DALHOUSIE UNIVERSITY

It is unusual to need/be able to get consent from people who participated in previous research. But sometimes it is possible and necessary. This template will not fit every imaginable study, as different types of studies require different details. Adapt it to fit your research. Feel free to cut and paste from any example in this document.

CONSENT FORM

[Template #4: Secondary use of existing research data]

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 [Lead Researcher] who is a [student, postdoc, researcher] at Dalhousie. 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. 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.

It is key to explain why you need consent. The people being approached consented to participate in previous data collection. Generally, you would be analyzing those data to address a new question, or possibly comparing their data with data collected in a different project. In essence they need to know what they consented to the first time, and what you propose to do now that is new and different. Make very clear what research question their data is being used to address.

How Will Data be Used

Make very clear what you will do with people's data that they did not previously consent to – new analyses, new comparisons, new questions addressed. People allowed their information to be collected for specific purposes, they have a right to say no to its use for new purposes.

Who Will be Included in the Research Study

This section should explain what characteristics people needed to have to be in the initial study, and if only some are being selected to be part of the new proposed analyses how those will be selected. The language should be simple and direct.

Example: "The study you were originally in included all seniors from this community between the ages of 65 and 85 who lived in their own homes. For the current analysis, we will only include those between the ages of 70 and 80, so the data are directly comparable with the data from the [name] study that was conducted in [place]."

Possible Benefits and Risks

Describe any potential benefits participants may derive from their study participation (there may be none). 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 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 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. 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]."

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) 494-3423, 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 understanding of the purpose of the new analyses and/or questions.
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 the survey data that was previously collected by _____ in order to address [new research question or topic].

I agree that my survey data can be used for this study.

_____	_____	_____
Name	Signature	Date

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

_____	_____	_____"
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. Getting participants to sign two copies is not required, and in fact may compromise privacy if the participant copy is not stored securely.