HREBA | Health Research Ethics Board of Alberta Clinical Trials Committee

HREBA – Clinical Trials Committee
1500 – 10104 103 Avenue NW
Edmonton Alberta T5J 4A7

Genetic Informed Consent Form Template

Genetic Research Studies

In genetic research there are potential health, legal, societal, and emotional issues to consider. Often, the genetic testing is a sub-study of a much larger study. It is important that the issues related to genetic testing not get lost in the body of a consent form, which describes the main portion of the study. Thus you need to use a separate consent form or an addendum to the consent form. You can find an example form in Deschenes M. Cardinal G. Knoppers BM, Glass KC (2001).

The investigator(s) 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 (i.e. you), and should be phrased in a tone that is respectful to patients (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.) You must include a footer that contains the following information: version number and date, a place for patient initials, and page numbers. This is a template, so if any item is obviously irrelevant, it need not be included. You must put this document on your letterhead.

*Note: The CTC will not review the protocol unless it meets **all** mandatory and verbatim requirements. Once you add these sections to your Genetic Informed Consent, please delete any redundant clauses.*

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

Mandatory and Verbatim:

Research Project and Title: _____

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. Purpose of the genetic research

3. Procedures

4. Voluntary Participation

5. Risks and Discomforts
   - physical, psychological, social, economic
   - Please note that the risk of individual harm arising from participating in genetic research is unclear. Inclusion of the following paragraph may offer some clarity but you should only insert it IF it reflects what you and the sponsor are actually doing. Otherwise, the paragraph could be modified, as needed, to reflect the reality:

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"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 in your medical record. Despite these efforts, however, we cannot guarantee you with 100% certainty that your genetic information could never be linked to you."

6. Benefits

7. Confidentiality
   - Sample storage (identification, location, length of storage, safeguards to protect privacy, withdrawal of sample, unlinking/anonymization procedure, sample destruction)
   - Disclosure of results to the patient, family members, third parties

8. Commercialization – a statement/explanation that the subject has given up his/her right to share in potential commercial benefits

9. Tiered consent (examples, not exhaustive)
   - Permitting coded* use of their biological materials for the proposed study only, with no further contact permitted to ask for permission to do further studies,
   - Permitting coded use of their biological materials for the proposed study only, with further contact permitted to ask for permission to do further studies,
   - Permitting coded use of their biological materials for any study relating to the condition for which the sample was originally collected, with further contact allowed to seek permission for other types of studies,
   - Permitting coded use of their biological materials for the proposed study only and anonymized use for any kind of future study,
   - Permitting only anonymized (unlinked) use of their biological materials in research,
     **coded = identifiable, traceable. Biological materials that are unidentified for research purposes but can be linked to their sources through the use of a code.*

10. 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 patient:
      a. is provided with all appropriate information (for each individual patient);
      b. understands the information;
      c. has had all questions adequately addressed; and
      d. has the capacity to consent.

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

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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)

We have given you a copy of this form 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.

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11. The following is required for inclusion only in studies where incompetent subjects are recruited and who may become competent at a later date:

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 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)

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

Witness' signature _____
(Optional)

We have given you a copy of this form to keep for your records and reference.