

RESEARCH CONSENT FORM



Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title: Biorepository

Principal Investigator: Biorepository

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

Summary of Important Information

We are asking you to participate in this research study. Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not impact the clinical care you receive at Boston Children's Hospital (BCH).

In this research study we will collect tissue samples and store them in a biorepository (sample bank). Researchers can use the stored samples for future research related to your condition as well as many other diseases or conditions. Your samples may be shared with other researchers at BCH as well as researchers at other hospitals, universities, companies, and businesses. The repository will remove all information that could identify you from the samples before sharing them with other researchers.

It is important to consider reasons why you would or would not want to participate in this research.

If you decide to provide samples for this biorepository, you will be asked to provide one or more of the following types of samples: blood, stool, saliva, intestinal biopsies, surgical tissue, oral swabs, nail clippings, hair, urine and/or a skin biopsy during clinical visits and procedures. You will also be asked about your medical history or we can obtain this information from your medical record.

Researcher may use your samples for future research studies. They may create a "cell line" in the laboratory. A cell line can continue to grow and make more cells indefinitely. Your samples may also be used to create a type of cell known as pluripotent stem cell. Stem cells can be used to create other types of cells and tissues. Whole

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genome or whole exome analysis may be performed on your samples to study your genes and the role they play in health and disease.

The most important potential risks to know about are bleeding and/or infection from blood draws and intestinal and/or skin biopsy samples. Some people involved in genetic studies feel anxious about the possibility of carrying an altered gene that places them at risk or may be passed on to children. There might be social and economic disadvantages associated with genetic information. Researchers who receive samples from the biorepository sign an agreement to not use the samples and/or information to try and identify you. Generally, tests done for research purposes are not meant to provide clinical information. Research findings will generally not be provided to you. The collection of stool, oral swabs, hair, nails, and urine are unlikely to result in adverse events. For a complete description of risks, refer to the risk section on the consent form.

You will not benefit directly from taking part in this study.

The research funds will cover cost associated with the study. We may bill your health insurer for routine items and services you would receive even if you did not take part in this research. You will not receive any remuneration for your participation in this study.