Consent and Authorization Documents
General Requirements – Minimal Risk

Elements to be included in minimal risk information forms: e.g. survey/questionnaire research.

The principal investigator may delegate the provision of information for the consent; however, the investigator retains ultimate legal and ethical responsibility for ensuring the subject: 1) is provided with all appropriate information; 2) understands the information; 3) has had all questions adequately addressed; and 4) has the capacity to consent.

Please note the following general points when preparing your information and consent forms. Failure to follow these instructions may result in the submission being returned without review.

- Reading level should not exceed **grade eight**
- Use simple lay language and explain medical terms and avoid the use of jargon
- Proof-read for spelling and grammatical errors and inconsistencies across materials
- Indicate that the document is an information form in the title on page 1
- Version date of the form should appear in the footer on every page format
- Number each page with page number and total number of pages (e.g., "page 5 of 14")
- Use font size 12 or larger
- Must use IWK Health Centre letterhead on page one or IWK logo
- Write in the second person (i.e. referring to the potential research subject as "**you**" or "**your child**")
- Write in short sentences and use short paragraphs
- Avoid the terms patient and use either the term **"participant"** or **"subject"** – be consistent
- Write out all acronyms the first time they appear in the consent form
- Be consistent throughout the forms. For example, if you refer to a research assistant on the first page, be consistent on all other references
- Consent forms originating in the United States must be adapted to remove/alter clauses, which are only appropriate to the US health care system

Minimal Risk Information Form Template – Detailed instructions

The following headings **SHOULD** be used where appropriate. For many minimal risk survey studies, documentation of the consent process with a signature page is not required. Return of the questionnaire will be considered implied consent. The information form should be retained by the research subject.

Research Title
Provide a descriptive title of the study. This need not be the exact title under which the research was approved and funded, but should not be deceptive.

Researcher(s)

For each researcher provide:

- Their name
- Professional designation (e.g., MD, RN etc.)
- Relevant institutional affiliation(s)
- Role in the project (e.g., principal investigator, co-investigator)
- If researcher is a student this must be clearly stated, and the identifying information of the supervisor included

Funding

- Provide the name of any sponsor or funding agency of the research (e.g. pharmaceutical company, CIHR, IWK Health Centre)

Introduction and Purpose

- State that the project involves research
- Explain the topic that is being explored, the hypothesis that is being tested, and/or the question the research is seeking to answer

How will the researchers do the study?

- Describe the research design (e.g. questionnaire study)
- State whether the research is being done at a single site or is part of a multi-center project
- State how many subjects are anticipated to be enrolled at this site and in total

What will I be asked to do?

- Provide a brief description of what participation will entail for the research subject
- Clearly state the time that will be required for participation

What are the burdens, harms, and potential harms? (Potential Harms and Benefits may be captured in one section).

- Describe all foreseeable harms and potential harms (including physical, reproductive, emotional, psychological, social, legal, financial risks and/or inconvenience)
- Describe precautions that will be taken to minimize the probability of harm and severity that harm will occur
- For questionnaires, the possibility of distress to the subject should be mentioned, if applicable

What are the possible benefits?

- Explicitly state that there may be no direct benefits to the subject from the investigational intervention
- Describe the possible direct benefits to the subject from study participation, including the probability of occurrence
- Benefits of study intervention should not be guaranteed
- Do not include reimbursement of expenses as a benefit of participation

Can I withdraw from the study?

- State that the subjects can/cannot withdraw from the study after submission of the survey
- State that withdrawing from the study at any time will not affect the care the potential subject or his/her family will receive from the IWK Health Centre

Will the study cost me anything and, if so, how will I be reimbursed?

- Disclose any costs that will be incurred by the subject
- Indicate whether, and how much, the subjects will be reimbursed for expenses (e.g., travel, childcare) and/or inconvenience of participation, indicate how (if at all) reimbursement will be handled if the subject withdraws or is withdrawn prior to the conclusion of the study
- If there is to be no compensation include a statement to that effect

What about possible profit from commercialization of the study results?

- If applicable, describe any potential profit from commercialization of the results of the research and what, if any, plans have been made to share these profits with the research subjects. Any changes in the commercialization of the results must be reviewed by the REB for its consideration about informing subjects about the changes

Are there any conflicts of interest? (can be combined with previous section)

- Describe any actual, perceived or potential conflicts of interest (including financial conflicts) on the part of the researchers and/ or the institutions. If none, state that there are no conflicts. If relevant, include a statement indicating that the investigators are receiving payments for the conduct of the study

How will my privacy be protected?

- Describe the methods that will be used to protect subject's privacy
- Describe where and for how long records including data forms, identifying information, samples, video recordings, photographs etc. will be maintained in storage. For minimal risk studies, records should be stored for 5 years post publication
- If relevant, describe the extent to which privacy can be protected. Describe limits on the protection of confidentiality relating to ongoing monitoring of research activities (include identity and nature/purposes of access to the information, e.g. research sponsor, Health Canada, USFDA, REB IWK Audit Committee). If applicable, state that subject's privacy will be protected to the maximum extent allowable by law
- Anonymity – assurance of anonymity can only be given when the researcher will have no way of connecting data to individuals. Names and other easily identifiable elements should not be noted directly on documents that are sent out of the Health Centre
- State that if the results of the study are to be published, the participant's identity will remain confidential

What if I have study questions or problems?

- Provide the name and contact phone number and/or e-mail of the researcher who can answer questions about the study

What are my Research Rights?

- A statement regarding possible compensation if the subject is injured as a result of the research is mandatory. This section should include the following wording*:*

  Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject.

In no way does this waive your legal rights nor release the investigator(s), sponsors, or involved institution(s) from their legal and professional responsibilities. If you become ill or injured as a direct result of participating in the study, necessary medical treatment will be available at no additional cost to you. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive.

If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-7879, Monday to Friday between 8:00 a.m. and 4:00 p.m. or by email at researchethicsiwk@iwk.nshealth.ca.

Future contact/future research/other use?

- If the researcher would like to be able to contact the subjects again in the future to seek their involvement in subsequent related research projects, he/she must seek an explicit consent to future contact
- If the researcher would like to keep the information/samples gathered during this study for other research, he/she must seek an explicit consent for such future use
- If the researcher would like to use the information/samples gathered at some time in the future for purposes other then research (e.g., teaching), he/she must seek an explicit consent for such use

How will I be informed of study results?

- Describe how and when the subjects will be informed of the results of the research. Clearly distinguish between results that are specific to the subject and the results of the study in general
- The subject should not have to contact the researcher to obtain results. A method needs to be in place for the researcher to disseminate the results

Signature Page-Example

Study title:

Participant INITIALS:

Participant Consent
Please answer the following questions:

I have read or had read to me this information and consent form. Yes No

I have had the chance to ask questions which have been answered to my satisfaction before signing my name. Yes No

I understand the nature of the study. Yes No

I understand the potential risks. Yes No

I understand that by signing this consent form I am authorizing the access to my medical records. Yes No (add when applicable)

I understand that by signing this consent form I am authorizing the use of my samples for all the research described. Yes No

I understand that I have the right to withdraw from the study at any time without affecting my care in any way. Yes No

I have received a copy of the Information and Consent Form for future reference. Yes No

I freely agree to participate in this research study. Yes No

Would you like to receive information about the research results? Yes No

Name of Participant: (Print)

Participant Signature:

Date: _____ Time:

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY
I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study.

Name: (Print)

Signature: _____ Position:

Date: _____ Time:

STATEMENT BY PERSON OBTAINING CONSENT

I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating

Name (Print)

Signature: _____ Position:

Date: _____ Time:

Version date

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