

RESEARCH ETHICS HANDBOOK

Office of Research Services
MacEwan University



Fall 2023

Preamble

This document was created to compile all REB guidelines into one place, in order to address commonly asked questions related to research ethics.

As the research ethics landscape is constantly evolving, this document will continually be reviewed and updated. Should there be any discrepancies between this document and the most recent version of the [Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans](#) (TCPS2), the TCPS2 will always be considered correct.

The area of research ethics is not black and white, and it's not possible to cover all types of projects in one document. If you are still unsure of the requirements of your specific project, please reach out to the Research Ethics Board, REB@macewan.ca.



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Do I need ethics approval?

The definition of research is an 'undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation'¹
Is one of the intended purposes of the activity, project or data collection 'research'?

Yes or Not Sure

No or Not Sure

Will the undertaking involve living human participants² who may be observed, provide information, data, or responses to interventions, stimuli, or questions that are intended to help answer the research question?

Is the sole intended purpose of the undertaking for MacEwan quality assessment or management purposes to improve services or practices within a program, department, club or faculty³?

Yes

No

Yes

No

Will the undertaking involve individuals whose involvement is intended to answer the research question?

Will the undertaking involve the observation of people⁴?

Yes

No

Yes

No

Ethics review and approval needed.

Will the observation be in public places?

Ethics review not required.

Ethics review is not required when the research may involve individuals who are not themselves the focus of the research to obtain information. Such individuals are not considered participants¹⁰.

Yes

No

Ethics review is required.

Ethics review is not required for the observation of people in public places when it does not involve any staged intervention or direct interaction with individuals or groups, there is no expectation of privacy, and dissemination of results do not identify individuals.

Will the undertaking rely exclusively on publicly available literature or other information⁷?

Will the undertaking use a person's non-anonymous data or information that was collected for one purpose but now being proposed for another purpose⁸?

Will the undertaking involve the use of human biological materials derived from living or deceased individuals⁹?

Yes

No

Ethics review not required.

Ethics review may be needed. Contact the REO⁶.

Yes

No

Ethics review is required.

Yes

No

Ethics review not required.

Contact the MacEwan Office of Institutional Analysis and Planning (IAP)⁵ for information on the review of surveys and evaluations conducted on campus.

If your project involves collecting or receiving data to assess **external** organizations, it may need review. Contact Research Ethics Officer (REO)⁶ to discuss.

Flowchart References

1. TCPS2: Research Requiring Research Ethics Board Review, [Article 2.1 and Application](#)
2. TCPS2: Research Requiring Research Ethics Board Review, [Article 2.1 and Application](#)
3. TCPS2: Activities Not Requiring Research Ethics Board Review, [Article 2.5](#)
4. TCPS2: Research Exempt from Research Ethics Board Review, [Article 2.3 and Application](#)
5. MacEwan University Institutional Analysis and Planning, IAP@macewan.ca
6. Research Ethics Officer, REB@macewan.ca
7. TCPS2: Research Exempt from Research Ethics Board Review, [Article 2.2 and Application](#)
8. TPCS2: Secondary use of anonymous datasets does not require Research Ethics Board Review, [Article 2.4 and Application](#).

Secondary use of datasets that include identifiable information, or were originally collected with identifiable information and have since been anonymized, see [Chapter 5D: Consent and Secondary Use of Information for Research Purposes](#).

9. TCPS2: Research Requiring Research Ethics Board Review, [Article 2.1 and Application](#)
Also see [Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction](#)
8. TCPS2: Research Requiring Research Ethics Board Review, [Article 2.1 and Application](#)

Click [here](#) for the full Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2022)

Getting started...

MacEwan's Research Ethics Board (REB) uses an online platform called ROMEO to review and process all submissions for ethics review.

For MacEwan Faculty & Staff:

If you are a **MacEwan faculty or staff member**, and it is your first time submitting an application, please register for ROMEO by completing the [registration form](#). Once your registration has been processed, you can log in to the **Research Portal** using your MacEwan ID and password.

Your registration will be processed internally, and you should receive an email notifying you that your account has been created in **approximately 1 - 2 business days**.

For MacEwan Faculty & Staff, your [log in page](#) will look like this:

Ensure you are selecting '**Research Portal**' to log in.

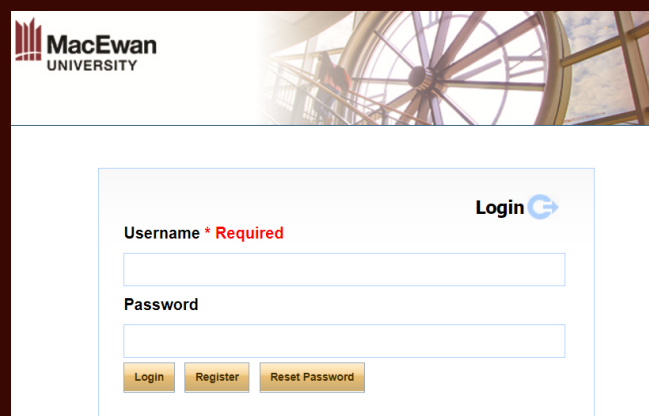


For MacEwan Students & External Researchers:

If you are a student or external researcher, you need to [register](#) for a ROMEO account before logging in.

After you receive a confirmation email, you will be able to log back in to the same website and begin your application.

For students and external researchers, your registration & log in page should look like this:



Requesting REB Exemption

There are two scenarios where research ethics exemption can be requested from the REB:

1. **Exemption for Dissemination Purposes**, in situations where a journal or conference requires formal REB documentation, and where the project itself was not research involving humans;
2. **Exemption for Release of Funds**, in situations where funding for research involving humans has been awarded to a faculty member, an REB approval is typically required in order to have the funds released to the researcher. However, the REB acknowledges that sometimes funds are needed to facilitate project activities other than those involving participants (ex. the researcher needs to hire a research assistant to fill out the ethics application, community engagement efforts).

Applying for REB Exemption

1. [Log in to ROMEIO's Research Portal](#), and complete and submit the 'Request for REB Exemption' form. Ensure the appropriate section of the form is completed (Dissemination vs Funding Release), and clearly describe how the activity(s) do not fall under the purview of the REB.
2. The request is reviewed in-office, and should take 1 - 2 business days.
3. In the case of exemption for funding release, a 90-day exemption will be issued, so that the researcher can access funds for research activities that do not involve human (or animal) participants.
4. Note that the exemption letter does not mean funding will be released, as the decision ultimately lies with the Associate Vice-President, Research (AVPR).
5. The AVPR will confirm, in writing, whether or not the release of funds will be approved; if it is approved, the grant officer will open the grant.
6. It is the responsibility of the researcher to ensure full ethics approval is obtained before the 90-day exemption period is over. Failure to do so may result in the grant being suspended. If the researcher does conduct research involving humans prior to receiving ethics approval, the grant may be terminated.

Externally approved studies: Does I need approval from MacEwan?

As a post-secondary institution, we get many requests to distribute recruitment materials from external researchers. While we work to foster a collegial and collaborative space for all types of research, there are instances where ethics review from MacEwan University is required, even if the project has ethics approval elsewhere. Note that this policy was developed after consulting similar policies at other Alberta post-secondary institutions.

You are an external researcher, and you want to:

a. compare responses from MacEwan to other institutions. If your research will be using responses that are identified as being from participants at MacEwan as a variable in your analysis, and/or identifying MacEwan in the dissemination of results, then MacEwan REB approval is required.

b. ask MacEwan faculty, staff, or administration (e.g., a Dean or Department Chair) to distribute recruitment materials, using a listserv, newsletter or faculty contacts. Using MacEwan resources and formal channels of communication in this manner for the purposes of recruiting research participants requires MacEwan REB review as you are directly using MacEwan as a recruitment site for your study*.

c. ask a member of the MacEwan faculty, staff, or administration, to share your recruitment materials using their personal social media accounts. Faculty or staff members are free to share study recruitment information on their personal social media accounts; this does not require MacEwan REB review.

d. email individuals (e.g., faculty, students, staff, administrators) you have identified on MacEwan's website using publicly available information to ask if they would be interested in participating in your study. Using publicly available information to contact individuals at MacEwan does not require MacEwan REB approval if you are only asking the person you are directly contacting to participate in your research, and are not asking them to forward the request to colleagues (see b above).

e. ask instructors to forward your recruitment materials to their students. Accessing students as research participants through an instructor requires MacEwan REB approval*.

**Please note that in situations where MacEwan REB approval is required, obtaining ethics approval from MacEwan does not obligate MacEwan faculty or staff to distribute your recruitment information. It only allows the researcher to request this.*

Externally approved studies: Do I need approval from MacEwan?

Obtaining MacEwan REB approval if you already have approval elsewhere is simple and straight forward. We have developed a streamlined process for obtaining approval from MacEwan if ethics approval has already been obtained elsewhere:

- a. [Register for our online system](#), ROMEO, as an external researcher.
 - b. **Select** 'Application for Externally Approved Studies'.
 - c. **Complete** the short form and attach a PDF of the approved application from your home institution, the approval letter, and any additional study-related materials (ie. consent form, recruitment material, study instruments)
 - d. Once received, the study is sent to the REB Chair for review, and a response should be issued within 2-3 business days.
-

If you are an **internal researcher**, and will be a coinvestigator on a project that is being administered through another post-secondary institution, primary ethics approval should be held at the host institution. **However, as a MacEwan faculty member, you must also ensure you have sought secondary approval from MacEwan's REB.**

Follow the steps outlined above to obtain ethics approval. Note that even though you may be a coinvestigator on the project itself, for the purposes of this review, you will be listed as the primary investigator within ROMEO. Once received by MacEwan's REB, it will be clear who the project principal investigator is, and how the rest of the study team is made up.

Please contact REB@macewan.ca with any questions or concerns.

Does my case study need ethics review?

To determine if your case study needs ethics review, consider the intent of the document; is it being developed for teaching or research purposes? Keep in mind the definition of research as determined by the [ICPS2](#) (2022), "Research is an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation."

Criteria for Teaching* vs Research-based Case Studies

Teaching*

does not require ethics review

Research

requires ethics review

Would be written as a "story"

Would have research objectives and question(s) (e.g., What, How, or Why)

Would be written to support problem-based learning

Would have case study method recognized as research method to collect empirical data

Would have learning objectives

Makes a conceptual or theoretical contribution to discipline, generates knowledge

Would require teaching notes

Could include development of a research instrument

Would value practical implications more than theoretical knowledge

Could have theoretical propositions in addition to practical implications

**Please note that a 'teaching case study' should not be confused with SoTL work, which is considered research and requires ethics review.*



The following pages provide information and examples for situations where **ethics review is not needed**, and for when **ethics review is needed**.

If you are ever unsure about your case study, please contact REB@macewan.ca for help.

Does my case study need ethics review?

Case Studies Not Requiring Ethics Review

Writing a report on a unique or interesting business or clinical case would not fall within the definition of research and would simply be considered accounts of individual cases. These cases are typically not generalizable, and information may be considered educational by sharing. It is expected that individuals are made aware of plans to create a report about their case, which may be published. Where appropriate, the reports should be de-identified.

Per the TCPS2 (2022) Articles 2.2-2.4, case studies **do not require REB review** if the author is relying exclusively on information that is:

- a. publicly available;
- b. is in the public domain with no reasonable expectation of privacy;
- c. relies on the natural observation of people in public spaces, or;
- d. secondary use of anonymous information, so long as the process of data linking does not generate identifiable information.



While ethics review may not be required for this work, it is still expected that the case study be conducted in an ethical manner, specifically around the privacy, confidentiality, and consent procedures; guidance for these issues can be sought by contacting privacy@macewan.ca.

Examples of case studies where ethics is not required:

- i. If you are anecdotally writing about a client receiving therapy or treatment, and the client is anonymous, then you do not need REB approval. However, you should ensure that individuals will be made aware of plans to create a report about their case which may be published, and consultation with the Information & Privacy Office may be needed.
- ii. If you are writing about an organization facing a challenge / decision point, with the objective of using the case in class to provide students with a real-life scenario to apply business concepts, then you do not need REB approval. Such cases put students "in the shoes of the protagonist" to discuss solutions and approaches to the challenge. While REB approval is not needed, you should ensure that individuals / organizations will be made aware of plans to create a report about their case which may be published.

Does my case study need ethics review?

Cases Requiring Ethics Review

When the author seeks to use data collected to answer a research question to generate knowledge, and the information being used to answer the research question does not fall under TCPS2 Articles 2.2 – 2.4, above, it is now considered research. This includes data initially collected for non-research purposes. **This requires REB review.**

Examples of case studies where ethics is required:

- i. You are analyzing a case report(s) to answer a specific research question, or are comparing two clients and their reactions to receiving treatment.
- ii. You are using the case study method to answer a research question. This may include one or more cases, and may focus on theory building, theory testing, or description. Typically, this method follows a well-defined process including defining a research question, selecting case(s), deciding on research protocols and data collection methods, data analysis, and integration with the literature, in order to contribute new knowledge to the discipline.

External Ethics Requirements

It is possible that journals or grant applications require formal documentation from the REB, even though the work itself does not require ethics review. Authors may apply to the REB for an exemption letter to be issued regarding their work.

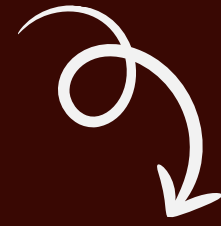
Contact:

Please contact the REB with any questions regarding the ethics requirements for your case study, at REB@macewan.ca.

Guidance regarding privacy and confidentiality for non-research studies can be sought by contacting privacy@macewan.ca.



Conducting Health Research at MacEwan



Research Using Health Information Governed by the Health Information Act

Health information in Alberta that is in the custody or under the control of a custodian or health information repository is governed and protected by the [Health Information Act](#) (HIA).

Researchers who propose to access/use health information, as defined in the HIA (diagnostic, treatment and care information, or, registration information), in their research must gain ethical approval for the project from a HIA Designated Research Ethics Board (under Part 5, Division 3 of HIA).

There are only three Research Ethics Boards (REBs) in Alberta that have been identified in the HIA as being able to review research involving health information;

- i. [Conjoint Health Research Ethics Board](#) – University of Calgary
- ii. [Health Research Ethics Board](#) – University of Alberta
- iii. [Health Research Ethics Board of Alberta](#) – Alberta Innovates

MacEwan University has formally delegated the ethics review of HIA-designated research to the University of Alberta. The intent of this agreement is to streamline the ethics review process research involving health information (as defined above), while still ensuring all appropriate and necessary ethical standards and participant protections are upheld.

MacEwan University researchers who are conducting HIA reviewable research will now only have to apply for ethics review through the University of Alberta using the [Alberta Research Information Services](#) (ARISE) system. **Researchers will no longer be required to also apply for ethics approval here at MacEwan. The MacEwan Research Ethics Board will accept the review conducted by the University of Alberta HREB without further scrutiny.**



If you are planning on conducting research that involves health information that falls under the Health Information Act, you will need access to the University of Alberta ARISE system.

Please follow the steps outlined on the following pages.

Conducting Health Research at MacEwan



Accessing the University of Alberta ARISE System

If you already have a University of Alberta CCID:

1. Log in to the ARISE System, click on your name in the top right-hand corner, and edit your profile by changing the Department to MacEwan University.

If you do NOT have a University of Alberta CCID:

1. You will need to request a guest CCID from their Research Ethics Office by completing the CCID Request Form. It may take 1-2 business days after you change the temporary password assigned to your CCID before you can log in to the online system. If you are not able to log in to the online system after 7 business days, please contact reoffice@ualberta.ca. Guest CCIDs must be renewed every twelve months.

2. Once you have your CCID, log in to the ARISE System, and select 'Request a Role'.

3. Scroll down to the bottom and select the "REB Principal/Co-Investigator" role, then click Continue to move to the second page.

4. On the second page, answer the four questions. For 3.0, set the Department/Employer to "MacEwan University (Department)". Leave 4.0 blank.

5. Click Continue and you will exit the form. Click on the left, then click OK to complete the request. You will receive a message right away that the role has been granted. If not, see Troubleshooting.



Conducting Health Research at MacEwan

Accessing the University of Alberta ARISE System

Receiving Notifications

The ARISE system sends system-generated notifications to inform applicants when an application moves through the review process (ie. when it is sent back to you for changes, when it is approved, when a renewal is due, etc).

The notifications will go to the @ualberta.ca email address associated with your UofA CCID but you can (and should) redirect them to your preferred email address.

To change your preferred email address:

- a) Log into the ARISE System.
- b) Click on your name (top right corner of the screen).
- c) Click on 'My Profile'.
- d) Click on 'Edit My Info' (on the left side of the screen).
- e) Enter your preferred email address in the Email field.
- f) Click OK to submit the change and exit the form.



Starting an Application

To start your application, click the button from your Dashboard.

- a) In Section 1.1 (5.0), list yourself as the local Principal Investigator.
- b) In Section 1.1 (6.0), set the Type of research/study to "External Researcher".

When the application is complete, *Save* and *Exit* the application. Click *Submit Study* on the left when you are ready to submit your ethics application for review.

Your study will initially route through MacEwan's Research Ethics Officer, and then will be automatically forwarded to the UofA HREB. From there, the project takes the regular UofA review pathway, and all questions regarding the status of your study can be directed to reoffice@ualberta.ca.

Once you obtain approval from the HREB, forward the approval letter to REB@macewan.ca; there is no need to complete an application at MacEwan.

If you are conducting health research and you wish to discuss whether or not this new review process applies to you, please contact the Research Ethics Officer at (780) 497-4280 or by email at REB@macewan.ca.

Autoethnography & Research Ethics

Purpose:

This guidance document has been created to highlight potential ethical challenges in conducting autoethnographic research and assist researchers in understanding when an REB application is required.

Definition:

Autoethnography is an approach to research and writing that seeks to describe and systematically analyze personal experience to understand cultural experience (Ellis, 2004; Holman Jones, 2005).

Is REB Approval Needed?

There are some instances in which REB review may be required for autoethnographic projects.

Self-studies done for the purpose of research, as defined in the Policy, and involving human participants falls within the scope of TCPS 2 and requires REB review (Application of Article 2.1).

Retrospective observations/reflections (data) about other people reported by auto ethnographers may be considered **secondary use of previously collected information**; originally obtained for purposes other than research – such as normal interactions during one’s daily life. If the data involves individuals other than the researcher, it is subject to TCPS2 Articles 2.4 (the individual is not known by the researcher, and ethics is not required), 5.5A, and 5.5B (the individual is known by the researcher, and ethics is required).

Prospective encounters/reflections for the purpose using an autoethnographic approach – intentionally going into an event with the awareness that observations will be contributing to research – the ethical implications are heightened.

In these cases, there is more opportunity for transparency with those who may be implicated in the research, and/or there is an increased possibility for a researcher to intervene and/or manipulate the environment and frame the resulting observations in a particular way to support the research objectives.



Autoethnography & Research Ethics

While the observation of people in public places generally does not require ethics review, if there is any intervention staged by the researcher, if there is a reasonable expectation of privacy, or if individuals will be identified in dissemination of research, then REB review may be required ([Article 2.3](#)).

If information is acquired in some **professional capacity** (lawyer, psychiatrist, journalist) then the researcher must abide by those professional standards before pursuing research and determining whether additional REB approval is required.

1. Ethical Considerations for Self-Studies

a. Self-studies: General

Self-study typically involves a scholarly reflection on one's own experiences in a particular context in order to answer a specific research question. Self-study may involve narratives, reflections and/or analyses of experiences based on the researcher's observations of, interactions with, or information about other individuals or communities. In self-study, at least the researcher is a research participant.

The REB must assess the ethical acceptability of self-study by considering its foreseeable risks, its potential benefits, and the ethical implications of the research. The researcher may be the sole participant, e.g. a researcher writing a self-study of his/her experience camping alone in the woods. REBs should assess the level of risk that the researcher is willing to assume to himself/herself.

b. Self-Study: Confidentiality Concerns

Researchers should be mindful of the possible negative consequences that may arise because of conducting autoethnographic research. For example, once researchers reveal their autobiographical experiences, their data may become irretrievable depending on their dissemination and data retention plans. Thus, it is important for researchers to think carefully about not disclosing things about themselves that they would not want others to know. This typically includes embarrassing items, intimate information, and stories that may have legal and/or professional implications. In cases where researchers wish to reveal sensitive information about themselves, they should consider implementing safeguards to protect their own confidentiality (e.g., publishing the document using a pseudonym, incorporating pseudonyms for all participants, changing the names of towns, schools, and so on).

Autoethnography & Research Ethics

c. Self Study: Consent Considerations

Given the dual roles that researchers play with respect to autoethnographic research – i.e., as both researcher and participant – they do not need to obtain explicit consent for their own participation. In virtue of researchers voluntarily deciding to conduct autoethnographic research projects, their consent to participate in research-related activities is tacitly implied.

However, researchers must convey to the REB that they are aware and appreciate what their participation in their project involves. This includes all the necessary information required for fully informed consent, such as the potential benefits of the research, the dissemination plan, the privacy and confidentiality safeguards in place, the potential risks involved in their participation, and so on.

2. Ethical Considerations for Autoethnography Involving Others

a. Autoethnography Involving Others: General

While researchers may be conducting research on themselves, individuals outside the research may be identified through these stories, and specifically through references to the communities they inhabit. The researcher must consider these potentialities when determining whether others are identified.

b. Autoethnography Involving Others: Confidentiality Concerns

Since participants (other than the researcher) may be featured in an autoethnographic project without the researcher actively engaging with participants – e.g., by conducting interviews, focus groups, etc. – it is important for researchers to be especially careful of the way participants are represented in their research. The same precautions that researchers take toward protecting their own privacy and confidentiality typically applies to protecting the privacy and confidentiality of those participants that feature in the story/study. Researchers should not disclose things about other participants in their autoethnographic project that one would not reasonably want others to know. This includes embarrassing items, revealing/intimate information, and stories that may have legal and/or professional implications.

Autoethnography & Research Ethics

Confidentiality Concerns, continued

Out of concern for welfare, regardless of whether they meet the definition of research participants, others mentioned in the study have a right to privacy protections. Individuals and/or groups mentioned in the study may not be aware that their interactions with the researcher would be included in a research project. The REB should assess whether the dissemination of the research could lead to the identification of individuals and/or communities and may pose additional risks to participants' and non-participants' privacy and confidentiality. This assessment should also consider the research context, and the level and relevance of privacy protections to others mentioned in the self-study. For example, participants, or other individuals implicated in the research, who seek or expect public acknowledgement of their contributions may not have the same expectations or needs for privacy protections.

c. Autoethnography Involving Others: Consent Considerations

If others are involved as research participants, the REB must assess how the researcher plans to manage the consent process. In general, researchers must seek participants' consent to participate in their project. If the material on which autoethnography is based (e.g., journal entries, recollections) was not originally intended for research, but is later proposed for research purposes, then the consent of the individual(s) and/or communities involved, if any, must be sought.

In some exceptional circumstances, the researcher may request an alteration to consent requirements if they satisfy the REB that the provisions of [Article 3.7A](#) are met.

If in doubt, ask us!

Feel free to contact the REB at REB@macewan.ca. if you have any questions or concerns about your autoethnography study!



Obtaining assent from children to participate in research



When children participate in research, researchers must secure the assent of the potential participant, and in most cases, also obtain the permission of the parent or guardian.

The assent process should involve taking the time to explain to the participant what will happen in the study, why the study is being done, what will be done to the participants, and that, if they object, that the research will be terminated and they will not be punished or scolded. Researchers must respect the decision of children who are capable of verbally or physically assenting to, or dissenting from, participation in research, even if the authorized third party has consented on their behalf (see [Article 3.10](#)).

The assent must be provided in a language that the participants can understand, while communicating the essential elements of consent without obscuring the important information in a lot of detail. The greater the cognitive capacity of the participant, the greater the amount of information that should be shared.

For children that are very young (younger than 7), it is not expected that they sign an assent form in order to participate in a study. Instead, an oral consent script using very simple language should be used to explain the research to the child, who can then indicate if they want to participate in research activities.

For children who are 7 to 14 years of age, an assent form is typically used, and younger children will need to have the assent read to them. For these reasons, the biggest challenge in writing assent forms is keeping the language and concepts appropriately simple.

Children 15 years of age and older are generally expected to give assent by signing the consent form used by their parents. However, if an investigator believes an assent form using simpler language is a better fit for a potential participant in this age group because of the complexity of the study or the nature of the study population, one may be used.

Although there are very formal requirements for the elements that must be present in a consent form, no such requirements exist for assent forms. This means that the investigator can propose assent content that he/she believes will best inform the potential participants about the study.

Obtaining assent from children to participate in research

Below are recommendations for methods to be used when obtaining assent from different age groups. Please note that the TCPS2 advocates for an approach based on the decision-making capacity of the individual (as long as it does not conflict with any laws governing research participation) rather than an age-based approach to consent; **it is up to the researcher to ultimately determine what method will best inform each of their participants about the study**, and to rationalize this to the REB.

Generally speaking, however, the length and details provided in the assent form should be proportional to the complexity of the study and the age of the participants.

Age	Method of Obtaining Assent
younger than 7	oral assent for very young children, with parental consent see appendix A
7-10	written assent for younger children, with parental consent see appendix B
11-14	written assent for older children, with parental consent see appendix C
14+	signed consent form with parent/guardian see regular consent form template

The following documents (Appendices A - C) are examples of assent form templates that researchers can use to develop their own study documents. **Word versions of the templates are available on the [MacEwan REB website](#).**



Obtaining assent from children to participate in research

Appendix A: Oral assent for very young children (ages 7 and under)

Hi. My name is [insert name]. I am here today because I want to find out why/how kids with [describe inclusion criteria in simple terms and a short description of the purpose of the study].

Your Mom/Dad/Guardian has said yes to let me ask you some questions.

If you are willing to answer my questions, [Insert a few (1-3) sentences explaining what is involved in participation] (e.g., we are going to play a bunch of quick computer games/do some puzzles/read some stories/I'm going to ask you some questions). Some kids who answer these questions find them interesting, but sometimes they find them a bit hard/boring, but that's ok, just try your best.

[If the research is personal/sensitive] I am going to keep everything you say/do here private. Only you and I will know what you do/say here today. I'm not going to tell your parents/teachers.

If you don't want to answer my questions, that's ok. I won't mind. Even if you say yes, but change your mind later, just let me know and we can take a break or stop for good and it isn't a problem.

Do you have any questions?

Do you want to try to answer some questions?

Researcher attestation:

I have explained this research study with _____ using understandable and appropriate language. They agreed to participate in the study.

Researcher Signature

Date

Obtaining assent from children to participate in research

Appendix B: Younger child assent (approximately ages 7-10)

Title of Study:

Principal Investigator(s):
Study Coordinator:

Phone Number(s):
Phone Number(s):

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about [insert topic and describe goals in simple language]. You are being asked to join the study because [insert name of condition or other reason(s) for inclusion].

If you agree to join this study, you will be asked to [describe procedures, (e.g., questionnaires, activities) in words a child would know and understand. Also include number of visits and time frame in words easily understood by a child].

Describe possible risks (e.g., discomforts) in simple language.

Will any part of the study hurt? (describe risks and discomforts using terms a child would know and understand; take into account a child's fears)

Use any of the following statements that are appropriate:

We do not know if being in this study will help you.

We expect that the study will help you by [describe how].

We may learn something that will help other children with [insert name of condition or topic under investigation] some day.

This study will help us learn more about [topic under investigation].

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Obtaining assent from children to participate in research

Appendix B: Younger child assent (approximately ages 7-10)

Before you say **yes** or **no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study please feel free to contact [Insert Study Contact name and contact #]

- Yes, I will be in this research study.
- No, I don't want to do this.

Child's name

Signature

Date

Person obtaining Assent

Signature

Date

If oral assent was obtained:

I have discussed this research study with _____ using language which is understandable and appropriate for the participant. I believe that I have fully informed them of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assent to participate in this study.

Researcher Signature

Date

Obtaining assent from children to participate in research

Appendix C – Older Child Assent (approximately ages 11 – 14)

Title of Study:

Principal Investigator(s):

Phone Number(s):

Study Coordinator:

Phone Number(s):

What is a research study?

A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study?

You are being asked to take part in this research study because we are trying to learn more about (Insert name of what is studied here). We are asking you to be in the study because (state why the child is being asked to participate). About (enter #) children will be in this study.

If you join the study what will happen to you?

Describe what takes place from the child's point of view.

We want to tell you about some things that will happen to you if you are in this study.

- You will be in the study for (insert duration of participation).
- We will use a needle to take some blood from your arm (#) times.
- We will need you to take (name of procedure) that will last (duration). This is (a simple explanation of what will happen). Your (mother/father/other) can be (location).
- We will ask you to sit with us and (talk about some things/look at some pictures). It will take about 1 hour to do this
- We will ask you to answer some questions about X.

Will any part of the study hurt?

Describe risks and discomforts using terms a child would know and understand; take into account a child's fears.

Obtaining assent from children to participate in research

Appendix C – Older Child Assent (approximately ages 11 – 14)

Will the study help you?

Describe any benefits to the child from participation in the research or if there are none omit this section.

Will the study help others?

Describe any benefits to society from the research.

This study might find out things that will help other children with (insert name of condition being studied) some day.

What do you get for being in the study?

You (and your parents) will get (enter amount or item) for (each visit/entire study).

Do you have to be in the study?

You do not have to be in the study. It's up to you. No one will be upset if you don't want to do this study. If you join the study, you can change your mind and stop being part of it at any time. All you have to do is tell us. It's okay, the researchers and your parents won't be upset.

What choices do you have if you say no to this study?

There are other ways to help your (insert name of condition being studied) if you don't want to be in this study. Provide examples.

This study is voluntary, so if you don't want to do it (nothing else will change)(there are no other choices).

Do your parents know about this study?

This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

Who will see the information collected about you?

The information collected about you during this study will be kept safely locked up.

Nobody will know it except the people doing the research.

The study information about you (will, will not) be given to your parents (or teachers). The researchers will not tell your friends or anyone else.

Obtaining assent from children to participate in research

Appendix C – Older Child Assent (approximately ages 11 – 14)

What if you have any questions?

You can ask any questions that you may have about the study. If you have a question later that you didn't think of now, either you can call or have your parents call (insert study telephone number).

Other information about the study.

- If you decide to be in the study, please write your name below.
- You will be given a copy of this paper to keep.

- Yes, I will be in this research study.
- No, I don't want to do this.

Child's name

Signature

Date

Person obtaining Assent

Signature

Date

If oral assent was obtained:

I have discussed this research study with _____ using language which is understandable and appropriate for the participant. I believe that I have fully informed them of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assent to participate in this study.

Researcher Signature

Date



Guidelines for Research Involving Indigenous Peoples of Canada

1. Purpose

The purpose of this guideline is to provide information on engaging and conducting research involving First Nations, Inuit, and Métis Peoples in Canada.

Note that this document is a general guideline meant to bring awareness to potential considerations and is not a checklist; each research project is unique and not all items will apply to every situation. It is the responsibility of the researcher to develop an understanding of how to best conduct their project in an ethical manner, given the considerations provided below. Please contact the Research Ethics Board if you have any questions about the items in this document.

2. Definitions

The following definitions are from the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2022).

Community: A group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A community may be territorial, organizational, or a community of interest.

Community-based research: research conducted at a community site that focuses not only on individuals, but on the community itself. Community-based research may be initiated by the community independently or in collaboration with a researcher.

Community engagement: a process that establishes an interaction between a researcher (or a research team) and a community with regard to a research project. It signifies the intent of forming a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and nature of the research.

Cultural heritage: a dynamic concept that includes, but is not limited to, First Nations, Inuit and Métis peoples' relations with particular territories, material objects, traditional knowledge and skills, and intangibles that are transmitted from one generation to the next, such as sacred narratives, customs, representations or practices.

Identifiable information: information that may be reasonably expected to identify an individual, alone or in combination with other available information.

Indigenous Peoples: In Canada, this term refers to persons of First Nations, Inuit or Métis descent, regardless of where they reside and whether their names appear on an official register.

Research agreement: a document that serves as a primary means of clarifying and confirming mutual expectations and, where appropriate, commitments between researchers and communities.

Traditional knowledge: the knowledge held by First Nations, Inuit and Métis peoples, the Indigenous peoples of Canada. Traditional knowledge is specific to place, usually transmitted orally, and rooted in the experience of multiple generations. It is determined by an Indigenous community's land, environment, region, culture, and language. It may also be new knowledge transmitted to subsequent generations.

3. Background

In accordance with the Canadian Constitution Act, 1982 Section 35 and the Tri-Council Policy Statement (TCPS 2), the Research Ethics Board (REB) acknowledges the unique status and affirms the rights of Indigenous Peoples in Canada. Indigenous rights have been interpreted to include a range of cultural, social, political, and economic rights including the right to land, as well as to fish, to hunt, to practice one's own culture, and to establish treaties.

Indigenous Peoples include persons who self-identify as being of First Nation, Inuit, or Métis descent, regardless of where they reside or whether their names appear on an official register. The REB recognizes the uniqueness and richness of the over 600 distinct Indigenous communities across Canada.



1. Asch, Michael. Home and Native Land: Aboriginal Rights and the Canadian Constitution. Agincourt: Methuen, 1984. 30.

4. The Scope of Indigenous Research

As emphasized in the [TCPS 2 Chapter 9](#), Indigenous research is research that includes a major Indigenous component. This includes the following:

- i. Research **conducted on** First Nations, Inuit, or Métis lands;
- ii. Projects where Indigenous identity is **a criterion** for research participation;
- iii. Research that **seeks input** from participants regarding Indigenous culture, heritage, artifacts, traditional knowledge or unique characteristics of Indigenous Peoples;
- iv. Research in which Indigenous **identity or membership** in an Indigenous community is used as a variable for the purpose of data collection and primary data analysis;
- v. Projects where **interpretation of data** results refers directly to Indigenous communities, peoples, language, history or culture;
- vi. Research that is likely to **affect the welfare** of Indigenous Peoples;
- vii. Research that involves **secondary use** of data or human biological material identifiable as originating from an Indigenous community or Indigenous peoples;
- viii. Research that involves **linking two or more anonymous data sets** or data associated with human biological materials, and there is a reasonable prospect that it will generate information identifiable as originating from a specific Indigenous community or segment of the Indigenous community at large.

Below are three examples of research involving Indigenous Peoples:

- a. A researcher is planning to visit a school located on First Nation land to explore a particular community's views with respect to the content of a piece of federal legislation. Since this project will be conducted on First Nation lands, it is considered research involving Indigenous Peoples.
- b. An investigator is seeking to explore the challenges faced by young adults entering the job market and is conducting a comparative study looking at the diverse challenges that members of different cultural and ethnic groups face, including Indigenous Peoples. Given that the research design of this project includes Indigenous identity as both part of the inclusion criteria, and as a variable for the purpose of data analysis, it is considered research involving Indigenous Peoples.
- c. A researcher wishes to explore the benefits and challenges of transmitting traditional knowledge, or Indigenous knowledge, orally. This project is considered research involving Indigenous Peoples because the analysis and interpretation of data is on or about Indigenous culture.

5. Conducting Indigenous Research

All research involving Indigenous Peoples of Canada must be conducted in a manner that is (I) respectful of Indigenous communities and individuals, (II) demonstrates concern for the collective and individual welfare of Indigenous peoples, and (III) is collaborative in nature; that is, the research should typically consult and engage the relevant Indigenous community/communities. The researcher will be given the opportunity describe to the REB, in the REB application, how each of these conditions are/will be met, prior to the initiation of any research activity.

I. Respect

Respecting Indigenous Peoples entails, among other things, respecting their unique history and culture, their forms of knowledge, and their structures of governance.

History & Culture

Investigators conducting research involving Indigenous Peoples should demonstrate to the REB a solid understanding of the particular community's history and culture that it seeks to engage with. This is especially important given the differences that may exist between the researcher's own culture and that of the community they plan to work with. A lack of understanding of an Indigenous community's history and culture can lead to the misappropriating or devaluing of Indigenous art, music, symbols, narratives, forms of knowledge, etc., and to violating existing norms regarding the proper handling of human tissue and remains.

Traditional Knowledge

Investigators conducting research involving Indigenous Peoples should be aware as to how their possible contribution to "Western knowledge" fits with the particular form of knowledge held by the Indigenous community that they are engaging with, and, more generally, with traditional knowledge.

If disagreement about interpretation arises between researchers and the community and it cannot be resolved, researchers may consider the following options;

- (a) providing the community with an opportunity to make its views known, or
- (b) accurately reporting any disagreement about the interpretation of the data in their reports or publications.

This should not be construed as giving the community the right to block the publication of findings. Rather, it gives the community the opportunity to contextualize the findings (p. 128). The data remains the property of the Indigenous community and should not be incorporated into other research activities – the secondary use of data – without the prior informed consent.

Self-Governance

Investigators conducting research involving Indigenous Peoples should consider how best to seek the necessary permissions from all appropriate bodies. In some cases, and depending on the community, this may include not only a formal leader, but also an elder, an elder's circle, a knowledge keeper, or a specific council or association, in addition to individual research participants, but in other cases, it's possible that none of this would be needed. Regardless, investigators conducting research involving Indigenous Peoples should demonstrate respect and understanding toward the particular community's authority structure it seeks to engage with, irrespective of how complex or different it may seem. This includes respecting the most vulnerable individuals in a community, including sub-groups who may not have a voice in formal leadership.

II. Individual & Collective Welfare

Research involving Indigenous Peoples in Canada has typically been conducted by non-Indigenous researchers, and in a manner that has not benefited – and sometimes harmed – both Indigenous communities and individuals. Given this troubling history, it is imperative that all investigators conducting research involving Indigenous Peoples demonstrate to both the REB and the relevant Indigenous community that the potential harms that may arise because of the research being conducted are outweighed by the potential benefits. This is necessary in order to ensure that the welfare of Indigenous individuals and communities are taken seriously.

For research involving Indigenous Peoples, the potential benefits are to be understood as beneficial not only by the researcher, but also by the relevant Indigenous community. The onus is on the researcher to describe what the direct benefits to the individual/community are and how they outweigh the risks associated with the study.

Possible benefits to Indigenous communities include:

- (a) **local hiring/training** of members of the Indigenous community as research assistants, data analysts, translators, etc.;
- (b) **recognition** of Indigenous peoples' contribution to the project (if desired by the community);
- (c) **sharing** the results of the research with the community (if desired by the community); and
- (d) **adjusting** the research design so as to better fit the particular community's needs and priorities.



III. Collaboration & Engagement

Researchers engaging with Indigenous Peoples should consider the authority and important role that communities play with respect to this type of research. Researchers are encouraged to (a) familiarize themselves with any ethical guidelines that the particular Indigenous community it seeks to engage with holds (such as OCAP- Ownership, Control, Access, and Possession), and (b) create a community engagement plan laying out how they intend to respect and acknowledge the community that they seek to engage with.

OCAP (Ownership, Control, Access, and Possession)

Many Indigenous communities across Canada have adopted an ethical guideline called OCAP to govern the ethical conduct of research that takes place on their own lands. OCAP is a set of principles aimed at protecting Indigenous ownership, Indigenous jurisdiction, and Indigenous information.

Researchers working and engaging with communities that have adopted their own ethical codes (such as OCAP) are encouraged to familiarize themselves with such codes. They are also advised to consult the REB with respect to certain rules or guidelines that might be inconsistent or in tension with the ethical guidelines laid out in the TCPS 2. Inconsistencies or tensions between a community's ethical code and the TCPS 2 should be identified and addressed in advance of initiating any research.

Community Engagement Plan

Typically, investigators conducting research involving Indigenous Peoples will provide the REB with a formal community engagement plan. This plan should outline how the researcher has engaged, or intends to engage, the relevant Indigenous community, and the nature of this engagement. In accordance with the TCPS 2 "the nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community and shall be appropriate to the community characteristics and nature of the research" (p. 154). Alternatively, researchers may provide relevant information detailing their relationship with the community, and how the community has already been engaged prior to the initiation of the research project. Note ethics approval is not needed in order to begin the engagement process.



Investigators conducting research in/with Indigenous communities should 'ensure, to the extent possible, that they take into consideration the views of all relevant sectors – including individuals and subgroups who may not have a voice in the formal leadership. Groups or individuals whose circumstances may make them vulnerable may need or desire special measures to ensure their safety in the context of a specific research project. Those who have been excluded from participation in the past may need special measures to ensure their inclusion in research' (p.117).

For examples of different types of research projects involving Indigenous Peoples, along with appropriate community engagement plans, see [Article 9.2](#) of the TCPS 2 entitled "[Nature and Extent of Community Engagement](#)".

Two Possible Exemptions:

Investigators conducting research involving Indigenous Peoples may be exempted from providing the REB with a community engagement plan if:

- i. the research participants are not identifiable as part of a particular community, or
- ii. the welfare of the relevant community is not likely to be affected by the research project.

If a project involving Indigenous Peoples is exempt from a community engagement plan, individual consent still must be sought.

The onus is on researchers to demonstrate to the REB that their project involving Indigenous Peoples falls under one of the two exemptions, otherwise, typically, research involving Indigenous Peoples should include a community engagement plan.

6. Research Agreements

It is recommended that research involving Indigenous Peoples where a community has formally engaged with a researcher or research team through a designated representative shall set out, in a research agreement, the terms and undertakings of both the researcher and the community before participants are recruited.

A research agreement may address the following questions:

- What is the nature of community participation?
- How will individual consent be obtained?
- What is the process by which amendments will be made to the agreement?
- How will potential benefits be distributed?
- Who is responsible for what part of the project design?
- How will data be collected, managed, and stored?
- What is the process for data analysis and data interpretation?
- How will credits pertaining to the research project be assigned?
- How will authorship be determined?
- Who will have the intellectual property rights or how will these be shared?
- How will possible benefits or royalties flowing from intellectual property be distributed?
- How will the data be disseminated?
- In the event that a dispute arises, what is the conflict resolution process?
- How will secondary materials or any other anticipated secondary use be managed?



The exact content of a research agreement will vary based on the nature of the research project, as well as the values and priorities of the community that the researcher or research team plans to engage with. Above are just some of the more common items that research agreements typically address, but the document itself can be as informal or as formal, as deemed appropriate for the situation.

For specific guidance on what to include in your research agreement or steps on how to construct a research agreement, please consult the [Office of Research Services](#).

Alternatively, if the researcher believes that a research agreement is not necessary, then the researcher will have the opportunity to describe to the REB in the ethics application why an agreement is not needed.

All page number references refer to the online version of the [TCPS 2 \(2022\)](#).

Ethics Review for Course-Based Research

Background and Determining Eligibility

Frequently, undergraduate courses incorporate class projects and other activities for the purposes of developing research skills. These projects may be carried out by individual students, small groups or as a single class project. **Research activities included within a course for pedagogical purposes (i.e. the objective is to provide students with exposure to research methods in their field of study) are defined as research and are therefore governed by ethics review policies.**

To qualify for approval under course-based ethics student research assignments **must be:**

1. no more than minimal risk;
2. the participants must be drawn from the general population, and;
3. be capable of giving free and informed consent.

In addition, the student projects must not involve major deception, sensitive topics, physically invasive contact with the participants, or require ethics approval from another institution.

Examples of research activities that could be approved under course-based review include:

Having students conduct interviews, administer standard tests, or distribute questionnaires to individuals recruited from outside of class to help develop interview or questionnaire design skills.

Conduct "mini" research projects where students pose general questions while gathering responses from participants recruited from outside of class and using those responses for presentation.

Example of a research activity that would not be approved course-based ethics approval:

*Children recruited through public elementary schools will be shown an educational video to see if it enhances their learning of that topic. This project **would not be approved** under course-based ethics because it would require ethics review from Edmonton Public Schools. This study would require regular REB approval.*



Example of a research activity that **would not require** course-based ethics approval:

Students distributing questionnaires to classmates, or students collecting data from computer administered tests from classmates; where data will be analyzed and presented only to classmates. **Ethics would not be required.** Course based ethics approval is only required if participants are being recruited from outside of class.

Determining Eligibility

Note that the following questions should be used as a general guide to determine if the research assignment(s) within your course can be covered by a course-based ethics review. Please use this guide prior to completing and submitting the ethics application. If you are unsure of the answer to a question, contact the Ethics Officer to discuss further.

Part I

In order for your course to be considered appropriate for course-based ethics review, the following questions should be answered **YES**:

1. Do the projects potentially involve human subjects (beyond classmates) who are 18 years or older and are not considered part of a special or vulnerable population(children, Indigenous or minority groups, those with mental illness, etc)?
2. Is the primary purpose of the research to teach students about research or how to conduct research?
3. Will the research only be disseminated within the classroom/agency involved, or within the MacEwan University community (e.g. in a university poster session)?
4. Is the application for a set of minimal risk research projects occurring within the scope of a course at MacEwan University?

If the answer to any of the above is **NO**, please contact the Ethics Officer at (REB@macewan.ca) to discuss your project further.



Part II

In order for your course to be considered appropriate for course-based ethics review, the following questions should be answered **NO**:

1. Is this an Honour's Thesis or Independent Study research project?
2. Is this an undertaking that can potentially extend knowledge through a disciplined inquiry or systematic investigation? In other words, is there a possibility that any of these projects will further knowledge in the field and may be published or disseminated outside the university (i.e. by disseminating at conferences outside of MacEwan University, publishing in peer-reviewed journals, reports to the media)?
3. Will the projects be health-related (i.e. obtaining biomedical samples, collecting health information)?
4. Will any of the projects involve physically invasive contact with the participants?
5. Will projects involve any sensitive or incriminating topics/questions or information that could place participants at risk (e.g. participation in an illegal activity)?
6. Will any of the research projects involve major element(s) of deception for the participants?
7. Are any of the projects a direct extension of the course instructor's research?

If the answer to any of the above is **YES**, please contact the Ethics Officer (REB@macewan.ca) to discuss your project further.

Applying for Course-Based Ethics Review

To see if your project meets the requirements for a course-based review, and to submit your application to the Research Ethics Board, simply [sign in to ROMEO's Research Portal](#) using your regular log in, and complete the form entitled, '*Course-Based Research Ethics Board (REB) Application*'.

These applications are reviewed by the REB Chair, and will take up to 3 business days for initial processing.

Conducting Research in your Classroom

One of the main issues to consider when conducting research within a course that you teach is the student-instructor relationship. This is common when conducting scholarship of teaching and learning (SoTL) research. Due to your dual role of instructor and researcher, the power balance of this relationship may influence the decision of the student to take part in research. For example, students may feel as though their grades may suffer if they decide not to participate in your project.

1. Obtaining Consent from Students

If the course instructor is the principal investigator, they should not be obtaining consent from the students in the classroom. A co-investigator, who is not involved in the course, may explain the research and the consent to the students while the instructor leaves the classroom. The students should be given appropriate time to ask questions and decide if they want to participate.

If you are obtaining paper consent in the classroom, the signed consent forms should be held in a sealed envelope and not be made available to the course instructor so they remain unaware of which of their students have agreed to participate. The student should also be provided with a copy to keep along with any other relevant materials.

2. Consent Items

It should be made clear to the students that they may withdraw their consent at any time, with no explanation or penalty, and they may choose to skip any or all questions being asked. Participation is voluntary and should be anonymous, with no identifying questions being asked.

It should be reiterated in the consent that their decision to or not to participate will in no way affect their performance in the course, and that the instructor will not have access to data until after final grades have been submitted.



3. Access to Data

Surveys/Questionnaires

Collection of data should be anonymous, wherever possible.

If the surveys/questionnaires are conducted electronically, participants may wish to withdraw before submitting online form; this data should not be stored, and the collection of IP addresses disabled.

After a survey/questionnaire has been submitted, submissions will not be able to be removed should a participant wish to withdraw after this point. This should be made clear to the participant in the consent form.

If data from survey/questionnaires need to be linked to student-specific course outcomes, data collection cannot be anonymous. In these cases, the instructor should not have access to the surveys/questionnaires until all final grades have been submitted for the course.

Blackboard Information

Accessing information through blackboard, for purposes other than its original intent, often requires ethics review **and** approval from the privacy officer (privacy@macewan.ca). This particularly the case if it is being accessed by an individual who does not already have the ability to view the information, and is being used for research purposes (as opposed to course improvement).

4. Presenting/Publishing Research

Non-research activities, such as program evaluation or quality improvement projects, do not require ethics approval in order to present or publish results. However, the information should not be disseminated outside of MacEwan unless it is anonymized/presented in aggregate form.



Contact the Research Ethics Officer,
with any questions at reb@macewan.ca

CONTACT US

with any questions



[VISIT OUR WEBSITE](#)

[EMAIL US](#)

CALL US
780-497-4280