**Genetics Research Consent form language**

**Version Date: April 23, 2018**

This document provides template language that should appear in consent forms of studies that involve genetic research. The SickKids REB strongly recommends that study teams use this template language when creating consent forms for their study.

**How to use this document:**

If your study involves genetic research, specific genetics language should be included in different consent form sections. Use the appropriate SickKids Consent form template (interventional, observational, etc.) and insert the language contained within this document as appropriate. This template lists all possible headings (consent form sections) where genetics specific language may be necessary. Please ensure all applicable language is added to the appropriate headings.

Consent Form Headings

*GREY Highlighted text*: General instructions

**BLUE text:** Guidance and example language.

**BLACK text:** SickKids approved template wording and/or examples that should not be altered without justification.

Note that specific example language for your study may not be provided in this document. If there is no template language for your specific situation, please create your own.

Consent Form Headings

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**Genetic Research Consent Form Language**

**To be inserted into Consent Forms of studies involving genetic research**

Why is this study being done?

This study will involve genetic research. Genetic research involves isolating your genes from your sample(s). Every person has their own unique set of genes, or “genome”. Genes carry the information that helps to determine your characteristics. Genes are made up of DNA; between people, the DNA sequence of a gene can vary slightly. These differences in DNA sequence are called variants. These variants may or may not be harmful. Genes are passed down from parents to children, but sometimes genes can change between generations or because of other factors (e.g., environment). Genetic research is being done in this study [because/in order to understand…explain reason for genetic research].

What samples will be collected as part of this study?

What type of research will be done on my samples? (For biobank consent)

In this study, we will do [insert type of genetic test: whole genome sequencing/whole exome sequencing/ a detailed examination of one gene for few genes. Explain the genetic test.] To do this test, we will need to [explain sample collection]. This test will [insert the results/outcome the test will provide].

What are the risks, harms or discomforts of the study?

When you give your biological sample (blood or saliva) for genetic testing or research through a biobank or for future research, you are sharing genetic information, not only about yourself, but also about biological (blood) relatives who share your genes or DNA.

Genetic information can never be fully de-identified. Procedures have been put into place that are designed to make it very difficult for the results from genetic research to be linked to you.  However, there is a risk that information gained from genetic research could eventually be linked to you. Due to the rapid pace of technological advances in genetics, there may be a risk that the genetic information in the samples could be linked back to you. While this is very unlikely at this time, rapid scientific advances mean that re-identification may be more likely in the future. There is also a risk of unintentional release of information. The potential re- identification or unintentional release of your information could lead to loss of privacy and to possible future discrimination against you or your biological relatives. The potential future use of genetic information is unknown and therefore not all potential future risks are known.

You should be aware that genetic information cannot be protected from disclosure by court order.

The potential psychological and social risks of participating and receiving genomic information are not fully known at this time. It may be upsetting to learn about genetic causes and medically actionable findings. Because parent(s) and children can share genetic variants, the discovery of harmful variants in your genome may lead to identifying the same variants in your family members’ genome. It may be upsetting to learn that other members of your family share harmful genetic variants with you.

If family members are also participants in the study:

While the study team will take precautions to protect your confidentiality we cannot guarantee that other members of your family will respect your privacy.

What are the optional part(s) to this research study?

*Please note that depending on the nature of the study and the specific sub-study, the REB may request a separate consent form for a sub-study.*

Optional means that you may refuse to consent to this part of the study without affecting your participation in the main study. Please take your time to make your decision.

**Biobanking of blood/genetic material: (if applicable)**

Biobanking involves the collection of your biological samples or tissues to store for future research use. A biobank is a type of facility that receives, stores, processes and distributes biological [samples](http://www.biobankcentral.org/resource/glossary.php#Biomaterials) as well as data related to those samples. Biobanks provide scientists with access to the samples and study data to conduct other research. We would like to biobank your samples and genetic information for future research. We don’t know the type of studies will be done with your sample(s) in the future.

**Cell lines: (if applicable)**

Your tissue sample may be used to create a living tissue sample called a “cell line” that can be grown in the lab.  This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. Cell lines allow us to have a source of your DNA.

**We may do the following with your cell lines: (if applicable)**

* There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells, or the mixing of human and non-human cells in animal models.
* The cell lines may be used to develop treatments for a variety of diseases and conditions.

**If Induced Pluripotent Stem Cells (iPSCs) cells will be created, include the following:**

We may use the cells taken from your [specify source of cells, e.g. skin] to create a type of cell known as a stem cell (pluripotent cell).  This type of cell can be used to create different types of tissue, including [specify type of cells, e.g. cardiac, muscle, etc.] cells.  Your cells might be used in research involving genetic alteration of the cells.

**If organoids will be created, include the following:**

We may use the cells taken from your [specify source of cells, e.g. skin] to create what is called an “organoid”.  An organoid is a group of cells, grown in the lab, that are designed to mimic organ structure, such as liver or kidney, and its function.  Organoids can be used to help understand diseases and treatments for them.

Below are options for participation. Please initial next to your preference(s).

|  |
| --- |
| **Future Research of Cell Lines:** |
| Initials | Yes, you can store my cell lines for future research purposes |
| Initials | No, you cannot store my cell lines for future research purposes |

|  |
| --- |
| **Future Research of Cell Lines with for-profit companies:** |
| Initials | Yes, you can share my cell lines with for-profit commercial companies such as pharmaceutical companies. |
| Initials | No, you cannot share my cell lines for-profit commercial companies such as pharmaceutical companies. |

**Genomic Sequencing Data:**

Genomic sequencing allows us to test a person’s DNA and find variations in DNA sequence for thousands of their genes at the same time. Your genomic sequencing data is unique to you and will have important health information about you.

We would like your permission to use your de-identified and or anonymized genomic sequencing data in future research. Please initial next to your preference:

|  |
| --- |
| **Future Research of Genomic Sequencings data about me:** |
| Initials | Yes, you can use my de-identified and or anonymized whole genome sequencing data for future research purposes. |
| Initials | No, you cannot use my de-identified and or anonymized whole genome sequencing data for future research purposes. |

We would like your permission to use your de-identified and or anonymized genomic sequencing data in future research with for-profit companies like pharmaceutical companies. Please initial next to your preference:

|  |
| --- |
| **Future Research of Genomic Sequencings data about me:** |
| Initials | Yes, you can use my de-identified and or anonymized whole genome sequencing data for future research purposes with for-profit companies. |
| Initials | No, you cannot use my de-identified and or anonymized whole genome sequencing data for future research purposes with for-profit companies. |

What if the researchers discover something about me?

**Primary Findings:**

We will tell you if the genetic analysis identifies a genetic variant believed to be a cause of your condition. The study team will make appropriate referrals to discuss these findings. These findings will have to be verified in a clinical lab before the information is used for your health care and other important decisions.

**Secondary Findings:**

In genetic research, the researchers may learn something about you that they didn’t expect. For example, the researchers may [insert anticipated incidental findings e.g. find out that you have another medical condition]. This is called a secondary finding. **Secondary findings are information that was discovered unintentionally.**

Some secondary findings may be **medically actionable.** Medically actionable secondary findings mean there is a high chance of a health problem AND treatment and/or screening is available for this health problem.

If we discover medically actionable findings or if any new clinically important information about your health is obtained as a result of your participation in this study, we will let you know. We will only talk to you about those medically actionable findings that we think are likely to have a major effect on health. Seeing a medical specialist could be helpful as there might be specific health recommendations for you and/or family member(s). We will work with you, your family and your doctor(s) during this process. Because many of these variants are passed from parent to child, identification of one of these variants in you could have implications for biological (blood) family members’ (such as parent(s) and siblings) health as well. Any medically actionable secondary findings identified through this research study need to be validated in a clinical laboratory. This will be discussed with the doctor involved in your care.

**American College of Medical Genetics and Genomics (ACMG) list of variants: (if applicable – not required)**

The ACMG maintains a list of disease-causing variants associated with serious but preventable/treatable illnesses that should be reported back to the patient if found. We will actively search for these variants. If you want to know more about these variants talk to your doctor or the research team.

**Medically non-actionable findings: (If applicable)**

There are also medically non-actionable findings. These findings may indicate there is a high chance for a disease but there is currently no treatment and or screening available (e.g., Alzheimer’s or Huntington’s Disease). We will not return these findings to you; we do not return information on incidental findings that are not medically actionable. We will not place this information into your medical records at SickKids.

**Carrier status information:** **(If applicable)**

Sometimes, secondary findings may reveal information about carrier status. Some people are “carriers” of a genetic disorder; this means they have the gene that causes a disorder but they are not affected by the disorder. Children of carriers may be at an increased risk to have that specific genetic disorder.

Since knowledge of carrier status can be important for future family planning, if we discover a secondary finding about your carrier status of a serious disorder, we can talk with you about that finding. You can choose if you want to receive carrier status information.

If applicable: We will ask you again about your choices if we have test results to tell you.

Please initial next to your preference about receiving carrier status information:

|  |  |
| --- | --- |
| Initials | Yes, I want to be informed if I am a carrier for a major hereditary condition. We will ask you to tell us which groups of disorders you wish to learn about and which you do not.  |
| Initials | No, I do not want to be informed if I am a carrier for major hereditary condition. |

How will my privacy be protected?

**If applicable: Sharing of your samples and data is a mandatory part of this research study:**

Your de-identified samples [insert sample types] and de-identified/anonymized whole genome sequencing data will be shared with [insert who]. This is a mandatory part of the study, which means it is required for the research study. If you do not consent to the mandatory parts of the study, you cannot be part of this study.

**If applicable: Research data will be sent to central repositories:**

Your genetic data will be sent to and stored in a central repository (storage place), which are sometimes called data banks. These data banks will store your genetic information indefinitely and allow other researchers to access your data for more research studies. [insert options if optional]

Include the following language for NIH funded Genetics study:

All NIH funded genetic such as this research study, requires anonymized genetic data to be kept at the National Human Genome Research Institute. Your anonymized genetic data will be sent and stored at National Human Genome Research Institute, this is not optional.

Your genetic data will be publically available to anyone without restriction. This is known as **open access**. Although only experts will know how to interpret this information, there is a chance that somebody could connect you with the information from the study of the sample you give.

Your genetic data will be available to anyone who requests access to these data banks.

Your DNA and health information will be stored and shared with other researchers at universities, hospitals or government agencies around the world, with appropriate reviews and agreements in place. These samples and information will be available for any research purposes such as [insert example of research question/topic], development of new scientific methods, research into genetic links to [insert detail, e.g. behavioural traits.