



Athabasca
University

AU RESEARCH ETHICS

Surviving the Ethics Approval Process Unscathed!

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Focused on the future of
learning.

AU Ethics Review Requirements and Influences

- **Tri-Council Policy Statement** on Ethical Conduct for Research Involving Humans, 2014 (TCPS2 2014) (effective December, 2014)
 - <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
 - Dictates that **all** research conducted under the auspices of the university, **funded or not**, must undergo ethics review (i.e. research conducted by AU faculty, staff or students regardless of where the research is conducted)
- **Agreement on the Administration of Agency Grants and Awards by Research Institutions**
 - Ties access to/distribution of funding to ethical review requirements of TCPS2
- **AU Ethics Policy**
 - <http://www2.athabascau.ca/secretariat/policy/research/ethicpolicy.htm>
- **FOIP in Alberta**
 - Outlines the conditions for access to AU (or other institutional) research participants/data

Elements of ethics review: Key questions

1. Human participants?

- Interactions with humans in order to gather **their** data, including data which may have been generated previously for a non-research purpose.

2. Minimal risk, or greater?

- Greater than minimal risk = full Research Ethics Board review
- Minimal risk = delegated review

TCPS Elements of ethics review: 3 Key Criteria

Concern for Welfare

- Risk in proportion to benefit
- No unnecessary risks
- Impact on participants & community

Respect for Persons

- Respect for **Autonomy**
- Protect Developing, Impaired or Diminished Autonomy
- Voluntariness
- Informed choice
- Freedom from influence
- Capacity
- Impact of decisions & influences on the participant and community

Justice

- Treatment of people fairly & equitably
- **Fairness** – treating all people with equal respect & concern
- **Equity** – distributing benefits and burdens of research; no segment of the population is unduly burdened or denied benefits of knowledge generated from research
- Vulnerable populations
- Justifiable inclusion
- Power – researcher/participant

Research with humans imposes several responsibilities on researchers and institutions

- Considering a research project from the perspective of the participant.
- Ensuring research involving humans meets high scientific and ethical standards that respects and protects the participants.
- Commitment to the advancement of knowledge within an ethical framework that includes rigorous analysis, scrutiny and adherence to professional/disciplinary standards

Proportionate Approach to Research Ethics Review

- Ethics Review **is NOT** about putting unnecessary barriers or roadblocks in the way of ethical research
- The TCPS2 advocates a ‘proportionate’ approach to ethics **review** and the REB operates within this framework
 - Proportionate review doesn’t mean ‘lesser’ ethical duty/care it means that the greater the potential/likelihood of risk, the more stringent the scrutiny should be given to a project (i.e. Delegated vs. Full Board review) (However, the reviewers will still expect a full and complete, well thought out research ethics application to be submitted!)
 - The REB is tasked with ensuring that researchers (be they faculty, staff or students) have fully considered all ethical principles/requirements prior to beginning their research project

Application Process

AU Ethics Webpage:

<http://research.athabascau.ca/ethics/index.php>

Research Ethics Portal

(ALL applications)

<http://research.athabascau.ca/research-portal/index.php>

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Application Forms and Deadlines

Application Forms

All ethics applications are accessed and submitted online through the Research Portal. Please review the applicable instructions below PRIOR to beginning the application process:

- Instructions for Staff - Human Ethics approval application
- Instructions for Students - Human Ethics approval application
- Instructions for Supervisors of Graduate students

Guidelines for Applicants are available to assist you in completing your ethics application.

Templates for Students

- Information to Participate and Informed Consent template
- Patient Informed Consent template
- Online Informed Consent template
- Recruitment Poster template

Application Deadlines

- First Friday of every month, for the regular monthly REB meeting; EXCEPT, there will be NO July or August meeting.

- Review the instructions document BEFORE you dive into the portal and complete your online application:
<http://research.athabascau.ca/research-portal/students.php>
- Review the “Guidelines for Applicants” document on the Research Ethics webpage: <http://research.athabascau.ca/ethics/policies-guidelines.php>
- Complete the application thoroughly, and check the ERRORS tab to address all necessary items – SAVE OFTEN!
- Use plain language; provide definitions for specialized terms or acronyms

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Frequently Asked Questions

Contact Us

AU Research Portal

The AU Research Portal allows researchers to submit certification and research funding applications electronically for committee review and approval.

Researchers can use the AU Research Portal to:

- › apply for approval from the AU Research Ethics Board for research projects involving human participants
- › apply for internal funding
- › apply for departmental and institutional approval of external funding applications
- › collaborate on applications with your research team and administrators
- › receive notifications and reminders regarding the status of your applications and required renewals
- › track your applications as they move through the approval process and beyond
- › apply for approval from the Animal Care Committee for research projects involving animals

If you are accessing the Portal for the first time please review the instructions located in left hand menu of this webpage.

BEFORE beginning your online application, please review the applicable instructions document found in the left hand menu on this page.



[AU Research Portal](#)

Updated March 03 2015 by Student & Academic Services

Getting Started

In order to access the AU Research Portal, you must first [create an account](#). Once registered, [login](#) to complete the application forms.

Contact Us

For assistance [contact](#) AU Research Portal.

TIPS for Completing the Online Application

1. Choose your supervisor as a ‘signing authority’ for your application in the “**Approvals**” tab so your application gets routed to your supervisor to approve when you ‘submit’ the application. If you don’t find your supervisor in the list of signing authorities, call the Ethics Office to have him/her added to the list.
2. **SAVE** often—before moving on to each tab!
3. Read the questions **carefully** and answer fully! Be sure to include citations within the body of your responses to questions 1.2 and 1.6.
4. Provide **details**, even if they seem ‘obvious’ to you.
 - e.g. “..electronic data will be stored in a password protected file, on a password protected laptop in my locked office.”
5. Use the templates for informed consent and invitation to participate provided in the application if at all possible (this will ensure that all necessary elements of informed consent are covered in your documentation!).

TIPS for Completing the Online Application

6. Check for consistency! Your responses to the questions must be consistent throughout the application and in line with the information you are providing to potential participants.
 - e.g. if you state in question 1.6 that a survey should take approx. 10-15 min to complete, make sure the informed consent document provides this time estimate;
 - if you indicate in question 8.11 that withdrawal of data is not possible because it is anonymous, don't inform participants that if they end their participation their data will be removed from the study.
7. There is no 'spelling/grammar check' feature within the portal – consider formulating longer responses in a wordpad or notepad and copying and pasting it into the online application form. (if you use a word document, you may find the formatting causes some issues in the portal)
8. We are advised the portal is 'browser' sensitive – if you have problems try a different browser. If you are working on a Mac, the Safari browser definitely causes issues!

Include all necessary info in your application...

- **Be sure to upload all necessary appendices, such as....**
 - CORE Tutorial *Certificate of Completion* **(New requirement)**
 - References list**** *your application will be returned if this isn't included!*
 - Informed consent document(s)
 - Recruitment/Invitation to Participate documents
 - Copies of any Survey Questionnaires or Interview Questions
 - Approvals from other institutions/organizations if needed
- Any other documents mentioned in the application

Areas to pay close attention to...

- **Conflict of Interest**
 - Issues around use of students or employees as participants
 - Guidance available on the AU website – **AU Guide for Research in Dual-Role Situations**: “Involving Students or Others Related to the Researcher as Participants”
- **Data Storage and Security Details**
 - Who, where, how, for what amount of time; method of destruction according to data format (hard copy notes, computer files, audio tapes, etc.)
 - Security measures employed (password protections; locked cabinets; encryptions)
 - **SSHRC Funded?** SSHRC Data Archiving policy applies
http://www.sshrc-crsh.gc.ca/about-au_sujet/policies-politiques/statements-enonces/edata-donnees_electroniques-eng.aspx
- **Voluntary Consent – Free, Informed & Ongoing**
 - Is participation truly voluntary? Can respondents really withdraw at any time without negative consequences? Can their data be withdrawn at any time or are there limits to when this can occur?

Areas to pay close attention to cont'd...

- **Incentives to Participate**
 - Issues around extravagant or excessive incentives which may influence the free, voluntary consent
- **Time Commitment for Participants**
 - Be sure to comment on the time it will take participants to be involved in your study and whether there will be follow-up, or specific effort expended, etc. (e.g. You are asked to complete an online survey that should take 10 – 15 minutes of your time; You will be asked to complete 15 minutes of low impact aerobic exercise one day a week for 3 weeks).
- **Secondary use of data**
 - If you will be accessing/using data or information previously gathered or compiled for a purpose other than the current research purpose, this is secondary use of data. Check the Guideline for Use of Secondary Data for details on the requirements for ethics approval and consent.
- **Ensure participants are invited to contact the AU Research Ethics Office** if they have concerns or comments
 - Advise participants that the study they are asked to participate in has been reviewed by the AU Research Ethics Board and provide them info on how to contact the Ethics Office: Phone: 1-800-788-9041, ext. 6718 e-mail: rebsec@athabascau.ca

Reviewing your application: Ethics Decisions

Regular Decisions:

- **APPROVED, with no further requirements**, other than the final report at the conclusion of the research project and any necessary ethics renewal requests for projects ongoing for longer than 12 months
- **REVISIONS REQUIRED (Conditional Approval), revisions/clarifications or conditions must be dealt with before final approval is issued**
 - Resubmitted/revised application will be reviewed by the Chair on behalf of the Board / Departmental Ethics Review Committee.
 - Research **CANNOT** proceed until final approval is given
- **UNABLE TO APPROVE**
 - Reason(s) for decision and guidance for resubmission will be included in the results memo. Resubmission may be reviewed by the REB or Chair.

A Separate Process: Gaining Access to Conduct Research

- **Research involves staff or clients as participants**
 - Freedom Of Information and Protection of Privacy (FOIP) & Personal Information Protection and Electronic Documents Act (PIPEDA) legislation impose responsibilities on organizations as holders of confidential personal information
- **Research involves use of organization's resources**
 - Electronic & physical bulletin boards, e-mail lists, stored data
 - Staff assistance with participant recruitment or data collection
 - On-site recruitment or use of meeting rooms to conduct interviews
 - Access to private documents, proprietary information
- **Just because you work there does NOT mean you have access for 'research' purposes**
 - Permission must be sought from executive level
 - School Board Superintendent, Principal, Executive Officer
 - You may be subject to multiple ethics reviews

A Separate Process: Gaining Access to Conduct Research at AU

- **Recruitment contact – staff or student participants**
- **Research use of AU systems, staff assistance, physical resources, or proprietary information**
 - Electronic & physical bulletin boards, e-mail lists, stored data, private documents
 - Assistance with participant recruitment or data collection (*note: AU policy stipulates that personal information of students/staff will not be provided directly to researchers*)
- **AU Request for Institutional Permission to Access Resources for Research** is coordinated by the Ethics Office AFTER Final Ethics Approval
- Evidence of support for access/recruitment from the faculty/department from which you wish to recruit participants, or access/use resources is needed

See AU Policy & Procedures: *Institutional Permission to Access Resources for Research*
<http://ous.athabascau.ca/policy/#POI>

Life after ethics approval...

There will be some reporting to do regarding your research project, e.g. modification requests; ethics renewal requests; project completion (final) report, etc.

These types of reports are termed “**Events**” in the Research Portal. To submit an “**event**” form, you will:

1. Login to the Research Portal
2. Access your application located under “**Applications: Post Review**”
3. Click on the EVENTS tab to the left of your application
4. Choose the appropriate form
5. Complete the event form (saving along the way!) and Submit!

Resources & Training: Online Tutorial and Webinars

- On-line **TCPS2 2014: CORE Tutorial**
 - Required for all Graduate Students conducting research with humans
 - Certificate of Completion must be *uploaded to your Application for Ethical Approval*
 - Registration keeps track of where you left off
 - <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>
 - *When registering, choose OTHER and fill-in 'Athabasca University'
- **Recorded PRE-led Webinars** – various topics, elaborating on TCPS2
 - http://www.pre.ethics.gc.ca/eng/education/view_webinar-voir_webinaire/
- **Produced by the Interagency Panel on Research Ethics (PRE)**
 - National body responsible for implementation and changes to TCPS
<http://www.pre.ethics.gc.ca/>
- **Resources for Research Participants (that you may wish to have available)**
<http://pre.ethics.gc.ca/eng/education/brochure/>

Other AU Resources

- **Guidelines for Applicants**
 - <http://research.athabasca.ca/ethics/policies-guidelines.php>
- **Templates for Recruitment and Informed Consent documents** (also uploaded to the “Attachments” tab in the student ethics approval application form)
 - <http://research.athabasca.ca/ethics/templates-samples.php>

AU Ethics Webpage:

<http://research.athabasca.ca/ethics/index.php>

More Information / Advice:

Researcher and supervisor comments
are always welcome!

rebsec@athabascau.ca

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