Health Sciences North
Horizon Santé-Nord

Using this template

The goal of this template is to provide a skeleton for a consent form for your study. It is intended as a guide only. The consent form must be appropriate in length and in content to the characteristics of each study.

- The form should be written for the average person, which means it should be written below an 8th-grade reading level. Use brief, simple statements rather than long detailed explanations.
- The form is written to keep the voluntary nature of research at the forefront of the potential participant's mind.
- The style must be simple. Avoid using scientific or medical words or expressions. If you must use them please use lay terms. Legalistic phrases or expressions are also to be avoided so the consent form does not read like a contract.
- **All section headings of this template are highly recommended. If a section is not applicable to your study, please delete. Otherwise, if you believe that an exception may be required, please contact the RSO at rso@hsnri.ca**
- For template consent forms provided by the sponsors (either industry or another academic institution), please review the points outlined in this guidance document and revise the consent form accordingly to meet the HSN REB standards. Please contact the Research Services Office for guidance at rso@hsnri.ca
- The first page should be on letterhead or have the institutional logo of the organizations involved in the study (e.g., HSN, HSNRI, NECC, LU, etc.).
- Some general considerations:
    - Use a font size appropriate to the target population e.g. larger font size for an older demographic
    - Written consistently in the second person (you/your) except signature section (first person)
    - Version number and date on all pages in footer (Page x of y)
    - Review all red and italicized wording, update as required and delete any instructions
- Please note: if this is a clinical trial that is regulated by Health Canada or other body e.g. the FDA, there are other requirements for the contents of the consent form. Please contact the Research Services Office for guidance at rso@hsnri.ca

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Title

Principal Investigator: Name of Investigator

Funding Agency/Sponsor: Name of Funding Agency/Sponsor (if applicable)

Emergency Contact: *For greater than minimal risk, include 24 hour night/emergency phone numbers.*

You are being invited to take part in a research study.

This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at any time.
- You will not be penalized if you decide not to participate in or quit the study later.

Conflict of Interest /Funding Support

Please include details of any actual or potential conflict of interest concerning this study.

If applicable, insert for industry sponsored or funded trials:
The sponsor of this study is providing money to Health Sciences North to do this research.

Why is this study being done?

Explain the study purpose

Why do I have the option of joining the study?

List condition, disease or explain the reason.

How many people will take part in the study?

List the number of people that will take part in this research study at Health Sciences North.

If applicable for multisite studies, list the number of people that will participate in the entire study.

If I agree to join this study, what would I need to do?

The first part of this section should describe the study OVERALL, including the following information:

- *how long each study visit will take and overall duration of the study;*
- *explain the difference between standard therapy and the study procedures;*
- *if participants will be assigned to different arms – what this means and how will this be done.*
  For example, 'You will be assigned at random, (like flipping a coin OR like rolling the dice), to one of XX number groups.'

THEN: Describe the procedures chronologically using simplistic language, short sentences (1-3) lines and short paragraphs (less than 6 sentences). The use of subheadings may help to organize the section and increase readability. Explain study procedures ONLY ONCE, and then represent what will happen at each study visit with a study chart of procedures – as opposed to repeating each procedure multiple times in different visit captions.

Include explanation of what the participant's responsibilities include e.g. taking medication at home, patient diaries, online medication compliance checks, etc.

If applicable, add information regarding audio/videotaping and explicit options to consent (or not) to recording.

Collection of biological samples

Include details about the collection of human biological materials (i.e. tissue, organs, blood, plasma, urine, saliva, other bodily fluids, embryos, fetuses, fetal tissue and human reproductive material).

NOTE: Collection of samples/tissues for future unknown research and/or banking (i.e. where the research purpose is not yet known) must have a separate informed consent form if it is not the main purpose of the study.

Include details on what the sample/tissue is to be used for (i.e. current research study, commercial use (for profit) or future unknown research/banking)

Describe the type and amount of sample/tissue to be taken, the manner in which sample/ tissue will be taken, the safety and invasiveness of acquisition; the conditions of preservation of the sample/tissue; how long the sample/tissue will be stored, the location of storage (i.e. ***Company/Institution Name, City, Country****) and how the sample/tissue will be disposed.*

Describe whether the participant will receive the results of any testing.

Describe whether the sample/tissue will be linked to the participant, the safeguards to protect the participant's privacy and confidentiality.

***When collecting and banking genetic material**, address the associated ethical issues, including future contact of participants, families, communities and groups.*

How long will I be involved in the study?

Indicate how long the entire study will last.

Indicate how long the participant's participation in the study will last.

Indicate the reasons why the study or the participant's participation in the study may be stopped early.

For phase II and III clinical trials, include information about access to the study treatment once research participation is over.

What are the potential harms or risks if I join this study?

This section should include all physical, psychological, financial and social risks etc. in lay terms.
When applicable, include a statement about risk to the participant or fetus if the participant is or becomes pregnant.
Ensure that you distinguish the risks between different groups the participant could be assigned (e.g. investigational treatment vs. standard of care).

What are the potential benefits if I join this study?

If direct participant benefits are not expected, then use the following standard clause:
You may not directly benefit from participating in the study.

OR

If direct participant benefits can reasonably be anticipated as a result of participating in the study, then describe these benefits; however, DO NOT OVERSTATE any potential benefits. Conclude with the following standard clause:

However, you may not get any benefit from being in this research study.

You may also state the possible benefits to society in terms of advancement of knowledge, and/or benefits to people with the participant's particular circumstance.

Do not include monetary reimbursement in the benefits section. If applicable, this should be included in a separate section.

Do I have to join this study? What other options are there?

Choose the appropriate paragraph to match your study population

***Option 1: When the participants are patients or general public**:*

You can choose not to participate in this study. If you choose not to participate, *<describe the options still available to them (e.g. no treatment, standard treatments, supportive care, etc.)>*.

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting the medical care, education, or other services to which you are entitled or are presently receiving at this institution. Your study doctor will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Option 2: When the participants are employees of the hospital:

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. Your decision will not affect your current or future employment at Health Sciences North. The research team will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

How would you keep my information confidential?

Describe whether or not records will be kept confidential. If records will not be confidential, describe how records will be presented, and if they will be archived. If records will be kept confidential, describe the controls that will be put in place to do so.

Describe whether their information will be kept confidential if the study is published.

We will keep your data for *<specify a period of time>*.

Describe how the participant's data and biological samples will be handled if they decide to withdraw from the study e.g. data and samples will be retained / discarded / kept with permission.

Conclude with the following standard clause:
These are some reasons that we may need to share the information you give us with others:

- If it's required by law.
- If we think you or someone else could be harmed.

Other groups that may look at your study records include:

- The Health Sciences North Research Ethics Board, the research ethics committee that oversees the ethical conduct of this study at this hospital
- *If applicable:* HSN staff with authorized access
- *If applicable: [Name of funding agency]*

- *If applicable: [Applicable regulatory authorities]*

Would it cost me money to be in the study?

A clear statement must be made about any costs for participation in the study.

Would I be paid if I join this study?

A clear statement must be made about any reimbursement the participant will receive for being in the study (i.e. parking costs, food, $$ for time, extra credit etc.) Be sure to indicate if these amounts are to be pro-rated for study visit completion.

NOTE: The REB will take into consideration the nature and amount of compensation (i.e., the compensation alone should not serve as sufficient inducement for the participant to volunteer).

Who do I contact if I have problems, questions, or want more information?

Enter Investigator and/or study coordinator contact information here.

For any comment or questions about your rights as a participant in a study, you may contact the Research Ethics Board of Health Sciences North at 705-523-7100 ext. 2409 or email your questions or concerns to reb@hsnsudbury.ca. The Research Ethics Board is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

If applicable, add information about what would happen and who to contact if the participant has a research related injury.

Declaration of Consent

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction;
- I have read each page of this form and I understand the requirements of participating in this research study;
- *If applicable:* I authorize access to my personal *<health>* information, *<medical record>* and research study data as explained in this form;
- *If applicable:* By signing this consent form you are saying it is okay for the study doctor/staff to collect, use and disclose information about you from your personal health records as described above.
- I understand I have rights as a research participant and that by signing this form I do not give up these rights;
- I voluntarily agree to take part in this study.

The box below is to be used for studies where there is collection of optional samples (i.e. for a sub-study directly related to the main study)

☐ I **agree** to allow my *< type of sample(s) >* to be collected for the optional study(ies) as described in this consent form.

☐ I **do not agree** to allow my *< type of sample(s) >* to be collected for the optional study(ies) as described in this consent form.

Signature of Participant	PRINTED NAME	Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

Signature of Person Conducting the Consent Discussion	PRINTED NAME	Date