DALHOUSIE UNIVERSITY

Templates will not be appropriate for every imaginable study, as different types of studies require different details. Adapt them to fit your research. Feel free to cut and paste from any example in this document.

CONSENT FORM

[Template #3: secondary analysis of personal records]

Project Title:

Lead researcher:
Name, affiliation and contact information

Other researchers:
Names, affiliations and contact information. Include student supervisor if applicable

Funding provided by: If the study is funded, state name and description of the funder here

[Versioning: After receiving ethics approval, add the date of approval and the consent form version number in the footer. The first approved version is v1.0. If subsequent amendments to the consent form are requested and approved, the date of approval and version number (e.g. v2.0) must be updated.]

Introduction

State clearly that this is research and participation is voluntary.
Example: "We invite you to take part in a research study being conducted by [lead researcher] who is a [student, postdoc, researcher] at Dalhousie University. Taking part in the research or not is entirely your choice. There will be no impact on [your studies/your employment/your performance evaluation/the services you receive] if you decide not to participate in the research. The information below tells you about what is involved in the research, what you will be asked to do and about any benefit, risk, inconvenience or discomfort that you might experience.
You should discuss any questions you have about this study with [researcher name]. Please ask as many questions as you like. If you have questions later, please contact [Lead Researcher Name]."

Purpose and Outline of the Research Study

This section briefly explains the overall approach of the study in plain language, and what the researcher hopes to achieve. It should provide enough information so that the intent of the study is clear, without unduly influencing the reader toward participation. Include basic study

design. Be clear why the study requires the use of personal records, and cannot be done without access to those. Avoid the use of coercive language (e.g., "the success of my project relies on your participation"). Research jargon should be avoided, unless it is explained carefully.

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 three core courses will be compared from before and after the curriculum change."

Possible Benefits and Risks

Describe any potential benefits that the participants may derive from their study participation. Where there are no anticipated direct personal benefits to participants, this should be explicitly stated. More altruistic benefits (e.g., contribution to knowledge) should be realistically assessed, not overstated. The text should not imply that these benefits are guaranteed.

Example: "Participating in the study will not benefit you directly, but we hope to learn things that will benefit others."

Risks: Potential harms 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: "There is a slight possibility that someone from the clinic could recognize your name while retrieving data from patient files. All office staff have a commitment to confidentiality. There is also a slight risk that the study could find that people with ____ are at higher risk for ____, which could have negative repercussions for that community. Our intent is to analyze the data and provide practice recommendations that focus on ___, rather than ___."

How information will be protected:
Privacy: If steps will be taken to ensure others outside of the research team do not know whose data is included in a study this should be explained. Participant anonymity should only be assured if no one, including the researchers, will know who the participants are.
Example: "Your participation in this research will be known only to [member(s) of the research team]."

Confidentiality: This means not disclosing information about participants, or who they were. Research participants should be informed how their data will be treated (e.g., coded/de-identified) and stored (e.g., locked file cabinet, password protected on a computer), and who will have access to it. This should be described clearly and in terms that are easily understood. Use of ID numbers, pseudonyms, altering identifiable demographics and so on should be mentioned here. If files linking data with contact information are retained, their secure and separate storage should be described.
Example: "The information that we gather about you will be kept confidential. Only the [research team at Dalhousie University] will have access to this information. All your identifying information (such as your name and contact information) will be securely stored separately from your research information. We will use a participant number (not your name) in our written and computer records so that the research information we have about you contains no names. During the study, all electronic records will be kept secure in an encrypted file on the researcher's password-protected computer. All paper records will be kept secure in a locked filing cabinet located in the researcher's office."

Participants should be told what measures will ensure that they will not be identifiable in reports or publications.
Example: "We will describe and share our findings in [thesis, presentations, public media, journal articles, etc.]. We will only report group results and not individual results. This means that you will not be identified in any way in our reports."

Data retention: Describe plans for the data after data analysis is complete. This includes whether/when data will be destroyed. If data will be retained, describe confidential storage and whether data will be stripped of identifiers prior to storage. If there is potential for future use of the data for further research, this should be described. Some journals require retention of raw data for specified periods of time, and most disciplines have norms regarding data retention. What matters ethically is that participants know your plans.
Example: "Once the study is over your data will be [describe plans for data de-identification/anonymization, retention, long-term storage, further use and/or destruction]."

Data repositories: If the researcher might or will submit research data to a data repository, information about that should be provided.
Example: "De-identified data generated from the information you provide in this research may be shared publicly (most likely in digital form via the internet) to advance knowledge. I plan to deposit the data in a public research database called [name/website of repository]. I will

remove or replace personal information that could identify you before the data (e.g. [describe what this is in the context of this research]) are shared in an effort to ensure that no one will be able to identify you. Despite these measures, I cannot guarantee your anonymity or predict how those who access the data will use them."

Study Withdrawal

If there is an option to withdraw from the study this should be described. Generally it will not be possible, as data will have been de-identified.

How to Obtain Results

If study results will be made available to participants, describe what and how.
Example: "We will provide you with a short description of group results when the study is finished. No individual results will be provided. You can obtain these results by [including your contact information at the end of the signature page/visiting website address in approximately X months/ accessing other location]."

Questions

Participants must be provided with a means of having their questions about the study addressed. Ideally, a local telephone contact and electronic mail address should be available.
Example: "We are happy to talk with you about any questions or concerns you may have about your participation in this research study. Please contact Researcher Name (at 902 494-****, researcher.name@dal.ca) [or Supervisor Name (at 902 494-****, supervisor name@dal.ca)] at any time with questions, comments, or concerns about the research study (if you are calling long distance, please call collect)."

Participants may also wish to voice concern about the research to the university. Contact information for Research Ethics must be provided.
Example: "If you have any ethical concerns about your participation in this research, you may also contact Research Ethics, Dalhousie University at (902) 494-1462, or email: ethics@dal.ca" (and reference REB file # 20XX-XXXX)."

Signature

Not all informed consent processes require a signature. The TCPS simply requires researchers to document consent (Article 3.12). This could mean orally confirming consent, and recording that this has been done. If a signature is obtained, it should be on a separate page, as below. This allows researchers to collect the signature pages but leave the detailed study information, and contact information, with participants.

Signature Page

Project Title: [Insert study title]

Lead Researcher: [Name, affiliation, contact information]

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.

The signature consenting to study participation should indicate anything that is required for participation, and any limits on withdrawal.
Example:
"I have read the explanation about this study. I have been given the opportunity to discuss it and my questions have been answered to my satisfaction. I understand that I have been asked to allow researchers to use my child's school records for a study about _____. I understand that no one will know whether my child was included in the study, and that participating or not will have no repercussions for me or my child at the school. Once my child's records have been analyzed, there will be no way to withdraw them.

I agree that my child's records can be used for this study.

_____
Name of child

_____ _____ _____"
Parent's name Signature Date

Optional:
I agree to have my child's data included in a public research database ☐Yes ☐No

_____
Name of child

_____ _____ _____"
Parent's name Signature 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: _____”

The signature of the researcher or a witness is not required. Asking participants to sign two copies is not required, and in fact may compromise privacy if the participant copy is not stored securely.