician, between student and teacher, between prison administrator and inmate, between employer and employee, and other like relationships. Researchers must evaluate these problems and take steps to eliminate them before the research can be undertaken. Consent must be obtained under conditions that do not involve explicit or implicit coercion that place limits on the freedom and voluntariness of participation.

1.9.2 Documentation of Consent

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

1.9.3 Exceptions

The REC-HS 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 REC-HS documents 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 practicably be carried out without the waiver alteration;
- d. whenever possible and appropriate, the participants shall be provided with additional pertinent information after participation; and
- e. the waived or altered consent does not involve a therapeutic intervention.

In studies including randomization and blinding, neither the research participants nor researchers may know to which condition participants have been assigned. Such methods are not regarded as a waiver or alteration of the requirements for consent if participants are informed of the probability of being randomly assigned to one condition of the study or another.

If the methodological requirements of a study make concealment of the goals of the study or the risk involved necessary, the investigator has a special responsibility to determine whether the use of these techniques is justified by the study's prospective scientific, educational, or applied value. The investigator must indicate why the objectives necessitate such concealment, and whether alternative procedures are available that do not use concealment. Studies involving concealment normally should not be conducted if there is greater than minimal risk involved because meaningful prior consent usually is not possible. Particularly in cases of concealment, it is necessary to advise participants that they can withdraw from the study at any time without penalty and without losing the guarantee of anonymity. In the case of behavioural and questionnaire research where full disclosure about the nature and objectives of the research could bias and invalidate results (for example, in communications intended to change attitudes or in studies of incidental learning), the explanation should be given immediately after data collection or as soon as is consistent with the research design and methods. Participants should be fully informed as soon as possible of the purposes and aims of the research, and any uncertainties should be removed. The investigator should remove any misconceptions that may have been fostered and should re-establish any trust in the research community which may have been lost, assuring the participant during post-briefing that the research procedures were neither arbitrary nor capricious, but necessary for scientifically valid findings.

Even when fully informed consent has not been obtained for participation, participants can sometimes exercise their consent at the conclusion of the study, following post-briefing. In cases where the participant expresses concerns about the study, the researcher may be able to give the participant the option of withdrawing his or her data. This approach should be used only when the withdrawal of the participant's data shall not compromise the scientific validity of the research.

1.9.4 Procedures for Obtaining Informed Consent

Researchers shall provide to prospective subjects, or to authorised third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Section 1.9.3, at the commencement of the free and informed consent process, researchers or their qualified designated representatives shall provide prospective participants, as a minimum, with the following:

- a. information that the individual is being invited to participate in a research project;

- b. comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
- c. a comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;
- d. an assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and shall be given continuing and meaningful opportunities for deciding whether or not to continue to participate;
- e. the possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors; and
- f. the name, and contact information for, a person who may be contacted in the case of concerns, complaints, or consequences.

Appendix 3 describes additional information that may be necessary in order to obtain fully informed consent

1.9.5 Participation in Research by Persons Who Are Not Legally Competent

Competence refers to the ability of prospective participants to give informed consent in accord with their own fundamental values. It involves the ability to understand information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent. This ability may vary according to the choice being made, the circumstances surrounding the decision, or the time in question. Competence to give consent, then, is not all-or-nothing condition. It does not require prospective participants to have the capacity to make every kind of decision. It does require that they be competent to make an informed decision about participation in particular research. Competence is neither a global condition nor a static one; it may be temporary or permanent.

Researchers shall comply with all applicable legislative requirements of the jurisdiction in which participation takes place.

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research participants when;

- a. the research question can only be addressed using the identified group(s); and
- b. free and informed consent shall be sought from their authorised representative(s); and
- c. the research does not expose them to more than minimal risks without the potential for direct benefits for them.

1.9.6 Consent Requirements for Persons Who Are Not Legally Competent

For research involving incompetent individuals, the REC-HS shall ensure that, as a minimum, the following conditions are met:

- a. The researcher shall show how the free and informed consent shall be sought from the authorised third party, and how the participant's best interests shall be protected.
- b. The authorised third party shall not be the researcher or any other member of the research team.

- c. The continued free and informed consent of an appropriately authorised third party shall be required to continue the participation of a legally incompetent participant in research, so long as the subject remains incompetent.
- d. When a participant who was entered into a research project through third-party authorisation becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.
- e. Where free and informed consent has been obtained from an authorised third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent shall preclude his or her participation. If a legally incompetent participant expresses or exhibits behaviour that suggests a desire to cease participation after the research procedure has commenced, such indication shall be deemed dissent, and the procedure shall be terminated.
- f. *Regardless of third party consent, all attempts should be made at informing the legally incompetent individual as to the nature of the project.*

1.9.7 Consent for Videotape and Audio Recordings

Some research projects may involve videotaping the participants or audio recordings. Extreme care must be taken to ensure that the participants (or their representatives if the participants are not legally competent) are informed as to the use of this medium and the possibility of their being identified. A separate waver for Video and Audio capture must be attached to the original informed consent form.

1.10 PRIVACY AND CONFIDENTIALITY

Researchers shall comply with all applicable privacy legislation of the jurisdiction in which information collection takes place. Information regarding the Province of British Columbia's Freedom of Information and Protection of Privacy Act may be obtained from the office of the Vice-President, Finance.

Where possible, participants must be guaranteed privacy and anonymity, and their responses must be treated with confidentiality. If anonymity and confidentiality cannot be assured or granted, potential participants must be made aware of the limitations and of the possible consequences before they are asked for their consent to participate.

1.10.1 Personal Interviews and Other Information Collection

Subject to the exceptions in Section 1.4.2, researchers who intend to interview a participant to secure identifiable personal information shall obtain REC-HS approval for the consent and interview procedures used and shall ensure the free and informed consent of the respondent as required in Section 1.4.2. For the purposes of this sub-section, interview includes face-to-face, telephone or other electronic encounters, and individualized questionnaires which the researcher may use to gather personal information about participants. As indicated in Section 1.4, REC-HS approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances.

Subject to the exceptions in Section 1.4.2, researchers shall secure REC-HS approval for obtaining identifiable personal information about participants through interviews and direct or indirect observation, and through access to records or materials containing personal information. REC-HS

approval for such research shall include such considerations as:

- a. the type of data to be collected;
- b. the purpose for the which the data shall be used;
- c. limits on the use, disclosure, and retention of the data;
- d. appropriate safeguards for security and confidentiality;
- e. any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular participants;
- f. anticipated secondary uses of identifiable data from the research;
- g. anticipated linkage of data gathered in the research with other data about subjects, whether those data are contained in public or personal records; and
- h. provisions for confidentiality of data resulting from the research.

1.10.2 Secondary Use of Data

Secondary use of data refers to the use in research of data contained in records collected for a purpose other than the proposed research itself. Common examples are patient or school records or biological specimens, originally obtained or produced for therapeutic or educational purposes, but subsequently are proposed for use in research. Secondary use of data also refers to instances in which data were obtained for one REC-HS approved project, but subsequently are proposed for use in new research. The issue of secondary use primarily becomes of concern when the data can be linked to individuals, and becomes critically important when the possibility exists that individuals could be identified from published reports of the research.

If identifying information is involved, REC-HS approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REC-HS that:

- a. identifying information is essential to the research; and
- b. they shall take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimise harms to subjects; and
- c. individuals to whom the data refer have not objected to secondary use.

Depending on apparent risk of the data collection procedures, the REC-HS may also require that a researcher's access to secondary use of data involving identifying information be dependent on:

- d. the informed consent of those who contributed data or of authorised third parties; and/or
- e. an appropriate strategy for informing the subjects; and/or
- f. consultation with representatives of those who contributed data.

Researchers who wish to contact individuals to whom secondary use data refer shall seek the authorisation of the REC-HS prior to contact. The REC-HS shall evaluate the adequacy of the means by which original confidentiality guarantees are respected in making such contacts.

The implications of data linkage in which research subjects may be identifiable shall be approved by the REC-HS. Advances in the ability to link databases create both new research opportunities and

new threats to privacy. These techniques provide means for addressing previously unanswerable questions and for generating better social and health-related information. The values underlying the ethical obligation to respect privacy require researchers and the REC-HS to exercise caution in the creation and use of data of this kind. Where such issues arise, the REC-HS must inform itself of relevant statutory frameworks, and the criteria required by government for authorisation of use of data in governmental data banks.

1.11 CONFLICT OF INTEREST

Researchers hold trust relationships with research participants, research sponsors, institutions, professional bodies, and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity, or ethical duties.

Researchers and REC-HS members shall disclose actual, perceived or potential conflicts of interest to the REC-HS. The REC-HS should develop mechanisms to address and resolve conflicts of interest.

1.12 INCLUSION IN RESEARCH

An important aspect of the principle of justice is the fair distribution of benefits and burdens. Members of society should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from potential benefits of research participation.

Where research is designed to survey a number of living research subjects because of their involvement in generic activities (e.g., in many areas of health research or in some social science research such as studies of child poverty or of access to legal clinics) that are not specific to particular identifiable groups, researchers shall not exclude prospective or actual research subjects on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, sex or age, unless there is a valid reason for doing so. Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity. These statements are not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic (as in a study of an identifiable group of painters who happen to be all of one sex, colour or religion, or of a religious order which is restricted to one sex).

Subject to the provisions in Section 1.9, people who are not competent to consent for themselves shall not be automatically excluded from research which is potentially beneficial to them as individuals, or to the group that they represent.

1.13 CLINICAL TRIALS

1.13.1 Clinical Equipoise

Clinical equipoise means a genuine uncertainty on the part of the expert health sciences community about the comparative therapeutic merits of each arm, or condition, of a clinical trial. The tenet of clinical equipoise provides the moral foundation to the requirement that the health care of participants not be disadvantaged by research participation.

1.13.2 Special Requirements for REC-HS Review of Clinical Trials

Phase I non-therapeutic clinical trials shall undergo both stringent review and continuous monitoring by an REC-HS independent of the clinical trials sponsor.

In combined Phase I/II clinical trials, researchers and the REC-HS shall carefully examine the integrity of the free and informed consent process. Where appropriate, the REC-HS may require an independent monitoring process.

The REC-HS shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected.

1.13.3 Placebo Controls in Clinical Trials

The use of placebo controls in clinical trials is generally unacceptable when standard therapies or interventions are available for a particular patient population. Consistent with clinical equipoise, a placebo may be used as the control treatment in a clinical trial in the following circumstances:

- a. there is no standard treatment;
- b. standard therapy has been shown to be no better than placebo;
- c. evidence has arisen creating substantial doubt regarding the net therapeutic advantage of standard therapy;
- d. effective treatment is not available to patients due to cost constraints or short supply. (This may only be applied when background conditions of justice prevail within the health care system in question; for example, a placebo-controlled trial is not permissible when effective but costly treatment is made available the rich but remains unavailable to the poor or uninsured.);
- e. in a population of patients who are refractory to standard treatment and for whom no standard second-line treatment exists;
- f. testing add-on treatment to standard therapy when all participants in the trial receive all treatments that would normally be prescribed; or
- g. patients have provided an informed refusal of standard therapy for a minor condition for which patients commonly refuse treatment and when withholding such therapy shall not lead to undue suffering or the possibility of irreversible harm of any magnitude.

When a clinical trial involving a placebo control is undertaken, the researcher and the REC-HS must ensure that patients or authorised third parties are fully informed about any therapy that shall be withdrawn or withheld for purposes of the research, about the anticipated consequences of the withdrawing or withholding of the therapy, and the reasons why the investigator deems a placebo-controlled trial to be necessary.

1.14 HUMAN GENETIC RESEARCH

The potential ability to identify all human genes and their mutations has profound social implications. Misunderstanding or misuse of the results of genetic testing has the potential to interfere with an individual's self-identity and sense of self-worth, and to stigmatize the entire group to which that individual belongs. Researchers and the REC-HS shall exercise care in identifying risks to individuals and groups posed by genetic research.

The genetics researcher shall seek free and informed consent from the individual and report results to that individual if the individual so desires. Where appropriate, free and informed consent shall also involve the family and/or relevant social structures as far as practical and possible.

The researcher and the REC-HS shall ensure that the results of genetic testing and genetic

counselling records are protected from access by third parties, unless free and informed consent is given by the participant. Family information in databanks shall be coded so as to remove the possibility of identification of subjects within the bank itself.

Researchers and genetic counsellors who involve families and groups in genetic research studies shall reveal potential harms to the REC-HS and outline how such harms shall be dealt with as part of the research project.

Genetics researchers and the REC-HS shall ensure that the research protocol makes provision for access to genetic counselling for the participants, where appropriate.

Gene alteration (including “gene therapy”) that involves human germ-line cells or human embryos is not ethically acceptable. Gene alteration for therapeutic purposes and involving human somatic cells may be considered for approval.

Though the banking of genetic material is expected to yield benefits, it may also pose potential harms to individuals, their families and the groups to which they may belong. Accordingly, researchers who propose research involving the banking of genetic material have a duty to satisfy the REC-HS and prospective research participants that they have addressed the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, withdrawal by the subject, and future contact of participants, families and groups.

At the outset of a research project, the researcher shall discuss with the REC-HS and the research participant the possibility and/or probability that the genetic material and the information derived from its use may have potential commercial uses.

1.15 RESEARCH WITH HUMAN GAMETES, EMBRYOS OR FOETUSES

1.15.1 Research Involving Human Gametes

Researchers shall obtain free and informed consent from the individual whose gametes are to be used in research.

It is not ethical to use in research ova or sperm that have been obtained through commercial transactions, including exchange for service.

It is not ethically acceptable to create, or intend to create, hybrid individuals by such means as mixing human and animal gametes, or transferring somatic or germ cell nuclei between cells of humans and other species.

1.15.2 Research Involving Human Embryos

It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases where human embryos are created for reproductive purposes, and subsequently are no longer required for such purposes, research involving human embryos may be considered to be ethically acceptable, but only if all of the following apply:

- a. the ova and sperm from which they were formed are obtained in accordance with Section 1.15.1;

- b. the research does not involve the genetic alteration of human gametes or embryos;
- c. embryos exposed to manipulations not directed specifically to their ongoing normal development shall not be transferred for continuing pregnancy; and
- d. research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes.

It is not ethically acceptable to undertake research that involves ectogenesis, cloning human beings by any means including somatic cell nuclear transfer, formation of animal/human hybrids, or the transfer of embryos between humans and other species.

1.15.3 Research Involving Foetuses

Research may be undertaken on methods to treat, in utero, a foetus that is suffering from genetic or congenital disorders. Because the foetus and the woman cannot be treated separately, any intervention on one involves an intervention on the other. Accordingly, and consistent with the requirements of Section 1.9, research involving a human foetus requires the free and informed consent of the woman.

Research involving the use of foetal tissue should be guided by respect for the woman's dignity and integrity. Researchers should thus obtain the free and informed consent of the woman whose foetal tissue is to be used for research.

1.16 HUMAN TISSUE 1.16.1 Requirement for Ethics Review

Research proposing the collection and use of human tissues requires ethics review by the REC-HS. Amongst other things required by the TRU Standards and the REC-HS, the researcher shall demonstrate the following to the REC-HS:

- a. that the collection and use of human tissues for research purposes shall be undertaken with the free and informed consent of competent donors;
- b. in the case of incompetent donors, free and informed consent shall be by an authorised third party;
- c. in the case of deceased donors, free and informed consent shall be expressed in a prior directive

or through the exercise of free and informed consent by an authorised third party.

1.16.2 Requirement for Informed Consent

For the purpose of obtaining free and informed consent, researchers who seek to collect human tissue for research shall, as a minimum, provide potential donors or authorised third parties information about:

- a. the purpose of the research;
- b. the type and amount of tissue to be taken, as well as the location where the tissue is to be taken;
- c. the manner in which tissue shall be taken, the safety and invasiveness of acquisition, and the duration and conditions of preservation;
- d. the potential uses for the tissue including any commercial uses;
- e. the safeguards to protect the individual's privacy and confidentiality;

- f. identifying information attached to specific tissue, and its potential traceability; and
- g. how the use of the tissue could affect privacy.

1.16.3 Previously Collected Tissue

When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected tissue. The provisions of Section 1.16.2 may also apply here.

When collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized tissue), and when there are no potential harms to them, there is no need to seek donors' permission to use their tissue for research purposes, unless applicable law so requires.

1.17 RESPONSIBILITIES OF RESEARCHERS

Researchers, including student researchers are primarily and ultimately responsible for the protection of human research participants. In order to fulfill this responsibility, researchers must be competent in their areas of inquiry. They must be familiar with and comply with the TRU Standards and with other ethics guidelines relevant to their disciplines. Researchers must ensure that all individuals under their supervision have the training and competence needed to carry out their responsibilities. Principal investigators must ensure that all research personnel are familiar with and comply with the TRU Standards and other applicable ethics guidelines. Similarly, instructors who include research components in their courses must ensure that their students are competent to conduct the assigned research and that they are familiar with and comply with the TRU Standards and other applicable ethics guidelines. Adequate supervision of student research must be ensured, with greater care required as risk of harm to participants increases. Assistants, students, and others who conduct research under the supervision of others should understand that they are themselves researchers and therefore also bear personal responsibility for the ethical conduct of research with human participants.

Researchers have an ethical obligation to protect the welfare of their assistants, employees, and students by not exposing them to unsafe equipment, materials, and environments during the course of research.

See also: Undergraduate Student Research Guidelines

1.17.1 Reporting

Researchers must submit to the main Research Ethics Committee – Human Subjects an annual report regarding the status of their project as either ongoing or completed, and whether there were any issues that need to be brought to the attention of the Research Ethics Committee – Human Subjects. Annual reports are due May 1.

1.18 EDUCATION AND DISSEMINATION

The REC-HS shall be responsible for providing education for researchers about the ethical treatment of human research participants in general and the *TRU Standards* in particular. Divisions and the REC-HS shall be responsible jointly for providing education for REC-HS members about the ethical treatment of human research participants in general and the TRU Standards in particular.

The REC-HS shall be responsible for establishing a network for communication among the Divisional/School Ethics Review Committees (D/SERCs) in order to promote consistency of policy

interpretation and mutual assistance.

Appendix 1

The REC-HS may devise procedures by which research conducted by undergraduate students as part of their course work can be reviewed by specially constituted Divisional/School ethics review committees (D/SERCs).

Appendix 2

Tri-Council Policy Recommendations for Continuing Review of Research

The REC-HS should not normally carry out continuing ethics review, except in specific cases where the REC-HS believes that it is best suited to intervene. For research posing significant risks, the REC-HS should receive reports on the progress of the research project at intervals to be predetermined. These reports should include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed.

In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk might include:

- 1 formal review of the free and informed consent process,
- 2 establishment of a safety monitoring committee,
- 3 review of reports of adverse events,
- 4 review of patients' charts, and/or
- 5 a random audit of the free and informed consent process.

Appendix 3 Additional Information which May Be Required for Informed Consent Procedures

- 1 An assurance that new information shall be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation.
- 2 The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;
- 3 Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research.
- 4 An indication as to who shall have access to information collected on the identity of subjects, and descriptions of how confidentiality shall be protected, and anticipated uses of data;
- 5 An explanation of the responsibilities of the subject;
- 6 Information on the circumstances under which the researcher may terminate the subject's participation in the research;
- 7 Information on any costs, payments, reimbursement for expenses of compensation for injury;
- 8 In the case of randomised trials, the probability of assignment to each option;
9. For research on biomedical procedures, including health care interventions;
information about
 - (a) foregoing alternative procedures that might be advantageous to the subject, (b) which aspects of the research involve the use of procedures that are not generally recognised or accepted; and,
 - (c) particularly in trials of therapeutic interventions, the care provided if the potential subject decides not to consent to participation in the study;

9 The ways in which the research results shall be published, and how the subjects shall be informed of the results of the research.

Based on University of Alberta GFC 27 SEP 1999 – Mike Enzel Author TRU 31 May, 2001