GUIDELINES FOR APPLICANTS

Purpose of Guidelines
This document provides guidance for individuals preparing applications for review by the Athabasca University (AU) Research Ethics Board (REB) for ethical review of research studies involving humans.

Role of the REB & Departmental Ethical Review Committees
The REB review & Departmental Ethics Review Committees review ethics applications to ensure that research studies meet the highest ethical standards of research involving humans, in accordance with Athabasca University's Ethical Conduct for Research Involving Humans Policy and the Tri-Council Policy Statement (TCPS2 2022)

Provincial/Federal Acts
Research may be affected by provincial/federal Acts respecting freedom of information and protection of privacy and electronic communications. Researchers should familiarize themselves with the following legislation:

1) Alberta *Freedom of Information and Protection of Privacy Act (FOIPP)*, available at: http://www.qp.alberta.ca/1266.cfm?page=F25.cfm&leg_type=Acts&isbncln=9780779743568&display=html

2) Alberta *Health Information Act (HIA)*, available at: http://www.qp.alberta.ca/570.cfm?frm_isbn=9780779777365&search_by=link

Levels of Review
There are three levels of review:

Level 1:	Full REB Review	▪ External advice and expertise may be solicited
Level 2:	Delegated Review ▪ Chair Review	▪ Supplementary information to proposals that have been identified as requiring revision following full REB review is considered by the Chair. ▪ Reviews of Modification Requests ▪ Requests for Ethics Approval Renewal ▪ Emergency review of minimal risk studies ▪ Applications for Ethics Exemption ▪ Externally Approved Studies
Level 3:	Delegated Review ▪ Departmental Ethics Review Committee ▪ Delegated REB Review	▪ delegated review of minimal risk student-researcher studies ▪ review by 2 REB members of studies determined to meet the criteria for delegated review

The REB Guidance document "REB Guidance Determining Level of Risk & Type of Review" can assist applicants in understanding the level of risk of their projects and the likely mechanism for review that will be utilized.

Research Studies that Require REB REVIEW
All research studies involving humans, with the exception of the exclusions listed below, conducted by members of the university community or by external researchers who use AU resources or recruit participants from AU, must receive prior written approval from the AU Research Ethics Board (REB).

Further, studies that rely on secondary use of identifiable or non-identifiable human participant data must also seek REB review prior to accessing the data or seeking consent for use (if required). See Chapter 5, Section D of the TCPS2 (2022).

The 'university community' comprises all AU faculty, staff, research assistants, graduate students and visiting researchers. Approval is required irrespective of the source of financial support (if any) and irrespective of the location of the research study (in the latter case, as long as the investigator represents the work as AU research).

Review is available normally only to members of the AU research community, researchers in formal collaboration with AU members, or for research conducted at or under the auspices of AU by external researchers.

Research is understood to be "an undertaking intended to extend knowledge through a disciplined inquiry 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."

Exclusions (subject to FOIPP):
The following types of research / activities do not require REB review; however they are subject to Alberta legislation (FOIPP) as noted earlier.

1) Research about living individuals in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials of third-party interviews. Such research requires review by the REB only if the subject is approached directly for interviews or for access to private papers;

2) Course and/or program evaluations; and

3) Quality assurance studies, performance reviews or testing within normal educational requirements. However, performance reviews or studies that contain an element of research in addition to assessment may need ethics review.

Exclusions (excluded under FOIPP):
The following type of research does not require REB review and is excluded under the FOIPP Act:

1) Research undertaken by members of the university community under their own auspices, or under the auspices of another institution, and not under the auspices of AU.

2) REB review is normally required for research involving naturalistic observation. However, observation of individuals in public places where there is no reasonable expectation of privacy (e.g. at a political rally, public meeting, demonstration) should not require REB review, since it can be expected that the participants are seeking public visibility (AU Policy Ethical Conduct for Research Involving Humans, Section 4.1 "Exceptions to REB Review").

STUDENT RESEARCH:

Research Studies
A student must, at the planning stage, discuss his or her research study with the supervisor or professor. As the supervisor or professor oversees the research study, he/she is responsible for reviewing the student's application and indicating their support/approval before the application is sent forward for ethics review. The supervisor is copied on all correspondence relating to their students' applications. Instructions for adding your supervisor as an 'approver' on your application and guiding the supervisor on how to review a student application in the research portal can be found on the Research Portal website: Graduate student supervisor instructions | Research Office | Athabasca University

Course Assignments
Course assignments with no future research program or publication purposes are to be reviewed and managed by the course instructor under a *"Blanket Ethical Approval"*. Applications within these courses are not sent to the REB for review. **Students must follow approved procedures and utilize forms provided by the course instructor.**

APPLICATION PROCESS
All application forms and supporting documentation are submitted electronically via the Research Portal. Prior to starting the application process, applicants are ***strongly*** encouraged to review the information/instructions within the Research Portal, and on the Research Centre website, under Research Ethics.

1) Applications from faculty/staff researchers must be received **no later than the first Friday of every month**, for review by the REB that same month.

2) **AU Student applications** may be submitted anytime, and will be reviewed as quickly as possible by delegated review unless the research study is deemed to pose greater than minimal risk or contain other ethical considerations that warrant a full Board review.

3) **All researchers are *encouraged* to complete, and AU Students MUST complete the online *Course on Research Ethics (CORE) Tutorial*** and upload their certificate of completion to their Application for Ethical Approval: see the 'Research Ethics Training' page of the Research Ethics Website: Research ethics training | Research Office | Athabasca University

Overview of Research Study
Applications will be evaluated (at minimum) on the following criteria:

1) Purpose & Objectives
- The purpose of the study, research question(s) to be answered, etc.

2) Research Design / Research Method
- Example, exploratory, descriptive, experimental, quasi-experimental, survey, grounded theory, phenomenology, focus group, ethnography, case study, etc.

3) Data Collection Techniques
- Example, questionnaire, interview, performance videotape, field notes, pictures; structured, semi-structured, open-ended, etc. When proposing to utilize online tools for data collection such as survey software, virtual meeting software, recording and transcription software, applicants must be prepared to describe what information may be collected (and stored) by the proposed platform(s), how that information may be used (e.g. for product enhancement, training), where

information transmitted and gathered by the software is housed (e.g. whether in Canada, the US, other), and whether data collected may be subject to access under legislation in other countries.

4) **Method of Analysis**
   - Example, content, statistical, textual, grounded theory, etc.
   - Research instruments (questionnaires, interview guides, rating scales, etc.) must be uploaded with the application.

5) **Storage, Retention, and Disposition of Data (including data deposit)**
   - Details on how and where data in various formats will be stored, who will have access to the data, if the data will be destroyed, when the data will be destroyed (month/year) and how the data will be destroyed.
   - Details on whether data will be deposited in a repository made available to other researchers, the nature, security provisions, access provisions, etc. of the repository and the dataset. (Contact the Research Data Management Librarian for additional support, if required).
   - If there is an absence of retention guidelines within the professional research practice of the applicant's discipline, the REB suggests a minimum of five years. Be specific by considering encryption mechanisms, locked filing cabinets, password protections on computer equipment, etc.

6) **Conflicts of Interest**
   - Consult the following documents for information on conflicts of interest:
     - Tri-Council Policy Statement (TCPS2 2022) – Chapter 7
     - AU Guide for Research in Dual-Role Situations
     - AU Guidance – Incentives

Recruitment and Informed Consent
The REB recognizes that the procedures for obtaining informed consent may differ from research study to research study. Participants must be given enough time to think about the information before consent is collected. The information may be included in a recruitment instrument, a script, or an informed consent letter/form.

- A copy of each recruitment aid, information letter, script, informed consent letter, etc. must be uploaded to the application.

CRITERIA FOR INFORMED CONSENT
Applicants must provide **all of the information listed below** to research participants for each distinct component or phase of the study 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 Officer 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 Research Ethics Officer at 780.213.2033 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. Participants must be advised that their decision to participate is entirely voluntary and can be withdrawn at any time.

4) **Description of Research**
   - Purpose and data collection methods. Describe the expected duration and nature of the participation and any other unique or special aspects of 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. Identify and describe any incentive to participate as well.

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 any questions posed. Include information on how to withdraw and what will happen to any data collected to that point. Be specific about the limitations on data withdrawal and clearly articulate the last point at which this can occur.

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 secured and 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, access by a government or agency via regulation or law, 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, data deposit in a research repository 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.

- ***If broad consent [1] for the storage and future unspecified use of data and human biological materials is sought,*** the TCPS 2 recommends considering the following list of points when seeking consent for future storage and reuse of data. Please consider how each point may be relevant to your research as you construct your consent processes and any plans for data retention and deposit (Note: The TCPS2 does not allow for 'blanket' consent. Rather, it requires that specific restrictions be provided (e.g. use in a particular field of study, prevention of use by private industry, etc.):

    - the type, identifiability, and amount of data (or materials) being collected and stored for re-use, and for what potential purpose,
    - the voluntariness of the participant's consent, including any limitations on the feasibility of withdrawal,
    - a general description of the nature and types of future research that may be conducted, including whether the research may be conducted outside of Canada (if known),
    - risks and potential benefits of storage of data (and materials) and of their use in future unspecific research, including areas of uncertainty where risks cannot be estimated,
    - a general description of the repository and its governance,
    - a statement regarding participant's preference to being re-contacted for additional future research,
    - whether the data (or materials) could be shared with researchers not subject to the TCPS,
    - whether linkage of data gathered in the research with other data about participants (either contained in public or personal records) is anticipated, and
    - separate options for consenting to participate in a specific research project and for consenting to the storage of data (and materials for future unspecified research).

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.

[1] Note: the TCPS2 does not allow for "blanket consent" which is typically unrestricted…'broad consent' for the storage of data for future unspecified research can be sought but must always include specific restrictions (See Chapter 3, Section E of the TCPS2 (2022)).

10) **Informed 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 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.

12) **Non-written Consent**
- Is possible. When situations warrant, consent may be gathered in other ways than writing. In these cases, provide the script and description of other method that will be used for gathering and recording non-written consent and provide justification for why alternate means of consent is being used.

13) **Deemed Consent**
- Is often employed for online surveys or other types of anonymous questionnaires. To maintain anonymity, it is not appropriate to request someone to sign a consent form. Therefore, a statement such as *"You are giving your consent to participate in this study when you [press submit] or [return the questionnaire/survey]"* should be included somewhere in the instructions at the front and back of the instrument.

REB REVIEW - RESULTS

Written responses from the REB / Departmental Ethics Review Committee will be sent as soon as possible following the REB monthly meeting / delegated review. Responses can be one of those listed below.

Approved	Research can begin immediately upon receipt of the memorandum indicating Ethics Certification (*and any other necessary permissions/approvals are obtained).*
Revisions Required (Conditional Approval)	Research cannot be initiated. The researcher is required to submit additional information or revisions as outlined in the correspondence before approval is granted.
Revisions Required	*Research cannot be initiated.* Resubmission in accordance with the normal Deadlines for Submission of a complete, revised proposal that addresses the feedback provided, is required for reconsideration by way of full REB review.

APPEAL PROCESS
A researcher may appeal the REB decision. Please refer to the AU Ethical Conduct for Research Involving Humans Policy.

Researchers who are unsure about whether their proposed research requires (REB) review should consult the Research Ethics Officer at rebsec@athabascau.ca

Please contact the Research Ethics Officer at rebsec@athabascau.ca for clarification of these guidelines or the application process.