HREBA | Health Research Ethics Board of Alberta Clinical Trials Committee

HREBA – Clinical Trials Committee
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Participant Information and Consent Form Template
Standard Research Studies

Researchers must address three components in informed choice: competence, information disclosure and voluntariness (Refer the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans).

The investigator should supply the following information in ordinary language, avoiding jargon and supplying explanations (in lay terms) for crucial terms. The form must be in the 2nd person and should be phrased in a tone that is respectful to subjects (e.g. subjects should be *asked* to return for a final visit, subjects who become pregnant during the study should *be asked permission* to follow the pregnancy.) A footer must be included which contains the following information: version date, a place for subject initials, and page numbers. This is a template, so if any item is obviously irrelevant, it need not be included. This document must be placed on your letterhead.

*Note: The protocol will not be reviewed unless **all** mandatory and verbatim requirements are met. Once these sections are added to your Informed Consent, please ensure that any redundant clauses are deleted.*

Please refer to the Clinical Trials Committee – Standard Consent Form page of the website for a detailed list of required information to include in the informed consent form.

1. **The first page of the informed consent form must begin with the following**:

> **Mandatory and Verbatim:**
>
> **Research Project and Title:** _____
>
> **Primary Investigator:** _____
>
> **Co-Investigator(s):** _____
>
> **Sponsor:** _____
>
> This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

2. **Background/Rationale:**
   This section should include a description of the disease/condition being investigated, current standard therapy, possible deficiencies in the standard therapy and the rationale for the investigational treatment.

3. **Purpose/Objectives**
   This section should, in lay terms, reflect the primary objective(s) of the study, as contained in the protocol.

4. **Study Design**
   This section should explain such aspects of research design as randomization and blinding. In the case of double-blinds, include details of when and how a code may be broken. If deception is necessary for the research, debriefing is required and a description of the final consent process after debriefing should be included.

5. **For Placebo-Controlled Studies:**
   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 (1) the research, (2) the anticipated consequences of the withdrawing or withholding of the therapy, and (3) 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.

   Please use the following wording (if the placebo is used for blinding purposes only, use only the first two paragraphs):

   USE OF PLACEBO

   What is a placebo?

   A placebo is an inactive substance; it has no medication (drug) in it. It looks the same as the real medication.

   Why is a placebo used in this study?

   In a research study it is important to obtain accurate information. Many people who have X disorder (*explain the issues about the disorder that are relevant to the justification for the use of placebo).* A placebo is used in order to "blind" the study so neither you nor the study doctor will know whether you are on active drug. This is done so that you and your study doctor will not be influenced by expectations of the effects of the drug (*or list any other reasons).*

   What will I give up if I receive placebo?

   As previously mentioned, there are a number of treatments available for the treatment of X disorder. If you choose to participate in this study there is a _ in _ chance you will receive placebo. This will lengthen the time before you receive a treatment that may be effective. During this time you may experience worsening of your condition, including increased symptoms such as *list symptoms*. If your symptoms worsen and make you uncomfortable, you can withdraw from the study. You can do this at any time during the study.

6. **Study Procedures**
   This section should provide a detailed description of what participation will entail for the research subject (regular routines, nature of tests and procedures, amount of time spent at clinic visits, etc.). Identification of those procedures which would not be part of usual clinical care should be included.

7. **Risks and Discomforts**
   This section should include a description of the likelihood of any discomforts and inconveniences associated with participation and of known or suspected short- and long-term risks. This information should be categorized in percentages (e.g. less than 1%, 1-5%, 5-10%, etc.). On occasion, this information may be more easily read by the subject if presented in a tabular format.

   If there is a mandatory genetic portion to the study, please include the following paragraph:
   "There may be risks to your eligibility for employment, life insurance, mortgage insurance or private health insurance if the results of genetic testing were to be inadvertently disclosed to certain parties. Safeguards have been established to ensure that such disclosure will not occur. For example, we have taken steps to ensure that a coded number, rather than your name, will be used to identify your sample and that your name will not be disclosed in association with the sample at any time. In addition, the results of genetic testing will not be placed upon your medical record. Despite these efforts, we cannot guarantee you with 100% certainty that your genetic information could never be linked to you."

8. **Reproductive Risks**
   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 either by the protocol and/or site policy), 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 and/or site policy, a statement should be included indicating that permission to follow the pregnancy will be requested and the reason(s) for following the pregnancy.

9. **Benefits**
   This section should explain the probability and nature of direct and indirect benefits to the subjects and to others. Although not mandatory, the following statement is recommended, "*Although participation in this study may be of no benefit to you personally, it is hoped that what is learned here will be of future benefit to others suffering from disease X."* Items such as close physician monitoring and the free provision of medications and services may be seen by some subjects as inducements to participate and therefore, must not be listed as a benefit.

10. **Alternatives to Participation**
    This section should identify alternatives to enrollment in the research. The trade name(s) of commonly used medications should be listed. A discussion of the risks and benefits of the alternatives or a statement indicating that the study doctor will discuss the risks and benefits of the alternatives with the subject must be included.

11. **Confidentiality**
    This section should include an explanation of who will have access to information collected and to the identity of the subject, including a description of how confidentiality will be protected. The Health Research Ethics Board of Alberta – Clinical Trials Committee – Clinical Trials Committee must be included as having access to the information.

    Please include the following in this section:
    a. That personal health information will be collected as part of the study
    b. List what is included in "personal health information"
    c. That information will be kept confidential
    d. How confidentiality will be protected (i.e. use of code numbers, etc.)
    e. That study records will be kept separate from medical records
    f. That in some circumstances, sponsor and / or investigator may be required by law to release personal health information about subjects
    g. The purpose for which the information collected will be used (should be limited to the purposes of the study)
    h. Whether permission is being sought to disclose the subject's participation to their family physician

i. The health information collected will be checked from time to time against medical records by representatives from the sponsor, and that this implies that representatives of the drug company paying for this research will be able to view your medical records.
j. That other persons may also need to view subject's records, including representatives from the HREBA-CTC, the Health Products and Food Branch of Health Canada (if applicable), the United States Food and Drug Administration (if applicable), and/or other foreign regulatory agencies.
k. That where the groups / persons who need to see subjects' medical records are outside Canada, the privacy laws in these other places may be less strict than those in place in Canada
l. That study records must be kept for 25 years.
m. That subjects have a right to check health records and ask for corrections to be made.
n. That by signing the consent form they give investigator and sponsor permission to collect, use and disclose medical records as outlined in this section.

This section must also indicate whether or not the subject's primary care physician will be notified of their participation in the study and if any information about the subject will be sought.

If providing notification of participation to the subject's primary care physician is optional, the following must be included:

> We believe it is extremely important that your personal physician know, if you have one, that you are entered into a research study and may be taking a drug that could affect your health. With your permission, we will notify your personal physician that you are enrolled in this study.
>
> I consent to my primary care physician being notified of my participation in this study.
> ❑ YES ❑ NO
>
> Subject's Initials_____

If the primary care physician will be requested to provide the investigator with information regarding the subject, a consent for the release of this information (referred to in Section 34(1) of the Health Information Act) must be provided and must include the requirements outlined in Section 34(2) of the HIA. Consent for disclosure of information must be separate from consent to participate in the study but may be contained in the same form.

12. **Cost to Subjects**

This section should provide a description of any financial costs that the subject may incur as a condition of, or because of, participation in the research and whether these costs will be reimbursed. There must also be a statement that the Alberta Health Care Insurance Plan will not be billed for any visits, treatments or procedures related to the conduct of this study.

Where treatment is involved, subjects must be advised of who will be responsible for the cost of any remedies (prescription or non-prescription) that may be required to treat possible side effects.

Note: The CTC does not allow subjects to be paid for participation, however, reimbursement of out-of-pocket expenses is considered appropriate. This reimbursement should be based on a reasonable assessment of such costs and be justifiable by the principal investigator if called upon to do so by the HREBA – Clinical Trials Committee.

If subjects are to receive fees for participating in this research protocol, then a statement must be included in this section that states the nature of this reimbursement. If the amount is specifically stated in the budget then this amount must be included in the consent form document.
The Statement should include:

1. How the subject may apply to receive reimbursement
2. Maximum amount of reimbursement
3. Type of costs covered by reimbursement (i.e. travel, daycare, over the counter medicines)

This section must conclude with the following statement, where appropriate (e.g. in Phase I, II and some Phase III studies, where the prescribing indications for drug usage may be changing):

Mandatory and Verbatim:

We will assist you in ensuring that appropriate treatment for your condition continues once the study has been completed and/or the drug is no longer available through the study. There is no guarantee that the drug will be available to you at that time. If the drug has been approved for marketing, you or your health insurance may have to pay for it.

13. **Compensation for Injury**

A statement regarding possible compensation if the subject is injured as a result of the research is mandatory.

This statement must contain plain language; accurately describe the sponsor's policy; be appropriate for the study population.

Explain who will determine whether an injury is study-related. Where the policy is to have the study doctor and the sponsor (or sponsor's representative) make this determination, it must be clear how conflicts among the decision-makers are to be resolved. The Committee suggests that where there is a disagreement between the sponsor and study doctor as to whether an injury is study-related, an independent third party should make the final decision.

This section must conclude with the following statement:

Mandatory and Verbatim:

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to claim damages.

14. **Withdrawal from Study**

Information must be included regarding the provision of ongoing care for subjects who are screen failures; withdrawals for any reason; or subjects who complete the study.

If 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.

15. **Ethical Review**

If the investigator wishes to refer to the Research Ethics Review Committee's role, the following statement may be included: "The Research Ethics Review Committee has reviewed this protocol and has found it to be ethically acceptable."

16. **Signature Page**

Although the investigator can delegate the provision of information for the consent, the investigator retains ultimate legal and ethical responsibility for ensuring the subject:

1. is provided with all appropriate information (for each individual subject);
2. understands the information;
3. has had all questions adequately addressed; and
4. has the capacity to consent.

The last page of the informed consent form must end with the following:

Mandatory and Verbatim:

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 investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive. Your continued participation should be as informed as your initial consent. You will be informed in a timely manner if information becomes available that may affect your willingness to continue participating in this study. You should also feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact:

_____ _____

(Name of responsible investigator(s)) Phone number

Dr. _____ will be receiving financial compensation from the sponsors of this research protocol for your participation in this study.

If you have questions concerning your rights as a possible participant in this research, please contact the Office of the Health Research Ethics Board of Alberta – Clinical Trials Committee at: 780-423-5727 or toll-free at 1-877-423-5727.

Participant's name (please print) _____ _____
Date

Participant's signature _____

Investigator's name (please print) _____ _____
Date

Investigator's signature _____

Delegate's name (please print) _____ _____
(Optional) Date

Delegate's signature _____
(Optional)

Witness' name (please print) _____ _____
(Optional) Date

Witness' signature _____
(Optional)

A copy of this form has been given to you to keep for your records and reference.

For inclusion in pediatric studies only add:
The investigator will, as appropriate, explain the nature of the research to your child and his or her involvement in it, and will seek his or her ongoing cooperation throughout the project.

17. **Inclusion of Incompetent Subjects**
For inclusion only in studies where incompetent subjects are recruited and who may become competent at a later date, the following is required:

Mandatory and Verbatim:

SUBJECT'S ACCEPTANCE OF THIRD PARTY AUTHORIZATION

Because your illness (or injury) made it impossible for you to participate in the informed consent process, a third party authorization (e.g. family member) was obtained on your behalf. Your surrogate believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research.
The process of informed consent must be continuous throughout the research project. This means that you have the right to change your mind and, therefore, must be given opportunities to read all relevant consent materials, ask questions and then agree or disagree with the decision made by your surrogate to enroll you in this research project.

If you agree with the decision made by your surrogate to enroll you, your signature will affirm your participation in this study. If you do not agree with the decision made by your surrogate to enroll, you may withdraw now or at any other time from the study.

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 investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive. Your continued participation should be as informed as your initial consent. You will be informed in a timely manner if information becomes available that may affect your willingness to continue participating in this study. You should also feel free to ask for clarification or new information throughout your participation.

Please check the appropriate boxes to indicate your decision:

Agree with your surrogate's decision. ❑ Wish to remain in the study.

Do not agree with your surrogate's decision. ❑ Wish to withdraw from the study.

Participant's name (please print) _____ _____
Date

Participant's signature _____

Investigator's name (please print) _____ _____
Date

Investigator's signature _____

Delegate's name (please print) _____ _____
(Optional) Date

Delegate's signature _____
(Optional)

Witness' name (please print) _____ _____
(Optional) Date

Witness' signature _____
(Optional)

A copy of this form has been given to you to keep for your records and reference.