

# Ethical Approval of Research Relying Exclusively on the Secondary Use of Identifiable/De-Identified Data

*Questions with* \* are mandatory

[Name:\*](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/)  Click or tap here to enter text.

[Faculty:\*](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/)  Click or tap here to enter text.

[Project Title:\*](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/) Click or tap here to enter text.

1. Project Description

1.1. Lay summary of the research project *(rationale, purpose, background, data/records (biological materials) and methods to be used*) (approx. 300 – 400 words).\*

Click or tap here to enter text.

1.2 [Provide a clear statement of the purpose and objectives of the research project](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/).\*

Click or tap here to enter text.

1.3 [State the research question(s), and any associated hypotheses or proposition(s).](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/)\*

Click or tap here to enter text.

1.4 Describe the relevant theoretical/conceptual framework(s) underlying your research project and your methodological approach (approx. 150 words)..\*

Click or tap here to enter text.

1.5 Describe how the purpose of this current research builds on, and/or differs from, the purpose for which the information was originally gathered (approx. 250 words). \*

Click or tap here to enter text.

1.6 If this is a project that will involve several phases: Describe why this is appropriate for the project, and which phase(s) are included in this application?

Click or tap here to enter text.

1.7 [Describe](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/) the original/source data (or biological materials) collection, including: \*

1. how, why and when the data (or materials) were originally gathered;
2. from whom the data (or materials) were originally collected;
3. who collected the data (or materials) originally; and
4. if the data (or materials) were collected for research purposes, how were participants recruited?

Click or tap here to enter text.

1.8 Describe and justify the sample or sub-sample being used in this current project and explain the process through which you will identify, select and obtain the information (materials). \*

Click or tap here to enter text.

1.9 Has your proposed research been approved by the steward/custodian(s) of the source data (or materials)? If no, what is approval anticipated? \*

*Upload approval(s) in the Documents section of the Pure application record.*

Click or tap here to enter text.

1.10 How will research results be disseminated? \*

[ ]  Final research report to be provided to AU

[ ]  Article(s) to be submitted to academic and professional journals

[ ]  Presentation(s) at academic/professional conferences

[ ]  Research website open to the public

[ ]  Distribution of final report to participants upon request

[ ]  Distribution of executive summary to participants upon request

[ ]  Distribution of final report to host institution or organization

[ ]  Other: Click or tap here to enter text.

[*Research Involving Indigenous Peoples or Other Distinct Communities and Groups*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html)

1.11 Do the research questions/objectives include Indigenous Peoples? \*

Choose an item.

1.12 Will the analyses use Indigenous community membership as a variable? \*

Choose an item.

1.13 Will interpretation of results refer to Indigenous peoples, language(s), history or culture? \*

Choose an item.

1.14 Will the research questions/objectives focus on a distinct community or group? \*

Choose an item.

1.15 Will the analyses use membership(s) in a distinct community or group as a variable?\*

Choose an item.

1.16 [If your research includes Indigenous peoples, describe how you are incorporating the OCAP principles in your project. Or, if those principles are not applicable, are there comparable principles that you have considered?](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/)

Click or tap here to enter text.

1.17 If you answered Yes to any of the above questions in this section:

a. Describe the plan for community engagement and state whether ethical approval has been or will be sought from an Indigenous ethics review group or other community ethics review group, and

b. Describe how results will be returned to the relevant community/communities and append any research agreements concerning the data or samples.

Click or tap here to enter text.

1.18 [If applicable, describe how you are incorporating any culturally appropriate ceremony into your research protocol.](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/)

Click or tap here to enter text.

2. Informed Consent

2.1 If the data (or biological materials) were originally collected for RESEARCH PURPOSES, describe how informed consent was originally obtained from participants (including what information uses participants provided consent for and to what extent the original consent addresses the purposes of this current study).

*Attach original consent form in the Documents section of the Pure application record, if available.*

Click or tap here to enter text.

2.2 If data (or biological materials) were originally collected for NON-RESEARCH PURPOSES, will consent be obtained from individuals prior to using the data (or materials)?

Choose an item.

If yes, explain the consent process in detail. If not, explain why this would be impossible or impracticable, and why it is unlikely to adversely affect the welfare of individuals to whom the information relates.

*Attach consent form in the Documents section of the Pure application record.*

Click or tap here to enter text.

2.3 [Describe the inclusion criteria for participants and justify these criteria (e.g., age range, health status, gender, profession) and justify these criteria (e.g., research methodology, statistical requirement)? \*](https://austaff-my.sharepoint.com/personal/pdaniels_athabascau_ca/Documents/Microsoft%20Teams%20Chat%20Files/%22%20%5Co%20%22inclusion%20criteria%20for%20participants%20%28e.g.%2C%20age%20range%2C%20health%20status%2C%20gender%2C%20profession%29%20and%20Justification%20for%20these%20criteria%20%28e.g.%2C%20research%20methodology%2C%20statistical%20requirement%29.)

Click or tap here to enter text.

3. Data Retrieval and Analysis

3.1 Describe the data to be captured from the original/source data (or biological material) collection, and the variables to be used for the proposed analyses. Justify the use of each of these in relation to the study purposes. \*

Click or tap here to enter text.

3.2 Briefly Describe the data analysis plan. Indicate how the proposed analyses address the study's primary objectives or research questions. \*

Click or tap here to enter text.

4. Privacy, and Confidentiality

4.1 Indicate the level of identifiability of the original/source data (or biological materials) held by the steward/custodian. \*

[ ]  Anonymized (all identifiers have been removed and a key-code linking data/materials with individuals does not exist)

[ ]  De-identified/coded (a key-code linking data/materials with individuals exists but is not accessible to the researcher)

[ ]  Identifiable (information directly or indirectly identifies individuals)

4.2 Who will access the source data (or materials) to extract the data or samples for this research? Explain their role or qualifications. \*

Click or tap here to enter text.

4.3 If there is identifying information in the source data, how will the privacy of individuals whose data/samples are stored it the collection be protected during this data access? \*

Click or tap here to enter text.

4.4 Indicate the level of identifiability of the data (or samples) *that will be extracted from the source data* (or material) collection for use in this research. \*

[ ]  Anonymized (all identifiers have been removed and a key-code linking data/materials with individuals does not exist)

[ ]  De-identified/coded (a key-code linking data/materials with individuals exists but is not accessible to the researcher)

[ ]  Identifiable (information directly or indirectly identifies individuals)

4.5 If identifiers (direct and indirect) are being collected, indicate what they are:

[ ]  Surname and First Name

[ ]  Initials

[ ]  Address

[ ]  Full postal code

[ ]  First 3 digits of postal code

[ ]  Telephone number

[ ]  Social Insurance Number

[ ]  Email address

[ ]  Digital ID

[ ]  Full Face Photograph

[ ]  Audio or Video Recording

[ ]  Student ID Number

[ ]  Employee ID Number

[ ]  Full Date of Birth

[ ]  Year of Birth

[ ]  Age at time of data collection

[ ]  Professional Certificate/License Number

[ ]  Health Care Number

[ ]  Health Provider's Name

[ ]  Other, please describe: Click or tap here to enter text.

Justify why each item is needed to conduct this research.

Click or tap here to enter text.

5. Data Storage, Retention and Disposal

The University is currently working on additional tools to support researchers in *planning for their data storage*. The AU Research Ethics Board highly recommends that researchers submit a ServiceNow Ticket to IT *(asking to consult with the Research Tools Squad about storage options on a research project that requires ethics approval)*to assist you in adequately addressing the ethical considerations around data storage, retention and disposal.

5.1 Will this research involve linking separate data sets? \*

Choose an item.

1. If yes, describe why this linking is necessary and how it will be conducted and whether the linkage will increase the identifiability of the participants; and
2. Describe reasonably foreseeable risks to privacy and how these will be mitigated.

Click or tap here to enter text.

5.2 Describe any plans to link the data in this project with data associated with other studies or with data belonging to another organization or to create a research database or registry for future use. If not applicable, enter N/A. \*

Click or tap here to enter text.

5.3 Describe how and where study documents and data (both hard copy and electronic) and materials will be collected, handled, transported or transferred and stored during the data collection and analysis phase. In particular, indicate the steps that will be taken to protect the security of any directly or indirectly identifiable information, especially if it is shared with others. Include details on the physical security and technological security measures to be employed. \*

Click or tap here to enter text.

5.4 How long will study data or materials be retained after the study is completed and how will they be secured during this time? If that data will eventually be destroyed or irreversibly anonymized what procedures will be used for this? \*

Click or tap here to enter text.

5.5 Outline any plans for future use of the data or materials beyond the study currently being reviewed. \*

Click or tap here to enter text.

5.6 Do you have plans to deposit data into a repository? \*

Choose an item.

1. If yes, identify and describe the data repository, including what is its focus, who are its users, who can access deposited data and under what circumstances, and
2. Indicate how long the data will be kept in the repository.

Click or tap here to enter text.

5.7 Describe the data set to be deposited into the repository. If there is personal and/or sensitive information in the data, how will you prepare the data for submission to the repository and mitigate risks to privacy?

Click or tap here to enter text.

5.8 Will participants be given the option to opt in or out from having their information deposited? If yes, how will they do so? If not, please justify.

Click or tap here to enter text.

6. Conflict of Interest

It is expected that all members of the project team will review and abide by the "[Conflict of Interest in Research](https://www.athabascau.ca/university-secretariat/_documents/policy/conflict-of-interest-research-policy.pdf)" Policy and related Procedures and [Chapter 7 of the TCPS(2)](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter7-chapitre7.html).

6.1 Describe whether any dual role or conflict of interest exists for any member of the research team in relation to the individuals whose data or materials are being used (e.g. teaching relationship, familial, professional), and/or to study sponsors, and how this will be handled. \*

Choose an item.

7. Funding

7.1 Will some organization or person other than the researcher be providing funding to support this research project (e.g., cash/in-kind)? \*

Choose an item.

7.2 If funding will be sought, is pending or is approved, specify sources (whether internal or external):

Click or tap here to enter text.

7.3 Describe any expectations, expressed or implicit, that arise (or will arise) from the funder-researcher relationship. (Consider any potential, actual or perceived conflict of interest that may result from the relationship). \*

Click or tap here to enter text.

8. Attachments

*NOTE: You must upload all attachments in the Documents Section of the Pure application record.*

Attachments:

[ ]  Reference List

[ ]  Steward/Custodian Permission Letter(s), Documentation of Support

[ ]  Research Agreement(s)

[ ]  Original and/or new Consent Document(s)

[ ]  Flow Diagram Outlining Data Collection and Linkages

[ ]  Other: Click or tap here to enter text.