"ETHICS 101" – An Overview of Research Ethics at Athabasca University

A. Why Is Ethics Review Required for Research with Human Participants?

Present day ethical and legal frameworks for conducting ethical research with human participants has been influenced, in large measure, by three significant codes/reports created in response to atrocities, injustices and morally suspect research conducted on human participants: the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report.

The Nuremberg Code is a set of guidelines developed following World War II to ensure the atrocities committed by Nazi researchers would not be repeated. This code focuses on the principle that human beings MUST consent voluntarily to research before they are enrolled to participate.

The Declaration of Helsinki was developed by the World Medical Association in 1964 to outline ethical principles to follow when conducting research with human participants. A main focus of this document was the ethical complexities of conducting human participant research in foreign countries and ensuring that the protections for human participants not be lessened by things such as national ethical, legal or regulatory requirements.

A well-publicized case of research abuse of human participants in the U.S. (The U.S. Public Health Service (PHS) Syphilis Study—the Tuskegee experiment) was the impetus for the formation of the National Research Act in 1974, and subsequently the Belmont Report, which articulated three ethical principles for the responsible conduct of research with humans: *respect for persons, beneficence and justice*.

In Canada, the three federal funding agencies—CIHR (Canadian Institutes of Health Research, NSERC (Natural Science and Engineering Research Council) and SSHRC (Social Sciences and Humanities Research Council) collaborated together to articulate a national policy as a standard of ethical conduct for research involving human participants. This policy was first released in 1998 and has undergone several major revisions on its way to its present form, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (2014)* (TCPS 2). The policy focuses on the interdependent duties to research subjects shared by researchers, institutions and Research Ethics Board (REBs).

The three main principles in the TCPS 2 mirror those outlined in the U.S. Belmont Report: Respect for Persons, Concern for Welfare (Beneficence) and Justice.

All institutions across Canada that receive and administer funding from the Tri-Councils must develop institutional policy and procedures for the ethical review of research involving humans and adhere to the Tri-Council Policy in all its aspects.

SUMMARY

1. Ethical Review of research involving humans is **required** except in very limited and specific circumstances.
2. Ethical review of research involving humans is designed to ensure that researchers fully consider participants' autonomy, worth and dignity when designing and conducting their research and that the harms of research are eliminated or minimized, while the benefits of research are equitably distributed.

B. Policies, Principles and Legislation related to the ethical review and conduct of research involving human participants

The Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans (TCPS 2 (2014))* delineates the guiding ethical principles that Athabasca University must adhere to and uphold. This policy outlines three main principles that comprise the framework for ethical research with human participants.

Respect for Persons
This principle recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses not only those persons involved in research as participants, but also those who are participating because their data or biological materials are used in research. There is a dual moral obligation inherent in this principle—to respect autonomy and to protect those with developing, impaired or diminishing autonomy. Respecting autonomy is about giving due deference to a person's judgment and ensuring that the person is free to make choices without interference. An integral component for respecting this autonomy in research is the requirement to seek free, informed and ongoing consent for participation in research.

HIGHLIGHTS

- autonomy
- voluntariness of participation
- informed choice
- capacity

Concern for Welfare
A person's welfare is contingent on the quality of that person's experience of life in all its aspects—the impact on individuals of factors that include their physical, mental and spiritual health, and their physical, economic and social circumstances. Determinants of welfare can include housing, employment, security family life, community membership, social participation and other aspects of life. Two main factors contributing to a person's welfare are a person's privacy and the control of information about the person. The process of free, informed and ongoing consent must address these factors. The welfare of groups can also be affected by research. It is important to engage with groups whose welfare may be affected (by stigmatization, discrimination or damage to reputation, for example) to clarify these potential impacts of research and identify where negative impacts can be minimized.

HIGHLIGHTS

- risk must be in proportion to benefit
- no unnecessary risks
- consideration of the impact of participation on a participant and the community they are part of

Justice
This principle refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires that the benefits and burdens of research participation be distributed in a manner such that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it. Equal treatment does not necessarily mean treating all people in the same way. One major consideration related to fairness and equity is vulnerability. Vulnerability often is caused by limited decision-making capacity, or limited

access to social goods, such as rights, opportunities and power. Both individuals and groups can be found to be in vulnerable circumstances and may require special attention in order to be treated justly in research. Fairness and equity may be especially important considerations during the recruitment process. Inclusion criteria must be justified by the research question to avoid inequities that may be created when certain groups fail to receive fair benefits of research or are excluded from research arbitrarily for reasons unrelated to the research question (e.g. because they are more difficult to reach).

The policy further seeks to strike a balance between the recognition of potential benefits of research and the protection from harm of participants. Research Ethics Boards therefore are tasked with ensuring the level of scrutiny of a research project is determined by the level of risk it poses to participants.

HIGHLIGHTS

- fair and equitable treatment
- equal distribution of risks and benefits
- protection of vulnerable populations
- justifiable inclusion
- managing power imbalances

Access the Tri-Council Policy here: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

University Policy

Athabasca University has developed its own policy and procedures to clearly outline the requirement for ethical review of research with humans, to establish and authorize the Research Ethics Board to review all proposals for research with humans (that require ethical review), and outline the scope of ethical review.

Access Athabasca University's Policy and related procedures for *Ethical Conduct for Research Involving Humans* here: http://ous.athabascau.ca/policy/index.php#POE

Privacy Legislation

Research with human participants may also be impacted by federal and provincial privacy legislation. In Alberta, the *Freedom of Information and Protection of Privacy Act (FOIP)* applies to public bodies, such as Athabasca University. This legislation outlines the responsibilities of institutions related to the collection, use and disclosure of personal information and the right of access to records in the custody and control of a public body.

To satisfy the organization's responsibilities outlined in FOIP, researchers who may wish to recruit participants from a public body (or access data about humans that is in the custody and control of a public body) will likely need to obtain assistance and permission to do so, outside of, and in addition to, research ethics approval processes.

At Athabasca University, there is a policy and procedure related to *Institutional Permission to Access Resources for Research* that outline the requirements, process and procedures for requesting this permission. This process will be initiated on your behalf by the Research Ethics Office once ethical approval for your project has been granted.

Conducting Health Research in Alberta

Researchers should be aware that health information is governed by separate privacy legislation—*The Health Information Act (HIA)*. Researchers wishing to access, or use health information covered under this legislation will be subject to multi-institutional processes (i.e. ethical review will be required at Athabasca University and also at a designated Health Research Ethics Board (HREB)). Part 5, Division 3 of the HIA (Disclosure for Research Purposes) outlines the requirements, namely:

> A person who intends to conduct research using health information in the custody or under the control of a custodian or health information repository must submit a proposal to a research ethics board for review by that Board.

Access the *Health Information Act* here:
http://www.qp.alberta.ca/1266.cfm?page=h05.cfm&leg_type=Acts&isbncln=9780779791293

Other legal and regulatory requirements regarding consent and privacy

There may be other legal and regulatory requirements governing consent issues and privacy of information. It is a researcher's responsibility to ascertain and comply with all applicable legal and regulatory requirements (e.g. the Canadian Charter of Rights and Freedoms and the *Alberta Human Rights Act*).

C. ***Research*** Requiring Ethical Review

The TCPS 2 requires that review and approval by a Research Ethics Board (REB) must be obtained before research commences for:

1) *Research* involving living human participants.
2) *Research* involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells (from both living and deceased individuals).

Research is defined as: "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term 'disciplined inquiry' refers to an inquiry that is conducted with the expectation that the method, results and conclusions will be able to withstand the scrutiny of the relevant research community."

Determining whether *research* is the intended purpose of an undertaking is integral to differentiating activities that require ethics review by an REB and those that do not. This can be a difficult distinction, but it is important to note that the choice of methodology and/or intent or ability to publish ARE NOT factors that determine whether or not an activity is *research requiring ethics review*.

Human Participants are defined as "those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question."

D. Exemptions from Ethical Review

There is some ***research*** that is exempt from REB review where protections are available by other means:

1. ***Research*** that relies exclusively on publicly available information does not require REB review when the information is legally accessible to the public and protected by law; or the information is publicly accessible and there is no reasonable expectation of privacy. Examples of this type of information might be existing stored documentary material, records or publications, registries of death, court judgments, public archives, etc.

   This exemption applies not only to unidentifiable information, but also to identifiable information where that publicly available information carries no reasonable expectation of privacy (e.g. press recordings, artistic installations, official publications of private or public organizations, etc.).

   Research through the internet that is non-intrusive and does not involve any direct interaction between researcher and individuals also does not require REB review; however, one must be cautioned in this regard. There are publicly accessible digital sites where there may be a reasonable expectation of privacy and in such cases REB review is required.

2. ***Research*** that involves the observation of people in public places where it does not involve any intervention staged by the researcher or direct interaction with the individuals or groups; where individuals and groups targeted for observation have no reasonable expectation of privacy; and where any dissemination of research results does not allow identification of specific individuals.

3. ***Research*** that relies exclusively on secondary use of anonymous information or anonymous human biological materials (information/materials that NEVER had an identifier associated with them), as long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

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

NOTE: Anonymous information is distinct from anonymized or coded information. Anonymous information NEVER had an identifier associated with it; anonymized information is that which has been irrevocably stripped of direct identifiers and a code NOT kept to allow future re-linkage; and coded information refers to information where direct identifiers have been removed and replaced with a code (that may be accessed for future re-linkage).

There are also some non-research ***activities*** that do not require REB review, even though they may employ methods and techniques similar to those employed in research. These activities are not considered '*research*' as defined in the TCPS 2 and therefore do not require REB review. These activities include:

1. 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.

2. Creative practice activities. However, *research* that employs creative practices to obtain responses from participants that will be analyzed to answer a research question IS subject to REB review.

SUMMARY

1. Ethics review and approval is required for all research with human participants PRIOR to the start of a research project except in very limited and specific cases, identified as exemptions in the TCPS 2, Chapter 2.
2. When in doubt, ask!

E. Recruitment and Informed Consent

The three principles that inform ethics policy, *Respect for Persons, Concern for Welfare* and *Justice* are the driving considerations behind all research with human participants. The recruitment strategies proposed in a project (including considerations such as the target population, methods of identifying and inviting participation, criteria used to justify the inclusion and exclusion criteria proposed, etc.) require careful thought and attention to ensure that these three principles are upheld.

Closely related to recruitment is the informed consent process. *Informed Consent* is not a particular action or event but rather must be a free, understandable, ongoing process throughout the life of a research project from recruitment on. Participants are **always** free to choose to participate in research, end their participation in a research project (*at any time)* and to withdraw their consent to use any data collected from them (unless the deletion of data is impossible—as in an anonymous online survey where a particular response from a specific participant cannot be identified).

In order for consent to be considered **voluntary**, a potential participant must have the opportunity to ask any questions and receive satisfactory answers; they must not feel any pressure to participate nor be coerced to participate because of perceived or real conflicts of interest, group pressure, enticing incentives, or power imbalances. Participants **must** have assurance that there will be no negative consequences should they choose NOT to participate in a research project and participants should be confident that their anonymity and confidentiality is respected and protected.

When working with minors or those with developing, diminished or impaired autonomy, informed consent MUST be sought from an authorized parent/guardian; however, the assent of the individual participant must also always be sought and maintained where possible. Care must be given to consent documents and information to ensure they are comprehensible to both the parent/guardian and the participant.

The Research Ethics Board must review and approve all recruitment materials (scripts, information letters, postings, posters) and consent documents as part of the ethical review of the research project.

At minimum, the following information MUST be provided in order to meet the criteria for 'informed consent':

1) **Title** of the research study

2) **Contact information** for all researchers
   - Ensure that Athabasca University affiliation, program and/or course are noted where applicable. An additional name and contact should be given in case a participant has a concern with how the study is being conducted. In this regard, students must include the contact information of their supervisor or professor.

- The Research Ethics Office should also be provided as an alternate contact by inserting the following statement: *"This study has been reviewed by the Athabasca University Research Ethics Board. Should you have any comments or concerns regarding your treatment as a participant in this study, please contact the Office of Research Ethics at 1-800-788-9041, ext. 6718 or by e-mail to rebsec@athabascau.ca."*

3) **Invitation**
   - Include a statement that the individual is being invited to participate in a research study, with an explanation of why they have been selected to take part.

4) **Description of Research**
   - Purpose and data collection methods. Describe the expected duration and nature of the participation.

5) **Risks and Benefits**
   - Describe any potential adverse effects, including physical, psychological, social, economic and spiritual risks. Describe how adverse effects will be dealt with. Identify any benefits for the subject or participants, for the development of knowledge, or for a change in practice.

6) **Right to Refuse to Participate**
   - Right to refuse to participate and to withdraw at any time during the period in which data is being collected, without prejudice, must be explicitly stated. Indicate that the individual may refuse to answer some questions. Include information on how to withdraw and what will happen to any data collected to that point.

7) **Privacy, Confidentiality and Anonymity**
   - Identify the steps that will be taken to respect the privacy of participants, and to protect confidential data. Indicate how raw data will be stored. Indicate whether raw data will be disposed of, and if so, describe when and how according to the various formats in which it is stored.

   - If the study is SSHRC funded, indicate how you will meet the SSHRC Archiving Policy requirements.

   - Identify any agencies or individuals who will have access to data from this research study, or the report, now or in the future (e.g. employer, service provider, etc.). Indicate how the raw, confidential data from this study will be guarded against any misuse by any third party (e.g. employer).

   - If any secondary use of the data or future necessity to contact participants is anticipated (e.g. for any purposes outside completion of the present research study) it is advisable to word the consent documents in such a way as to facilitate such future actions. Secondary use will require further REB approval, if a later study is designed.

8) **If there is a likelihood that reportable information may arise**
   - If there is a likelihood that reportable information may arise during the research study, the following sentence must be included in all information letters where mandatory reporting would be applicable (e.g. protected populations, revelation of illegal or heinous act): *"All information*

will be held confidential, except when legislation or a professional code of conduct requires that it be reported."

9) **Results of the study**
   - Describe how and where results of the research study will be disseminated and whether or how they will be made available to interested participants.

   - **If the researcher is an AU graduate program student** and the research is a final research study or thesis the following publication statement is to be included: *"The existence of the research will be listed in an abstract posted online at the Athabasca University Library's Digital Thesis and Study Room; and the final research paper will be publicly available."*

   - It is possible to shield the final paper from public distribution in order to protect the privacy of participants; however, special arrangements must be made with the student's department head/supervisor to allow only the abstract to be posted and not the accompanying paper. In that case, the publication statement would be modified accordingly.

10) **Documenting Consent**
   - Under normal circumstances, participants must sign a letter or form to indicate their consent to participate based upon their consideration of the information the researcher has told them or provided them about the research study. A statement may be included, such as *"I have read and understood the information contained in this letter, and I agree to participate in the study, on the understanding that I may refuse to answer certain questions, and I may withdraw at any time during the data collection period."*

11) **Parental/Guardian Consent**
   - May be gathered for legally incompetent participants or those under 18 years of age; however, the assent of the individual participant must also always be sought and maintained. Individual information and consent documents or scripts should be worded at the appropriate comprehension levels for the parent/guardian and the research participant.

There are situations in which written consent is not warranted or possible. In such cases, the Research Ethics Board will expect to see the script to be used and a description of what method will be used for gathering and recording 'non-written' consent.

In cases where consent is **'deemed'** to be given (such as for online surveys or other types of anonymous questionnaires) where maintaining anonymity makes it inappropriate to gather written consent, researchers should include a statement such as *"You are giving your consent to participate in this study when you [press submit] or [return the questionnaire/survey]"* somewhere in the instructions at the front and back of the instrument used.

F. Obtaining and Maintaining Ethical Approval

All applications for ethical approval and necessary reporting forms are completed and submitted online through the AU Research Portal. You can access the portal from the Research Centre website: http://research.athabascau.ca/

There are specific forms for faculty/staff applicants, student applicants and an application to obtain confirmation of exempt research (in some instances an official notification that a research project is exempt from ethical review is needed).

Instructions on creating an account in the Research Portal and tips on how to complete an application can be found on the Research Centre website.

Ethical approval is granted for a period of one year. Ethics policy requires that ethical approval be maintained for the life of a research project involving human participants. If your project is a multi-year project or you are not able to complete your project within one year, a **request to renew ethical approval** must be completed online and submitted for approval.

Policy also stipulates that once your research project is completed, a **Project Completion (Final) Report** must be completed and submitted online to close out the REB's ethics monitoring activities and close your ethics file.

You will receive email notifications as these milestones approach to remind you of these reporting requirements. Failure to submit the required reports may affect a future application for ethical approval.

Ethics policy further stipulates that any unanticipated or adverse events that may occur during the conduct of a research project must be reported to the Research Ethics Board using the appropriate event forms in the Research Portal. Similarly, requests to modify or amend an approved research protocol must be submitted for approval to the REB via the *Modification Request* event form in the Research Portal.

G. Appeal of a Negative Decision (Denial) of the Research Ethics Board

In the event the REB makes a decision to deny an application for ethical approval, the applicant has the right to ask the REB to reconsider the decision and the REB is obligated to do so. If, after further review the decision of the Board is to deny an application, the applicant may appeal that decision within 30 days of receiving the decision. Appeals must be made in writing, to the Research Ethics Office at rebsec@athabascau.ca

H. Multi-Jurisdictional Research

If you are conducting research in collaboration with researcher(s) at another institution(s) or if you are intending to collect data or recruit participants from another institution, you will likely be required to obtain ethical approval from each institutional REB.

Currently, there are no reciprocity agreements between institutions. Chapter 8 of the TCPS 2 provides guidance and direction regarding review mechanisms dealing with multi-jurisdictional research: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter8-chapitre8/

I. Research with First Nations, Inuit and Métis Peoples of Canada

Conducting research with First Nations, Inuit and Métis Peoples of Canada requires some special considerations in its design, approach and conduct. Chapter 9 of the TCPS 2 outlines these considerations and provides insight and ethical guidance into research with our indigenous peoples.

Researchers working with First Nations peoples are well advised to familiarize themselves with this guidance. Access this particular chapter of the TCPS 2 here: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/

J. Qualitative Research

Researchers in social sciences and humanities may utilize quantitative or qualitative research approaches or a combination of both. Issues related to consent, privacy and confidentiality may have unique manifestations in qualitative research. Chapter 10 of the TCPS2 provides some specific guidance on these issues that are particularly relevant to qualitative research: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/

K. Resources and Training

AU Research Ethics website: http://research.athabascau.ca/ethics/index.php

Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans* TCPS 2 (2014) http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

Health Research Ethics http://www.aihealthsolutions.ca/initiatives-partnerships/health-research-ethics/

CORE Tutorial (*recommended):*

A comprehensive and interactive training resource has been developed by the Interagency Panel on Research Ethics (PRE) that provides an introductory tour of the Tri-Council Policy Statement. It is recommended that all researchers complete the CORE Tutorial but at this time, it is not a required component of ethical review. A Certificate of Completion is provided at the tutorial's conclusion that is recognized (and in many cases required) at institutions across Canada.

You can move through the tutorial as you desire. Progress is saved automatically, so there is no requirement to complete the tutorial in one session.

You may access the CORE Tutorial at: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

WEBINARS

There are also a number of recorded webinars related to research ethics and the TCPS 2 on the PRE website that provide excellent information. Webinars are available on subjects that include:

- Multi-Jurisdictional Research in the TCPS 2
- Research involving Frist Nations, Inuit and Metis Peoples of Canada
- Qualitative Research
- Governance of Research Ethics Boards
- Scope of Research Ethics Review

You may access the webinars at: http://www.pre.ethics.gc.ca/eng/education/webinars-webinaires/

Athabasca University Research Ethics Office

The Research Ethics Officer (REO) is available to offer guidance, advice and direction with regards to your research project and the ethical approval process. You may contact the REO at:

Email – rebsec@athabscau.ca
Phone: 1-800-788-9041, ext. 6718

AU Ethics Presentation – March 2017