

AU RESEARCH ETHICS

Surviving the Ethics Approval Process Unscathed!

Gail Leicht, Research Ethics Officer June 22, 2016

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



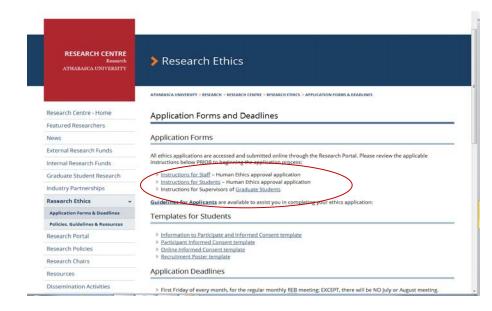
Application Process

AU Ethics Webpage:

http://research.athabascau.ca/ethics/

Research Ethics Portal (ALL applications)

http://research.athabascau.ca/portal/index.php



- Review the instructions document BEFORE you dive into the portal and complete your online application: http://research.athabascau.ca/ethics/ethical_review_application-students.php
- Review the "Guidelines for Applicants" document on the Research Ethics webpage: http://research.athabascau.ca/ethics/forms.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



RESEARCH CENTRE Research ATHABASCA UNIVERSITY

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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 <u>create an account</u>. Once registered, <u>login</u> to complete the application forms.

Contact Us

For assistance $\underline{\text{contact}}$ AU Research Portal.



Step 1: Create an Account

Create an account in the portal if you are accessing it for the first time:

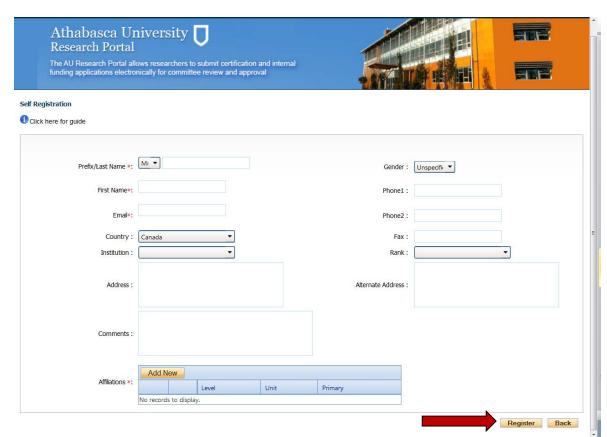
Go the Research Portal Website and Select "Register"





When you have filled out all the relevant information (including address, phone number, institution and email address) click on the "Register" button.

An email confirming your registration will be sent from the AU Research Portal to the email address you just registered (check your spam filters if the email doesn't come through)!





Copy the confirmation code and follow the link provided in the email. Paste the code in the appropriate box and choose and confirm your password. (NOTE: the confirmation code is only valid for a period of time....complete your registration promptly).

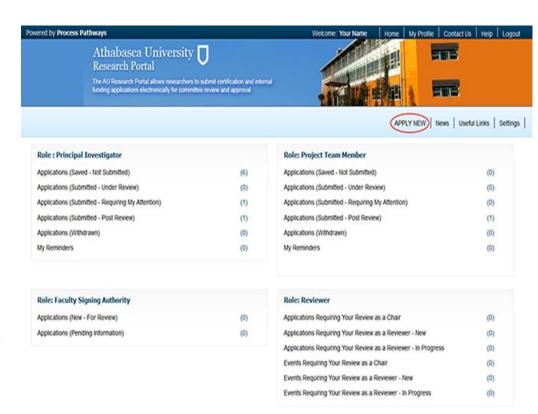
Process Pathways	
Athabasca University Research Portal The AU Research Portal allows researchers to submit certification and internal funding applications electronically for committee review and approval	
User Name Confirmation code	
Password	
Confirm Password	
	Cancel Confirm

If you have trouble with the conformation code – check to ensure there is no space before or after it as that seems to cause a problem!



Step 2: Creating an application!

- Login to the <u>AU Research</u>
 <u>Portal</u> using your email address and password information.
- Once you are logged into the portal and on your home screen, choose "Apply New" to begin a new application.





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.
- **2. SAVE** often—before moving on to each tab!
- 3. Read the questions carefully and answer fully! Be sure to include references/citations within the body of your responses to questions 1.2 and 1.6.
- 4. 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)
- 5. 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....
 - References list**** your application will be returned if this isn't included!
 - Informed consent document
 - Recruitment/Invitation to Participate documents
 - Approvals from other institutions/organizations if needed
- Any other documents mentioned in the application

Know that there is help....if you have difficulties, experience a road block or are just plain frustrated...please do email or call for assistance!



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 their 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 information.

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

Athabasca

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, 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.



Once your application is submitted what then?

After the review of your application, if you are requested to make *revisions*, here's what you do:

- 1. Login to the research portal
- Locate your application by clicking on the heading "Applications (Submitted

 Post Review)"
- 3. Make your revisions in ALL CAPITAL LETTERS so that any changes you make 'stand out' for reviewers (there is no 'formatting' available in the portal just yet!)
- 4. Upload any new or revised documents in the 'attachments' tab
- 5. Hit "Resubmit"

DON'T FORGET TO **SAVE** BEFORE YOU RESUBMIT!



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 responsibility 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
- AU Request for Institutional Permission to Access Resources for Research is coordinated by the Ethics Office AFTER Final Ethics Approval
- Researchers are expected to provide evidence of support for access/recruitment from the faculty/department from which you wish to recruit participants, or access/use resources

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



Life after application review and approval...

There will be some reporting to do regarding your research project, e.g. modification requests; ethics renewal requests; project completion (final) reporting, 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
- Access your application located under "Applications (Submitted Post Review)"
- 3. Click on the EVENTS tab to the left of your application
- 4. Choose the report form you need to make
- 5. Complete the event form (saving along the way!) and Submit!



Resources & Training: Online Tutorial and Webinars

- Produced by the Interagency Panel on Research Ethics (PRE)
 - National body responsible for implementation and changes to TCPS http://www.pre.ethics.gc.ca/
- On-line TCPS2 2014: CORE Tutorial
 - Introductory tour of the Tri-Council Policy Statement
 - Canadian resource for all students, faculty, REB members, general public
 - AU-recommended, but not 'required' or 'pre-requisite'*
 - Certificate of Completion (qualifies across Canada)
 - Registration keeps track of where you left off
 - http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/
 *When registering, follow instructions for institutions not requiring completion: 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/



Other AU Resources

- Frequently Asked Questions (FAQs)
 - http://research.athabascau.ca/faqs/ethics.php
- Guidelines for Applicants
 - http://research.athabascau.ca/ethics/forms.php
- Templates for Recruitment and Informed Consent documents (also uploaded to the "Attachments" tab in the student ethics approval application form)
 - http://research.athabascau.ca/ethics/forms.php

AU Ethics Webpage:

http://www.athabascau.ca/research/ethics/



More Information / Advice:

Researcher and supervisor comments are always welcome!

rebsec@athabascau.ca

Gail Leicht

Research Ethics Officer 1-800-788-9041, ext. 6718

