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 #1: Traditional with Signature Page]

Project title: Insert Title of Project

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. Choosing whether or not to take part in this research 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 terms like "case-control study" "open-ended interview" "participant observation" should be avoided, unless they are explained carefully, as they may not be meaningful to participants. If there is to be deception or incomplete disclosure of the purpose of the study for any reason, participants should be told that they will be given additional information about the study after their participation is complete (i.e., a debriefing).

Who Can Take Part in the Research Study

This section should explain what characteristics the participant must have to be eligible for participation 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 (e.g., "You may participate in this study if you are..."). Any conditions (e.g., being above or below a certain age) that exclude a participant from participation must also be listed here. If any screening activities are planned, these should be described.

What You Will Be Asked to Do

The study procedures must be stated clearly and in sufficient detail that the participant can understand what will be expected of them. The location, frequency/number and length of visits, types of procedures (e.g., interviews) and the duration of the study must be included. Example: "If you decide to participate in this research you will be asked to attend [one visit] to [researcher lab] located at [location]. The visit will take approximately [hours/minutes]. During the visit you will be asked to [describe activities]."

This description should only include the activities that the participant will *experience*. When several groups of individuals will take part in different components of the research, or different procedures, it is best to develop separate consent forms for each group to keep the descriptions simple and specific. If the study procedures involve multiple time points/visits it may be helpful to include a flow chart. If the study procedures involve use of physical equipment/instruments by the participant (or attached to the participant) a photo of the experimental set-up may be helpful.

Possible Benefits, Risks and Discomforts

Benefits: 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 might not benefit you, but we might learn things that will benefit others."

Risks: This should include all possible adverse events or side effects, along with the estimated probability of occurrence (if known) of any of the tasks or activities that participants will be involved in. This refers both to discomfort associated with physical procedures as well as the possibility of emotional or psychological distress caused by interviews or survey contributions. Where there is a possibility of economic repercussions, damage to relationships, risk to health, or loss of privacy, these should be described. The steps that will be taken by the researcher to minimize these risks should be stated. In some instances, risks may exist for communities associated with the study (stigmatization, community discord). These should be discussed.

Researchers should not categorically state that there is 'no risk' associated with a study. This suggests a guarantee that is not possible given the inherent uncertainty involved in research. Where the harms or discomforts are no greater than those that are related to common experiences of everyday life, they may be described as 'minimal'.
Example: "The risks associated with this study are minimal; there are no known risks for participating in this research beyond being bored or fatigued. You will be offered breaks between activities to reduce these risks."

Compensation / Reimbursement
If participants are to be compensated for their participation, the full extent of this compensation, and how it will be provided should be described. If compensation is in the form of a lump sum or gift, this should be granted even for those who withdraw without completion. If compensation is to be pro-rated according to the number of study components someone engages in, this should be explained. If participants are to be reimbursed for expenses incurred in relation to study participation (e.g., parking, transportation costs) this should be stated. Upper limits of reimbursement per person should be clear, so as not to create inappropriate expectations. If participants are not being compensated this should be stated.
Example: "To thank you for your time, we will give you a gift card worth $10 each time you engage in an assessment session."

How your information will be protected:
Privacy: If steps will be taken to ensure others outside of the research team do not know who participated in a study this should be explained. This would include such steps as collecting data where others will not see or hear the participant, ensuring third parties are not aware of who has been recruited, sending study communications without an identifiable return address, or without an email subject line that discloses study participation. 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 the data they provide 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 names or contact information (i.e. a key code), are retained their secure and separate storage should be described.
Example: "The information that you provide to us will be kept confidential. Only the [research

team at Dalhousie University] will have access to this information. The people who work with us have an obligation to keep all research information confidential. 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 also be told what measures will ensure that they will not be identifiable in reports or publications (as applicable).
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."

Limits to confidentiality: Any limitations on confidentiality should be stated clearly. For example, if focus groups will be held, participants should be informed there is no guarantee that other participants will maintain confidentiality.

Where there are limits to confidentiality that are imposed on researchers due to **legal obligations** (i.e., duty to disclose suspected abuse or neglect of a child, or the abuse or neglect of an adult in need of protection) this must be stated. *This is advisable for research that may inadvertently cause such disclosures to be made, and it is imperative for research that*

specifically deals with issues of sexual or child abuse, or abuse of adults in need of protection. A simple description of what the researcher will do in such a situation should be provided. Example: "We will not disclose any information about your child's participation in this research unless compelled to do so by law. That is, in the unlikely event that we witness child abuse, or suspect it, we are required to contact authorities."

If researchers have **professional ethical obligations** in addition to legal obligations that could foreseeably impose limits on confidentiality, these should be stated but should be distinguished from legal obligations. Example: "We will not disclose any information about your participation except as required by law or our professional obligations. If you inform us about abuse or neglect of a child [an adult in need of protection] we are required by law to contact authorities. If we notice that you are at an immediate risk of harming yourself or other people we are required by our professional code of ethics as social workers to seek assistance."

Data retention: Discuss plans for the data after data collection and analysis are 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 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."

If You Decide to Stop Participating

People have the right to withdraw from voluntary participation. Describe how this is possible. They might end an interview, choose not to return for a second data collection point, or decide after data is collected that they want to withdraw their data. Possibilities need to be explicitly stated. If there is a point after which removal of someone's study data becomes very difficult, or impossible, indicate when this is. If it will not be possible to remove data after it is collected (because it is anonymous/anonymized) state this.

Example: "You are free to leave the study at any time. If you decide to stop participating during the study, you can decide whether you want any of the information that you have provided up to that point to be removed or if you will allow us to use that information. After participating in the study, you can decide for up to [weeks/months] if you want us to remove your data. After that time, it will become impossible for us to remove it because it will already be [published/ analyzed/ anonymized]."

How to Obtain Results

Describe what study results will be made available 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. In addition, participants should be assured that they will be provided with any new information which might affect their decision to participate in the study (if this is applicable).

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)."

Other

See TCPS2 Article 3.2 for additional suggested consent form items that may need to be addressed for your particular study, such as conflict of interest, commercialization, and not waiving legal rights.

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 at the beginning of an interview. For some research (e.g., online surveys) it is inappropriate to get a signature, because signed consent eliminates what would otherwise be anonymity. Completion of an online survey itself is taken as implied consent. Completion of a paper survey can indicate consent, if the consent information is presented at the beginning of the survey.

If a signature is obtained, it should be on a separate page and not on the back side of the study information. 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 caregiver). 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. It should be clear from the format of the page that "I" refers to the research participant.
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 take part in [two interviews that will occur at a location acceptable to me, and that those interviews will be recorded. I understand direct quotes of things I say may be used without identifying me]. I agree to take part in this study. My participation is voluntary and I understand that I am free to withdraw from the study at any time, until [XX weeks/months] after my [second interview] is complete.

_____	_____	_____"
Name	Signature	Date

If some things are optional for participants, consent for those should be sought separate from overall study participation. Do not provide places for consent to specific items if they are not in fact optional. If, for example, in order to participate people must consent to being recorded and to the use of their quotes, that would be explained as above, with consent granted when the person consents to study participation. In contrast, if someone could participate but refuse recording or the use of quotations (the researcher would take notes), those items should be removed from the signature statement above and included as separate consent items.
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 take part in [an interview that will occur at a location acceptable to me]. I agree to take part in this study. I realize that my participation is voluntary and that I am free to withdraw from the study at any time, until [XX weeks/months] after [my interview] is completed.

_____	_____	_____"
Name	Signature	Date

Options (you can still participate in the research if you select no):

I agree that my interview may be audio-recorded ☐Yes ☐No
I agree that direct quotes from my interview may be used without identifying me ☐Yes ☐No
I agree to have my data included in a public research database ☐Yes ☐No

_____ _____ _____"
Name Signature Date

Separate consent should be obtained for waivers of confidentiality, and for asking permission to re-contact participants for future research (which should be described as explicitly as possible). Also, depending on research sensitivity it may be appropriate to confirm permission for the use of quotations after an interview is completed so that individuals will have a clearer understanding of what might be contained in quotations. This can be documented by having a second signature line that can be signed *after* data collection.

Example: "I confirm I have completed the interview and agree that direct quotes without my name may be used.
_____ _____"
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: _____"

Note: The signature of a 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.