**UNIVERSITY OF LETHBRIDGE**

**To**

**UNIVERSITY OF ALBERTA**

**MAPPING GUIDANCE**

This guidance is intended for paper ethics applications approved by the University of Lethbridge HPRC to transfer the application into the ARISE system. Applications should be submitted to REB 1 or REB 2. The REB that you would apply to would be [based on the methodology](https://www.ualberta.ca/research/research-support/research-ethics-office/human-research-ethics/research-ethics-boards/index.html) in your application. Use this document to map responses from your existing approved application, into the relevant sections of the ARISE application. References to ARISE application will be noted in the comments within the margin.

**SECTION A: GENERAL -** *This information is collected under the authority of the Alberta Post-secondary Learning Act and will be used for administrative purposes associated with the ethical review of your human participant research protocol. It will be treated in accordance with the privacy protection provisions of Part 2 of the Alberta Freedom of Information and Protection of Privacy Act (*<http://foip.alberta.ca/legislation/act/index.cfm>). *Questions about the collection, use or disclosure of your personal information collected on this form can be directed to Susan Entz, Ethics Officer, Office of Research Ethics, University of Lethbridge, Lethbridge, Alberta   T1K 3M4, Phone: (403) 329-2747 and Email:* *susan.entz@uleth.ca**.*

**A1. Researcher/Applicant Information**

 Name:

 Department:

 Telephone Number:

 Email address:

 Are you: [ ]  Faculty [ ]  Staff [ ]  Doctoral Student

 [ ]  Graduate Student [ ]  Undergraduate Student

 [ ]  Other:

**A2. Co-Investigator’s Information**

 Name:

 Department:

 Telephone Number

 Email address:

 Are you: [ ]  Faculty [ ]  Staff [ ]  Graduate Student

 [ ]  Graduate Student [ ]  Undergraduate Student

 [ ]  Other:

**The protection of human participants will be assured in accordance with the Tri-Council Policy Statement or with other guidelines if these have been agreed upon as more appropriate.**

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Signature of Researcher/Applicant Date

**When the Researcher/Applicant is a student, the supervisor must sign the following statement:**

**“I have reviewed this application and I deem it ready to submit to the Human Participant Research Committee for review.”**

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Signature of Supervisor Date

**A3. Student Thesis/Project Committee**

a) Is this research for an undergraduate or graduate thesis/project or applied/independent study?

 [ ]  Yes [ ]  No

b) If applicable, please provide the names, departments and phone numbers of your Committee members.

Name: Department: Email or telephone:

1.

2.

**A4. Title of Project:**

Indicate the title of your project. If this project is funded, the title should be the same as the title of your funded research.

**A5. Location of Research**

a) Indicate where the research will be conducted.

b) Does this project involve other centers, jurisdictions or countries? If so, please provide a list of the other groups who will be reviewing this protocol. (For example, the Lethbridge College Research Ethics Board must approve all posters to be posted on their campus.)

c) Will this study involve schools located in Zone 6? [ ]  Yes [ ]  No

*Note: If this study will involve schools within Zone 6, once HPRC approval has been granted, district/school approval will be coordinated through Research and Placement Services in the Faculty of Education prior to the start of the study. You will be notified upon receipt of district/school approval. If the study involves schools outside of Zone 6, it is the responsibility of the researcher to ensure that the appropriate district/school approval is obtained prior to the start of the research; a copy of the approval must be submitted to the Office of Research Ethics.*

d) Is this a class project (i.e., not an applied or independent study)? [ ]  Yes [ ]  No

If so, specify the course number and title:

*Note: A class project application is normally submitted by an instructor who is teaching a research course and whose students will be conducting a mini-research project for the course.*

**A6. Start/End Dates of Research Involving Human Participants**

Please state the proposed start and end dates of the research involving human participants. **NOTE: Research involving human participants cannot begin until Human Participant Research Committee approval has been received.**

Start date:

End date:

**A7. Scholarly Review**

Some research projects may require scholarly review. What type of scholarly review has this research undergone?

[ ]  None

[ ]  External Peer Review (e.g., granting agency)

[ ]  Supervisory Committee (e.g., student research projects)

[ ]  Special Review (please provide details)

**A8. Funding**

a) Is the project funded? [ ]  Yes [ ]  No

Funding approved – please specify source(s):

 1.

 2.

 3.

Funding pending – please specify source(s):

 1.

 2.

 3.

**A9. Conflict of Interest**

1. Are any of the investigators or their immediate family receiving any personal remuneration (including investigator payments and recruitment incentives but excluding trainee remuneration or graduate student stipends from the funding of this study that is not accounted for in the study budget?

[ ]  Yes [ ]  No

1. Do any of the investigators or their immediate family have any proprietary interests in the product under study or the outcome of the research including patents, trademarks, copyrights, and licensing agreements?

[ ]  Yes [ ]  No

1. Is there any compensation for this study that is affected by the study outcome?

[ ]  Yes [ ]  No

1. Do any of the investigators or their immediate family receive payments of other sorts from the funder for this study (i.e., grants, compensation in the form of equipment or supplies, retainers for ongoing consultation and honoraria)?

[ ]  Yes [ ]  No

1. Are any of the investigators or their immediate family, members of the funder’s Board of Directors, Scientific Advisory Panel or comparable body?

[ ]  Yes [ ]  No

1. Do you have any other relationship, financial or non-financial, that, if not disclosed, could be construed as a conflict of interest?

[ ]  Yes [ ]  No

Please explain if the answer to any of the above questions is Yes.

**Section B: Details about the PROJECT**

**B1. Purpose of Project**

Provide a brief and clear statement of the context and objectives of the project, including the key questions and/or hypotheses of the project (in two pages or less).

**B2. Description of Participants**

a) Indicate who you will recruit as potential participants in this study (e.g., undergraduates, school children, seniors) including any inclusion or exclusion criteria (e.g., over 65 years of age, self-identified as gay, speaks Blackfoot, speaks English), and the number of participants required.

b) If the participants or facilities will be offered compensation or incentive for participating in the research, provide details. Specify the amount, what the compensation/incentive is for, and how payment will be determined for participants who do not complete the study.

**B3. Recruitment of Participants**

1. Briefly describe how participants will be recruited (e.g., letter, phone, poster, third party) and who will do the recruiting. Describe any existing position of authority or power between the recruiter and the participant. Researchers should avoid recruiting their own students. If this is unavoidable, researchers should provide the name of a research assistant, not associated with the course, who will do the recruiting and obtain consent when the researcher is not present.

*If posters, newspaper advertisements, radio announcements or letters of invitation are being used, append these to this application. If recruiting through a third party, attach confirmation of permission from the organization if available.*

1. When and how will people be informed of the right to withdraw from the study? What procedures will be followed for people who wish to withdraw at any point during the study? What happens to the information contributed to the point of withdrawal?
2. Indicate how participants can obtain feedback on the research findings.

***Does the research specifically involve Aboriginal groups or communities?*** [ ]  Yes [ ]  No

***If the answer was Yes, please complete section B3d to B3j.***

1. If you will be obtaining consent from Elders, leaders, or other community representatives, provide details:
2. If leaders of the community will be involved in the identification of potential participants, provide details:
3. Provide details if:
* Property or private information belonging to the community as a whole is studied or used;
* The research is designed to analyze or describe characteristics of the community; or
* Individuals are selected to speak on behalf of, or otherwise represent the community
1. Provide information regarding consent agreements, including access, ownership and sharing of research data with communities.
2. Provide information on how final results of the study will be shared with the participating community (e.g., via band office, special presentation, deposit in community school, etc.).
3. Describe how you have engaged the community. For additional information on research involving the First Nations, Inuit and Métis Peoples of Canada, please refer to [Chapter 9 of the TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/).
4. Is there a formal research agreement with the community? [ ]  Yes [ ]  No

Provide details about the agreement or why an agreement is not in place, not required, etc.

**B4. Description of Research Procedures**

Provide a summary of the design and procedures of the research. Provide details of data collection (instrument, location, use of recording, etc.), and time commitment for the participants, etc. If applicable, identify any special training or qualifications that may be required for data gatherers. *NOTE: all study measures (e.g., questionnaires, interview guides, surveys, rating scales, etc.) must be appended to this application. If the procedures include a blind, indicate under what conditions the code will be broken, what provisions have been made for this occurrence, and who will have the code.*

**B5. Privacy Protection**

The next set of questions deals with anonymity and confidentiality. Refer to the brief descriptions below to assist you in answering these questions.

***a)   Anonymity****refers to the protection of the identity of participants.* ***Anonymity protection can be provided along a continuum, from “complete” to “no” protection, where complete protection means that no identifying information will be collected and there is no direct interaction between the researcher and the participant.****We remind applicants that university researchers should treat any personal information in accordance with the privacy protection provisions of Part 2 of the Alberta Freedom of Information and Protection of Privacy Act (*<http://foip.alberta.ca/legislation/act/index.cfm>).*If you have any questions about the collection, use, or disclosure of personal information under the Act, please contact the FOIP Coordinator, The University of Lethbridge, 4401 University Drive, Lethbridge, Alberta   T1K 3M4, Email:* *foip@uleth.ca**.*

1. Will the anonymity of the participants be protected?

 [ ]  Yes (completely) [ ]  Yes (partially) [ ]  No

2. If “yes”, explain how anonymity will be protected, and describe how this will be explained in the consent process.

3. If “no”, justify why loss of anonymity is appropriate, and describe how this will be explained in the consent process.

***b) Confidentiality*** *refers to the protection, access, control and security of the data and personal information. Confidentiality or non-disclosure agreements are recommended for all the individuals involved with the project (e.g., transcriptionists, research assistants, co-investigators, etc.). Append a copy of the confidentiality template if available.*

1. How will confidentiality be protected and how will this be explained in the consent process? Specify which personnel will have access to the listing of names and study ID numbers as well as other study information collected (use job titles rather than individual names.) Provide details on the location, manner of storage, and the proposed retention period of the information collected.

**B6. Potential Risks and Benefits**

|  |  |
| --- | --- |
| **To facilitate Human Participant Research Committee review and to determine whether the study involves more than minimal risk, please respond to the following questions. Does this project involve…** | **Check those that apply** |
| 1. Collection of data through invasive clinical procedures that are not required for normal patient care. |  |
| 2. Collection of data through noninvasive clinical procedures involving imaging or microwaves that are not required for normal patient care. |  |
| 3. Any other non-therapeutic risks that arise from procedures not directly related to patient care. |  |
| 4. Collection, use, or disclosure of health information or biological samples where the researcher is requesting that the requirement for informed consent be waived. |  |
| 5. Any procedures involving deception or incomplete disclosure of the nature of the research for purposes of informed consent. |  |
| 6. Any possibility that a breach of confidentiality could place participants at risk of criminal or civil liability or be damaging to participants’ financial standing, employability or reputation. |  |
| 7. Research questions or procedures that might be expected to cause participant psychological distress, discomfort or anxiety beyond what a reasonable person might expect in day to day social interactions (e.g., questions that raise painful memories or unresolved emotional issues). |  |
| 8. Investigations in which there is a previous or existing relationship between the investigator and participants (e.g., manager/employee, therapist/client, teacher/student). |  |

1. Outline any risks of potential physical or emotional harm or discomfort to the participants, and describe the measures that will be put in place to mitigate these risks. Explain why the research is important and the benefits of participating (compensation paid to participants is not considered a benefit).
2. Describe the anticipated dissemination of the study findings.
3. Indicate the steps taken to inform participants of the possible consequences of releasing information in the public domain, and describe how participants will be given an opportunity to review material where appropriate.
4. Outline the exit strategy for termination of the study. Some types of research involve intense or lengthy contact between a researcher and the study participant(s), which may result in a close personal relationship, especially if the research itself involves matters close to the heart of participants. For this section, applicants should consider the possibility that a strategy may be required for participants who have difficulty in disengaging from the project after their role is completed or the project has terminated. If this does not apply to your research, please indicate N/A. If the research involves vulnerable populations, carefully clarify the boundaries between the researcher and participants.

**B7. Obtaining Consent**

Advise the Committee how informed consent will be obtained. The Tri-Council Policy Statement ensures that informed consent be obtained in writing from all participants or, when appropriate from parents or legal guardians, unless there is a good reason for not doing so. If a consent form will be used, attach copies for the Committee. The Human Participant Research - Sample Letter of Consent is available at: <http://www.uleth.ca/research/human-participant-research-guidelines-forms>. Please ensure that the reading level of the consent form is appropriate to the population involved.

a) Clearly detail who will be obtaining consent and the procedures for doing so. If appropriate, specify whether participants will be randomly assigned to groups before or after consent has been attained.

b) If the participants are not able/competent to give fully informed consent (cognitive impairment, age, etc.), or if there are significant power differences in operation (professor/student, employer/employee, political or economic minorities, etc.), please specify, and describe steps you will take to obtain free and informed consent.  If participants are not competent to consent, specify who will consent on their behalf.

c) Do any of the procedures include the use of deception or partial disclosure of information to participants? If yes, provide a rationale for the deception or partial disclosure. Describe the procedures for debriefing the participants.

 d) **For the letter of consent/consent form:**

1. Extend an invitation to participate in the research project.
2. Provide a brief description of the project, including the purpose of the research, and a description of what is expected of the participant (e.g, the time commitment and the frequency of contact).
3. Describe the risks and discomforts (e.g., distress, inconvenience, psychological or social discomforts, fatigue, or physical safety issues). If the research project has the potential to identify upset, distressed or disturbed individuals, describe what arrangements will be made to assist these individuals, if need be.
4. Describe the benefits, including an explicit statement if there are no potential benefits to the participants (e.g., “You will not benefit directly from participation in this research”).
5. Provide assurance of anonymity and confidentiality – this statement should describe the steps taken to ensure anonymity and confidentiality, and should include information regarding who will have access to the data collected. **NOTE: Participants should be advised that their privacy cannot be guaranteed when electronic surveys are used.**
6. Outline compensation for participation in the research project, if applicable.
7. Provide a non-coercive disclaimer – this statement should indicate that participation is voluntary, and that refusal to participate will not initiate prejudice, penalty or loss of benefits to which the participant is otherwise entitled.
8. Provide an option to withdraw – this statement should indicate that participants may discontinue participation at any time without prejudice, penalty or loss of benefits. The process for withdrawal, in addition to information on the participant’s right to request the withdrawal of data, should be clearly explained along with an explanation of the conditions under which researchers would not be able to remove a participant’s data from the study. Where appropriate, participants who choose to withdraw should be consulted on the fate of their data.

1. Indicate the instances when the researcher may be obligated by law to report, to law enforcement or another agency, information revealed as a result of the research. **NOTE: Questions likely to result in reportable activities must be flagged for the respondent, and the respondent must be given the option to skip these questions.**
2. Provide a brief description of the anticipated use of the data.
3. Provide information on how participants will be informed of the results of the research.
4. Provide the name of the researcher, along with their institutional affiliation, and contact information for questions/clarification about the research project. Also include the following statement: “Questions regarding your rights as a participant in this research may be addressed to the Office of Research Ethics, University of Lethbridge (Phone: 403-329-2747 or Email: research.services@uleth.ca).”

e) **For telephone surveys**, informed consent should take place in the form of a verbal explanation of the above points. Append the script for this explanation to this application.

f) **For anonymous questionnaires**, include a cover letter that includes all the information normally provided in a consent form. Append a copy of this cover letter to this application.

**B8. Reporting Requirements**

Research is subject to continuing research ethics review from the date of initial ethics approval, throughout the life of the project by submission of the required report. Continuing research ethics review shall consist of an annual progress report (multi-year research projects), and an end-of-study report (projects lasting less than one year). Select the appropriate reporting requirement for the study:

[ ]  Annual renewal report (due on or before annual term date)

[ ]  End-of-study report (for projects shorter than one year in duration)