
Requirements for Informed Consent Forms ¹²³⁴⁵⁶

Informed consent is the process by which people give their permission to participate in a research study. Typically, research involving humans involves an Informed Consent Form, which is designed to give potential participants the information they need to make a decision about whether to participate in the research. The Informed Consent Form serves as an agreement between participants and researchers. Both parties must be able to keep copies of the Form for the duration of the research.

An Informed Consent Form must be written in language that the potential subject can understand. It must contain at least the following information:

- A statement identifying the researcher(s). This statement should indicate their affiliation with NBCC, and how they may be contacted.
- The form should not say that the study is "sponsored" or "endorsed" by NBCC. The group conducting the study can be identified in the text of the document, but not at the very top of a consent form, and the identification should not advertise the group.
- For student research, the name, affiliation, and telephone number of the student's supervisor(s).
- A statement identifying a person not directly involved in the research, for example the Department Head or Dean, who may be contacted should the subject have concerns about the research.
- A statement that the reader is being invited to participate in research.
- A clear statement of the purpose of the research.
- A full description of the procedures to be followed in the research (e.g. what is expected of participants, what they will be asked to do, what data will be collected).
- The period of time required for subject participation.
- A statement indicating that participation is voluntary, and that subjects are free to withdraw from the research, and to withdraw any data pertaining to themselves, at any time, without penalty.
- Include the following statement: "If changes are made to the study or new information becomes available, you will be informed."
- A statement indicating how subjects may receive information as to the outcome of the research.
- Where applicable:
 - A clear description of any potential risks associated with participation in the research.
 - A clear description of the potential benefits of the research, whether to the subject or to others.

¹ Informed Consent Form. [University of New Brunswick](#), 2012.

² Consent Form Guide. Appendix E. [Health Canada and Public Health Agency of Canada](#) – Research Ethics Board.

³ Informed Consent Process, [University of Alberta](#).

⁴ Consent Form Template, [Saint Mary's University](#).

⁵ Sample Consent Form for Human participants, [Selkirk College](#).

⁶ REB Sample Consent Forms, [Conestoga College](#).

- A statement concerning recording of subject participation (audio tape, video tape, photographic records, electronic data recordings, etc.); who will have access to the records, security provisions in storage, possible use in publication, and when they will be erased or destroyed.
- A statement concerning compensation for any injury incurred while participating in the research.
- A statement informing subjects that they may decline to answer specific questions (for any research involving questionnaires or interviews).
- A statement indicating how confidentiality will be protected. ○ A clear explanation of any inducements offered for participation, and of the consequences (if any) on those inducements if the subject withdraws before the research is completed.
- A separate consent form will be required if the study involves taking photographs, videotaping or sound recordings.
- State how, if at all, participants will be informed of the results of the research.

Children as Research Subjects

A parent or legal guardian must provide signed written consent for the participation of children in research. As well, assent of the child is normally required where the child is old enough to understand, and evident dissent is always an indication that the child's participation in the research should be terminated.

When participants under nineteen are considered by the applicant to be competent to consent without parental involvement, the applicant must provide justification for this conclusion.

Incompetent Adults as Research Subjects

For research involving adults of limited competence, signed written consent must be provided by an authorized third party. As well, assent of the subject is normally required, and evident dissent is always an indication that participation in the research should be terminated.

RECOMMENDED STATEMENTS TO ENSURE CONFIDENTIALITY⁶

Minimal Risk Research with students using INTERVIEWS to collect data

Every effort will be made to ensure confidentiality of any identifying information collected in this study:

- Interviews will be tape recorded and transcribed at which point, all identifying information will be removed.
- Tape recorded interviews will be downloaded onto a password-protected computer and the original recordings will be deleted.
- All transcribed interviews will also be stored on a password-protected computer.
- Only the research, will have access to interview data.
- The funding agency "xx" will only have access to coded data which will have identifying information removed.

Minimal Risk Research with students using FOCUS GROUPS to collect data

Every effort will be made to ensure confidentiality of any identifying information collected in this study:

Your identity will be known to other focus group participants and the researcher cannot guarantee that others in the group will respect the confidentiality of the group.

- We will ask you to sign below to indicate that you will keep all comments made during the focus group confidential and not discuss what happened during the focus group outside the meeting.
- Focus groups will be taped and video recorded and transcribed at which point, all identifying information will be removed
- Taped and video recorded focus groups will be downloaded onto a password-protected computer and the original recordings will be deleted.
- All transcriptions will be stored on a password-protected computer.
- Only the researcher will have access to focus group data.
- The funding agency “xx” will only have access to coded data which will have identifying information removed.

Minimal Risk Research with students using SURVEYS to collect data

Every effort will be made to ensure confidentiality of any identifying information collected in this study:

- The researcher will not collect your name or any other contact information. (Choose and include which of the statements below apply. Delete those not applicable)
- At no time will any specific answers be attributed to any participant. Internet protocol (IP) addresses will not be collected.
- In the event that IP addresses are collected, the Principal Investigator will ensure that the investigators will not be able to view the IP addresses of any of the responses.
- Only one (1) password to access the data exists; that password is held by the Principal Investigator.
- All survey-related data is SSL encrypted when transmitted to/from the web server (similar to what banks use to transmit secure information).
- All survey-related data is encrypted when stored on the web server’s storage system.
- All administrator access to the server is protected with strong passwords and where possible, firewall protection systems.
- Only the researcher will have access to focus group data.
- The funding agency “xx” will only have access to coded data which will have identifying information removed.

WHAT IS THE DIFFERENCE BETWEEN A WAIVER AND AN INFORMED CONSENT?⁷

An **Informed Consent** is defined as a legal document used to inform a person about the hazards and potential dangers of a particular activity. The legal definition is *"Permission to do something which is given with complete knowledge of all relevant facts, such as the risks involved or any available alternatives."*⁷

A **Waiver** is defined as a legal document that waives a person's right to seek damages from an organization or person. The legal definition is *"Relinquishment of a known contractual right by a party who has such a right, which will relieve the other party of his contractual duty. No consideration is necessary."*⁷

HOW TO AVOID PROBLEMS WITH CONSENT FORMS⁸

Consent forms should not be entitled, "Informed Consent." Informed consent is a process and a state one strives to approximate; it is not a piece of paper. The title tends to obscure the nature of the process and carries some risk by implying a degree of completeness that the form may not have.

Strike out formats ("You/Your spouse/your child"). These should not be used where they make the form difficult to read.

Consent forms should not begin with a statement advertising the service or group conducting the study. This is coercive. A simple, factual statement of who's running the study may be inserted in the text of the document.

Consent forms should not indicate that the student/supervisor recommends participation; nor should they "offer the opportunity" (as opposed to "invite") to participate. These are considered coercive.

Fill-in-the-blank formats, in which the features of a given study are "plugged in" to a stock format are discouraged.

The clause "only aggregate data will be presented" should be used only when it is true. Statements summarizing foregoing consent information should be used only when they genuinely clarify; they should be avoided particularly when they suggest a warning or limitation of liability or opportunity for redress.

Problem statements to avoid due to lack of clarity:

- "The possible risks associated with this study have been presented".
- "The method and purpose of administration of this study have been explained to you".
- "You have been made aware of certain risks and consequences".

⁷ University of Ottawa. Definition of an informed consent versus a legal waiver.

⁸ University of Minnesota, Informed Consent Process Guide.