IWK Health Research & Innovation Advancement

Consent and Authorization Documents
General Requirements

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 the type of information form (e.g., consent, authorization, assent) in the title on page 1 and in the footer of subsequent pages
- 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
- Avoid using words like "treatment" or "therapy" to refer to study interventions, as this may contribute to misperceptions that interventions being studied have known efficacy. Alternatives include "study drug", "research medication", "procedure" or "intervention".
- Be consistent throughout the forms. For example, if you refer to a research assistant on the first page, be consistent on all other references.
- In some cases, such as a survey or questionnaire, it is not necessary to have the subject sign a consent form, as the act of completing the questionnaire is considered implied consent. However the investigator must incorporate the elements of an Information Form in a cover letter to the questionnaire.

  as well as a statement such as "by completing this survey, I consent for my responses to be included in data analysis".my continuing on this survey you are consenting or anything?

- Consent forms originating in the US must be adapted to remove/alter clauses, which are only appropriate to the US health care system.

Consent/Authorization Template

The following headings **MUST** be used. If a heading does not apply to the research in question, this must be justified in the Research Summary. For most studies, documentation of the consent process will consist of an information sheet and a signature page, a copy of which must be given to the research subject.

Research Title

Provide the full title of the study on the title and signature page. Include the exact title under which the research was approved and funded. For titles that are particularly long or complex, please also provide a short title that is easier to understand.

Researcher(s)

For each researcher provide:

- the 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

- State that the project involves research
- Describe the initial consent process
- Describe the ongoing consent process
- If applicable describe what a clinical trial is

This section must include but is not limited to:

"You are being invited to take part in the research study named above. This form provides information about the study. Before you decide if you want to take part, it is important that you understand the purpose of the study, the risks and benefits and what you will be asked to do. You do not have to take part in this study. Taking part is entirely voluntary (your choice). Informed consent starts with the initial contact about the study and continues until the end of the study. A staff member of the research team will be available to answer any questions you have. You may decide not to take part or you may withdraw from the study at any time. This will not affect the care you or your family members will receive from the IWK Health Centre in any way. "

Why are the researchers doing the study?

- Explain the topic that is being explored, the hypothesis that is being tested, and/or the question the research is seeking to answer. Explain why and how the study might be important

How will the researchers do the study?

- Describe the research design (e.g. randomized, double-blind controlled trial or observational study.
- If using a double-blind method, include details of when and how a code may be broken
- Explain any specific research design techniques such as randomization, blinding, or placebo control. (explain these terms in lay language)
- 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
- If a placebo is used, define what a placebo is and explain the likelihood of receiving the placebo. The Tri-Council Policy Statement states, "When a clinical trial including a placebo control is undertaken, the researcher and the REB must ensure that subjects or authorized third parties are fully informed about any therapy that will be withdrawn or withheld for the purposes of the research, the anticipated consequences of the withdrawing or withholding of the therapy, and the reasons why the investigators deem a placebo-controlled trial to be necessary".

  The following issues should be addressed in the Informed Consent document in a section entitled "Use of Placebo". This section should address:

  - treatments that are currently used in the treatment of the disorder, including a discussion of their effectiveness,
  - why a placebo is necessary,
  - the risks to the subject during the period that standard treatment will be withheld,
  - measures that will be taken to reduce the risk to subjects.

What will I be asked to do?

- Provide a detailed description of what participation will entail for the research subject including all tests and interventions
- Clearly state the time that will be required for participation. A tabular form indicating the frequency and duration of visits to the study site may be helpful
- Clearly distinguish between what is being done as standard care and what is being done for the purposes of research
- Explain the difference between standard of care and care for research purposes.
- Describe accessing of health and any other personal records

What are the burdens, harms, and potential harms?

- 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
- Focus on those risks associated with the investigational aspects of the study. For questionnaires or interviews, the possibility of distress to the subject should be mentioned, if applicable
- Include information about the nature of all risks (i.e., how serious) and the probability of occurrence (i.e., how likely). This information may be more easily read by the subject if presented in a tabular format. Suggested wording – "*The following severe side effects are less likely, occurring in less than 10% of people taking the drug*".
- Acknowledge the possibility of unforeseen risks
- If the trial involves a placebo subjects must be informed of any therapy that may be withheld or withdrawn for the purposes of the study and the possible consequences of withholding this therapy
- If more than minimal risk, indicate who a subject should contact about injury or adverse effects
- Specify the total amount of blood to be drawn if necessary (5cc = 1 teaspoon); discuss risks such as bruising during blood sampling. EMLA or some other topical anesthetic should be offered for needle puncture if there is no contraindication
- If applicable, this section should explain risks regarding reproduction, lactation and fetal development. If the subject or subject's sexual partner must use contraception during the course of the study (required by protocol), the acceptable methods must be listed and for how long the subject must use contraception. Should a pregnancy occur and if required by the protocol, a statement should be included indicating that permission to follow the pregnancy will be required and the reason(s) for following the pregnancy

What are the possible benefits?

- Explicitly state that there may be no direct benefits to the subject from the investigational intervention. Suggested wording – "*Taking part in this study may be of no help to you personally. It is hoped that what is learned will be of future benefit to others suffering from disease X*".
- 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
- Do not include provision of more extensive diagnostic testing, monitoring, attention of medical staff as benefits. This implies that a potential subject who refuses participation will therefore receive lesser care from IWK and their medical team

What alternatives to participation do I have?

- Indicate that not participating in the study is one option. Also indicate that not participating in the study will not affect the care the potential subject or family receives at the IWK Health Centre
- If applicable describe all the options to participation available to the potential subject, as well as the possible risks and benefits of those options.
- Options should include, if appropriate, other treatments, and the option of no further treatment and/or comfort care.

Can I withdraw from the study?

- State that the subjects can withdraw from the study at any time.
- In those instances when it is not possible for a subject to withdraw from the research (e.g. part way through a surgical procedure), this should be explained
- 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
- Disclose if withdrawal of participation cannot include withdrawal of personal or study data compiled up to that point
- Describe the circumstances in which the subject may be withdrawn from the study
- Risks that may be associated with study withdrawal should be explained
- Subjects should be informed of procedures for safe and orderly termination should they decide to withdraw from the study before it is completed
- If the subjects withdraw or are withdrawn from the study and procedures are to be performed at a final visit, the subject should be asked to return for this. If the final procedures are to be performed for safety reasons, the reasons must be stated. If not for safety reasons, a clear statement must be included indicating that the procedures are not mandatory and that the subject may refuse to participate in this further evaluation

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
- The anticipated prorated payment if any, to the subject for participating in the study
- If there is to be no compensation include a statement to that effect

Are there any conflicts of interest?

- 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

What about possible profit from commercialization of the study results?

- 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

How will I be informed of study results?

- Describe how 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.
- *Suggest the following wording:*
    - *"Would you like to receive a copy of your results? Yes___ No___*
    - *"Would you like to receive a summary of the study results? Yes___ No___ Please provide your address"*

Once the research is complete will the research service/drug/intervention be available to me?

- If not applicable, do not add this section to the information form
- State whether the service/drug/intervention/device/program will be available to the subject once the research is complete and, if so, under what conditions. Suggested wording: *"We will help you in ensuring that suitable treatment for your condition continues once the study has been completed and/or the drug is no longer offered through the study. There is no promise that the drug will be available to you at that time. "*

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 studies involving more than minimal risk, storage of records for a minimum of 25 years or 10 years past the age of majority (for children under 5) is required. For minimal risk studies, records should be stored for 5 years post publication.
- 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 Research Audit Committee). If applicable, state that subject's privacy will be protected to the maximum extent allowable by law.

  When applicable, participants must be informed of the duty of the investigator to report any harm that maybe revealed as a result of the research.

Suggested wording:

Please note that, in the rare event that we should learn anything during the course of your child's participation in our study that would cause us to believe that your child is in danger of harming him/herself or others, Dr _____ would follow-up with you directly. Further, in accordance with provincial laws, in the rare event that we learn anything during the course of your child's participation in our study that would cause us to believe hat your child was being harmed, we would be required to report this to a child protection agency. If any issues do arise as a result of your participation in our study, you are encouraged to contact Dr. _____ at (902) 470- _____

- Describe where and what information about participation will be recorded apart from research files (e.g. in health records)
- State that if the results of the trial are published, the subject's identify will remain confidential
- 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
- Ensure it is clearly outlined if any study material is going outside IWK and explain why/how this will be executed

What if I have study questions or problems?

- Provide the name and contact phone number and e-mail of the researcher who can answer questions about the study. Also provide information as to when this person is available to research subjects.

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 must include the following wording:
- *Nothing written here about treatment or compensation in any way alters your right to claim damages".*
- *"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.".*

"Your signature on the 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 this 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."

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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 for future contact with participant signature
- 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

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 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

Page #

Assent Document

When appropriate, investigators are encouraged to fully involve children in the consent process for studies in which they will be participating. The nature of this involvement will depend on the developmental level of the child and the characteristics of the study. It is possible that a relatively young child would be capable to understanding a simple study, and provide informed consent. For children who are incapable of giving informed consent, they nevertheless may still possess the ability to provide or refuse assent to participation in research. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research:

1) does not involve interventions that may be of benefit to the subjects and
2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

The process of obtaining assent may proceed in variety of ways. One option is to provide an information form that explains the research procedures in a language that is appropriate to the child's age, experience, maturity and condition. This explanation should include a description of any risks, discomforts and inconveniences the child may experience if he or she agrees to participate. Provision of an information form for the child is considered to be an expected part of the assent process. However, an information form should be used when it will enhance a child's understanding of their participation in research.

An alternative to providing an information form for the child is to have a well-documented and explicit process to provide the same information that would be contained in an information form. In order for the REB to judge whether appropriate assent is being obtained, it is important that the process of providing information to the child is described in detail. The REB may also require an opportunity to observe this process. Justification for not using an information form must be provided.

Information forms used, must include the following headings to ensure that the relevant information is clearly conveyed to participants. Ensure that the information form is written at an appropriate level for study participants.(assents should be at Grade 2-3)

Title of Study (simplify)

Investigators

Why are we doing this study?

Describe the rationale for the study. Include, if appropriate, the reason why this child is being approached for the study.

What will happen during this study?

Describe all interventions and testing that participation in this study will require. Also describe anything that will be required of the child and his/her family (completion of forms, visits to the health centre etc) over the course of the study. Also describe how long the study will last, and how much time will be required for all study procedures.

Are there any good or bad things about this study?

Describe any benefits or risks associated with participation in this study.

Who will know about what I did in this study?

Describe who may have access to the study records, or results of testing done during the study. The following text may be used if appropriate: "No one except the researchers will know you are taking part in this study unless you want to tell them. Your name, your study forms and your chart will only be seen by people involved in the study, <possibly funding agency or regulatory bodies>"

Do I have to be in this study?

Suggested text is as follows: "You do not have to be in this study. No one will be mad at you and it will not affect how your doctor's look after you. If you don't want to be in this study, tell us. Even if you say yes now, you can change your mind later. Being in this study is totally up to you."

What if I have any questions?

Suggested text is as follows: "You can ask questions about the study any time, now or later. You can talk to your parents about things in the study you don't understand. You can also ask <study doctor, Dr. X, study nurse>. You can call him/her at XXX-XXXX".

Signature Page

Must be dated and signed by research participant, the person providing the information and person obtaining consent. The date must be entered at the time of signature.