**Introduction**

Biospecimen testing language - If your study includes any type of genomic sequencing, creation of cell lines, or creation of pluripotent stem cells please include the relevant sections below in your consent form.

**Consent language for research involving biospecimens**

***<<If any type of genomic sequencing will be done, include the following:*>>**

**This research includes sequencing of some, or all of your genes.**

**<<*Include the following sentence if whole genome sequencing will be done:>>* Sequencing all of your genes is called whole genome sequencing.**

**Genes are found in every cell in your body and they provide instructions to your body for how to grow and live. Genes have information that is unique to you and your family. It is now possible to figure out the makeup of every gene in your body by a process called sequencing. Since your genes are unique, it may be possible to identify you or other relatives by gene sequencing, even without your name or personal information. It is also possible that gene sequencing can identify genetic changes that cause, or put you at risk, for medical conditions.**

***<<If cell lines may be derived from tissue samples, include the following:* >>**

Your tissue sample may be used to make a living tissue sample (called a “cell line”) that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. Each cell contains your complete DNA.

***What you should know about the cell lines that will be derived in the course of this study?***

* There is the possibility that your cells or the derived 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 shared with researchers both inside and outside of Johns Hopkins, including commercial partners.
* The cell lines may be used to develop treatments for a variety of diseases and conditions.

***<<If iPS cells will be derived, include the following:* >>**

We may use the cells taken from your ***<<specify source of cells, e.g. skin>>*** to make a “pluripotent” cell. “Pluripotent” means that the cells can turn into any kind of cell, such as brain, heart, or kidney cells. For this reason, pluripotent stem cells can be used to study, and maybe one day help treat, diseases or injuries that have caused patients’ cells to die or become damaged.

Your ***<<specify source of cells, e.g. skin>>*** cells will be changed (“or induced”) into induced pluripotent stem cells (iPS cells). iPS cells can grow and divide outside of the body for many years, in what is called a “stem cell line.” Your iPS cell lines may also be used in future studies by other researchers at Johns Hopkins or other institutions outside of Johns Hopkins.

Your cells might be used in research involving genetic alteration of the cells.

***<<If organoids may be formed, include the following:* >>**

We may use the cells taken from your ***<<specify source of cells, e.g. skin>>*** to make what is sometimes called an “organoid”. An organoid is an organized cluster of cells, grown in the lab, which mimic parts of an organ’s structure and function. Organoids can be used to help understand diseases and treatments for them.

***<<If eggs/sperm will be donated for research, including those collected during the course of fertility treatment and in excess of clinical need, include the following: >>***

Researchers will use your eggs/sperm to make embryos for this research. None of the eggs/sperm you provide for this research study will be used to produce a baby or a pregnancy.

There is no guarantee that the researchers will be able to make embryos using your eggs/sperm. Researchers will discard any eggs/sperm that are not used in this research study and store or destroy the embryos made.

***<<If whole genome sequencing will be performed on fertilized eggs or cell lines derived from them, include the following: >>***

Researchers will perform whole genome sequencing (WGS) on the resulting embryos or the cell lines made from them. WGS looks for changes (mutations) in the DNA of the cells. Because the embryos will be partially genetically matched to you, this may reveal genetic information about you and your family. Efforts will be made to protect your privacy, which will be explained in the section “How will your privacy be maintained and how will the confidentiality of your data be protected?”.

Genetic testing may show information to researchers that may be important for your health. There ***<<(is/is not)>>*** a plan in place to share these results with you.

***<<If embryos made for fertility purposes and in excess of clinical need or made from donated eggs/sperm will be donated for research, include the following: >>***

Embryonic stem cells are obtained from embryos during their early development (about the 5th day after fertilization). These stem cells have the ability to turn into any kind of human cell, such as liver cells, heart cells, or nerve cells. For this reason, embryonic stem cells can be used to study, and maybe one day help treat, diseases or injuries that have caused patients’ cells to die or become damaged. The study doctor will attempt to make new human embryonic stem cells for research from embryos that are ***<<(not/no longer)>>*** required for reproductive purposes. The process of trying to make human embryonic stem cells will result in the embryo being destroyed.

None of the embryos that are donated to this research study will be used to produce a baby or a pregnancy.

Your agreement to donate embryos does not guarantee that the embryos will actually be used for this research. Researchers will routinely discard any donated embryos that are not used in this research.

***<<If this is a gene editing protocol, explain in what ways the embryos will be modified. >>***

*Please reference* [*Appendix 5 of the ISSCR Guidelines*](https://www.isscr.org/guidelines/appendices) *for “Considerations for Genome Editing Research”*

***<<Describe how the human biological materials will or might involve: (i) the introduction of the cells into humans; (ii) the introduction of the cells into the central nervous system of non-human primates; (iii) the introduction of the cells into non-human animals and whether there is a significant possibility of the cells giving rise to gametes; (iv) the derivation of gametes or embryos******; (v) formation of embryo models derived from such cells; or (vi) in vitro culture of chimeric embryos (hPSCs introduced into non-human embryos).* >>**

***<<Describe (i) whether the donated material will be coded or de-identified prior to research use; (ii) if the donors’ identities are retained (even if coded), whether donors can elect to be contacted to receive information through studies of the cell lines; (iii) that restricted and/or directed donation (e.g., to individuals or groups) are not permitted.* >>**

\*For additional guidance and sample informed consent documents for procurement of human biomaterials for stem cell research, see the [ISSCR Guidelines for Stem Cell Research and Clinical Translation 2021 Update](https://www.isscr.org/guidelines/#toc).