**Letter of Information / Informed Consent Form**

**Secondary Use of Personal Records/Information**

**[Template for AU Research]**

The Letter of Information / Informed Consent form should be:

1. Written in plain, clear language avoiding the use of jargon and acronyms.
2. Tailored to the reading level of the participants so they can understand what is required of them and make an informed decision about their participation.
3. Presented on this template.

Participants should be given a copy of the letter of information / signed consent form or advised to retain a copy for their own records.

Researcher(s) should retain a copy of the signed consent form in their records.

This template demonstrates the minimum information that should be included in the consent form. Additional information may be required depending on the nature and complexity of the project.

The template begins on the next page.

**Do not** include this instruction page with your form.

Directions for what to include in each section are written in *italicized red text*.

All *italicized red text* should be replaced with information specific to your project.

**LETTER OF INFORMATION / INFORMED CONSENT FORM**

**Secondary Use of Personal Records/Information**

*[Title of Research Project]*

*[Date]*

**Principal Investigator (Researcher):** **Supervisor *(if applicable)*:**

*[insert name and contact info] [insert name and contact info]*

You are invited to take part in a research project entitled ‘*your project title here*’.

This form is part of the process of informed consent. The information presented should give you the basic idea of what this research is about and what your participation will involve, should you choose to participate. It also describes your right to withdraw from the project. In order to decide whether you wish to participate in this research project, you should understand enough about its risks, benefits and what it requires of you to be able to make an informed decision. This is the informed consent process. Take time to read this carefully as it is important that you understand the information given to you. Please contact the principal investigator, *your name here* if you have any questions about the project or would like more information before you consent to participate.

It is entirely up to you whether or not you take part in this research. If you choose not to take part, or if you decide to withdraw from the research once it has started, there will be no negative consequences for you now, or in the future.

**Introduction**

My name is *your name here* and I am a *insert degree program* student at Athabasca University. As a requirement to complete my degree, I am conducting a research project about *briefly describe the project in lay terms 1 – 2 sentences*. I am conducting this project under the supervision of *your supervisor’s name here*. *If NOT a student, input appropriate description here.*

**What is the purpose of this research project?**

*Describe the purpose of the research, including what the project hopes to answer in plain language. Provide enough information so that the intent of the study is clear. Include basic study design and be clear why the study requires the use of personal records and cannot be done without access to those records.*

**Who Will be Included in the Research Study**

*This section should explain what characteristics people must have for their records to be included in the study, including any relevant personal history or attributes (the inclusion and exclusion criteria from the research ethics submission form). The language should be simple and direct. Example: “We will be including the records/charts/data from anyone who... during [timeframe]…”*

**How will data be collected and used?**

*Describe the procedures for retrieving and selecting eligible cases, what information from personal records will be seen, and by whom. Describe how data will be extracted from personal records. Briefly describe, in plain language, how the extracted data will be used in analyses.*

*Example: “A staff member will pull all student records for the years specified, and will select those eligible according to the above criteria, who have granted consent. He or she will prepare a duplicate Excel file in which student names and ID numbers have been stripped and replaced with unique study ID numbers. The research team will only see this duplicate file. Student grades in these courses will be compared from before and after the course revision date.”*

**What are the risks and benefits?**

*Identify any benefits to the participant, for the development of knowledge, or for a change in practice. State explicitly if there are no direct benefits to the participant.*

*Risks generally concern breach of privacy, which should be discussed. Where there is a possibility of repercussions to any individual or group, these should be described. In some instances, risks may exist for communities associated with the study (stigmatization, community discord). The steps that will be taken by the researcher to minimize risks should be stated.*

*Example: “In conducting these new comparisons between your data and similar data that has been conducted in [place and place] we may find that people here are \_\_\_\_\_\_\_\_\_ compared with the other two groups. This may [have repercussions].”*

**How will your privacy and confidentiality be protected?**

The ethical duty of confidentiality includes safeguarding participants’ identities, personal information, and data from unauthorized access, use or disclosure.

* *Include a statement about how participants’ privacy and confidentiality will be maintained. If confidentiality cannot be guaranteed (e.g. participants may be identifiable due to specific characteristics in the sample population), specify the limits to confidentiality.*
* *Describe any other limitations to confidentiality that may be applicable [if there is a likelihood that reportable information may arise during the research project (e.g. protected populations, revelation of illegal or heinous act), include a specific statement to address this. “All information will be held confidential, except when legislation or a professional code of conduct requires that it be reported.”*

**How will my anonymity be protected?**

Anonymity refers to protecting participants’ identifying characteristics, such as name or description of physical appearance.

*Limits to anonymity of participation and/or data, should be explained.*

*If anonymity is desired, researchers should assure participants that* Every reasonable effort will be made to ensure your anonymity; you will not be identified in publications without your explicit permission.

**How will the data collected be stored?**

* *Indicate how data will be stored, whether it will be disposed of and if so, how and when.*
* *Indicate whether data will be deposited into some form of data repository and if so, what the access to that data will be. Also describe to what degree the data will be anonymized before deposit and whether or not data will be openly available in the repository.*
* *Identify all individuals/agencies who will have access to data from the research project, or the report, now or in the future (e.g. supervisor(s); organization(s); whether the data be deposited into a data repository of some type).*
* *Describe the procedures/methods that will be employed to protect confidential data in all its forms (e.g. password protections and encryption on electronic data; use of pseudonyms (false names) or data codes; locked filing cabinets for hard copy data)*

***If you intend to use the data for future research purposes****, the following statement should be adapted and included:*

The data collected in this research project may be used – *[indicate whether it will be in an anonymous, or anonymized, or de-identified form]* by members of the research team in subsequent research studies exploring similar lines of inquiry. Such projects will still undergo ethics review by our Research Ethics Board. Any secondary use of anonymized data by the research team will be treated with the same degree of confidentiality and anonymity as in the original research project.

**Who will receive the results of the research project?**

*Describe how and where results of the research project will be disseminated and whether or how they will be made available to interested participants.*

* *If you are an AU graduate program student and the research is a final research project or thesis, include the following statement:* The existence of the research will be listed in an abstract posted online at the Athabasca University Library’s Digital Thesis and Project Room and the final research paper will be publicly available.
* *Be sure to comment on whether direct quotations or personally identifying information (with permission only) will be reported; or whether reporting is only in aggregate or summarized form.*
* *Be sure to highlight whether audio/video recordings will be used in dissemination of the research.*
* *State what information or feedback on the research project will be available or provided to participants after the project is complete (e.g. report, executive summary, poster presentation). Indicate how/if participants can access the project results without having to contact the principal investigator (e.g. available on researcher’s website).*

**Who can you contact for more information or to indicate your interest in participating in the research project?**

Thank you for considering this invitation. If you have any questions or would like more information, please contact me, (the principal investigator) by e-mail *insert e-mail address* or *insert any other means of contact you wish to use* or my supervisor by *insert e-mail address or phone number.* If you are ready to participate in this project, *please complete and sign the attached Consent Form and return it by* [*provide directions on who, where, how and by when]*.

Thank you.

*[nsert researcher name]*

**This project has been reviewed by the Athabasca University Research Ethics Board [REB File # \_\_\_]. Should you have any comments or concerns about your treatment as a participant, the research, or ethical review processes, please contact the Research Ethics Officer by e-mail at** **rebsec@athabascau.ca** **or by telephone at 780.213.2033.**

*If written consent is being obtained, the signature page should be signed and dated by the research participant or by the person authorized to sign on behalf of the research participant (e.g., a parent or care giver). In the latter instance, the participant’s name must also be clearly indicated.*

**Informed Consent:**

**Your signature on this form means that:**

* You have read the information about the research project.
* You have been able to ask questions about this project.
* You are satisfied with the answers to any questions you may have had.
* You understand what the research project is about and what personal records/information will be included in this study.
* You understand that you are free to withdraw your participation in the research project without having to give a reason, and that doing so will not affect you now, or in the future.

*Choose one of the following, as applicable to your project:*

* You understand that if you choose to end your participation **during** data collection, any data collected from you up to that point will be *Choose one of the following to complete the bullet point, as applicable:*

destroyed.

retained by the researcher, unless you indicate otherwise.

* You understand that if you choose to withdraw **after** data collection has ended, your data can be removed from the project at your request, up to *insert cut-off date here.*
* You understand that the records/information included in this study have been de-identified, and therefore cannot be removed.

***Include these checkboxes if they are relevant to your project****:*

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| I allow **de-identified data** collected from me to be archived/deposited in *insert name/description of archive/repository here* | ⃝ | ⃝ |
| I allow **identifiable data** collected from me to be archived/deposited in *insert name/description of archive/repository here* | ⃝ | ⃝ |
|  |  |  |

**Your signature confirms**:

* You have read what this research project is about and understood the risks and benefits. You have had time to think about participating in the project and had the opportunity to ask questions and have those questions answered to your satisfaction.
* You understand that participating in the project is entirely voluntary and that you may end your participation at any time without any penalty or negative consequences.
* You have been given a copy of this Informed Consent form for your records; and
* You agree to the inclusion of [*describe the personal records/information]* in this research project.

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Signature of Participant Date

If a summary of results is being offered to participants, this option can be provided on the consent form.

Example: “Please provide an email address below if you would like to be sent a summary of the study results.

Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”

Principal Investigator’s Signature:

I have explained this project to the best of my ability. I invited questions and responded to any that were asked. I believe that the participant fully understands what is involved in participating in the research project, any potential risks and that they have freely chosen to participate.

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Signature of Principal Investigator Date