Appendix 2: Example Consent Language (NIMH Repository and Genomic Resource-Compliant)

*Instructions to Investigators: Text in [brackets/yellow] should be customized to the specific purpose of the study; remove instructions upon completion. Text in* ***red*** *is important for compliance with submission of samples to the NIMH Repository and Genomics Resource (NRGR) and, while text does not need to be identical, the intent of centralized banking and wide sharing (non-profit or for-profit) should be retained in any final consent language used in an NIMH funded study, per NIH and NIMH sharing policies (*[*NOT-OD-14-*](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html%23sthash.4niFgE6O.dpuf)[*124,*](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html%23sthash.4niFgE6O.dpuf) [*NOT-MH-19-033*](http://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-033.html), [*NOT*](http://grants.nih.gov/grants/guide/notice-files/NOT-MH-21-265.html)*-MH-21-265,* <http://grants.nih.gov/grants/sharing.htm>). *Please make sure to also delete these instructions from the actual consent form.*

# INTRODUCTION

We invite you to take part in a research study at [*institution name*]. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at [*institution name*] or with family, friends, or your personal physician or other health professional. If you are signing this consent form as the parent or guardian of a minor who will participate, "you" in this consent form refers to your child. Depending upon the requirements of your institution, age-appropriate language for separate child assent documents may also be required. When your child turns 18 years old, she or he will be able to make decisions regarding ongoing participation in this research for herself or himself.

# WHY IS THIS STUDY BEING DONE?

*Instructions to investigator:* *If there is a preliminary plan to use samples now for a specific project, state the purpose of that project first, in addition to the following preferred generic language.*]

The National Institute of Mental Health (NIMH) would like to help scientists learn more the process of human diseases such as mental illnesses. Health information, cells and genetic material, or DNA, from persons who appear to have [*disorder X - try to make the language broad, e.g., ‘psychiatric disorder’ or even ‘medical conditions’*] as well as unaffected family members and healthy control subjects are useful for research. NIMH will store the health information, cells and DNA in a central location called a ‘repository’ or ‘bank’. NIMH will make these available to other scientists who want to do research. Any use of these materials would first need to be reviewed and approved by NIMH. We are contacting you to see if you would be willing to contribute your health information and a blood specimen to the repository for use in future research.

# WHY ARE MY CELLS AND DNA IMPORTANT FOR RESEARCH?

[*Instructions to investigators: this section text can vary but should inform subjects if you will be storing Cryo-preserved lymphocytes or other materials that can be reprogrammed that these cells may be used to generate LCLs, iPS or other reprogrammed cells for use in future genetic studies, drug development, etc.*]

Scientists can learn a lot from studying cells, DNA and health information from people with and without different medical conditions. These are critical for answering many important research questions, such as what causes the medical conditions and potential treatments for those conditions. It is important for scientists to be able to keep cells growing for future use, so that new experiments can be compared with experiments done before. To do this, scientists can introduce your cells to certain factors that turn them into other kinds of cells (a process called reprogramming) that can be kept alive, grown and stored indefinitely in the laboratory and in cell banks/repositories. There are different kinds of reprogrammed or ‘induced’ cells. Most commonly, a factor can be introduced to blood cells to make something called a lymphoblastoid cell line (LCL), which can be grown for a long time and be used to isolate DNA to study different genes. Your cells can also be reprogrammed to ‘pluripotent’ stem cells, which can become many other different kinds of cell types, such as muscle, nerve, and liver cells that are affected in a particular disease. Induced pluripotent stem cells (iPS cells) can be derived from many different kinds of donated samples, such as skin, blood, or hair. This is different from embryonic stem cells, which are also pluripotent but can only be derived from embryos. Sometimes cells can be reprogrammed directly to one specific type of cell, such as an induced neuronal cell (iN cell), which completely bypasses the pluripotent stage.

Cells and DNA obtained from you may be used in different types of research, for example:

* Looking at the DNA sequence/genetic code in your cells
* Altering some of the DNA within these cells
* Testing in animals to model diseases and treatments
* Developing and testing new drugs and treatments
* Techniques and uses that we cannot predict at this time

# HOW WILL MY CELLS, DNA AND INFORMATION BE STORED AND SHARED?

[*Instructions to investigators: this section text can vary but should inform subjects that cells will be stored indefinitely at a central repository and will be distributed as authorized by NIMH.*]

Cells, DNA and health information collected from you will be stored at the repository as a resource. This will include information about your medical history, family structure, age, sex, and medical symptoms. This may also include genetic information derived from the analysis of your DNA. Your cells, DNA and this information will be stored in a coded way to keep your personal identity anonymous, which means that it cannot be traced back to you or your family. You should know that it is very likely that these cells will be stored for many years, as they can be grown indefinitely. Any request for these materials from the repository would first need to be reviewed and approved by NIMH. The NIMH will provide this health information and biomaterials to qualified scientists at universities, private companies, and other institutions around the world for use in research. These scientists may not be currently working on this research right now. Society and medical research will benefit from sharing these cells and information among many researchers and institutions.

[*Include if applicable:* Information about your DNA as well as other health information will be put into one or more other publicly accessible databases (such as dbGaP or NDA) along with information from the other research participants. This information will be available to other researchers who have received approval from an NIH Data Access Committee.]

# *Instructions to investigators:* The above consent language is provided to assist in the development of consents for biomaterial submissions only. For consent language examples covering the collection of more detailed phenotypic and/or genetic information, please refer to other available NIH and NIMH guidance (<https://www.genome.gov/about-nhgri/Policies-Guidance/Genomic-Data-Sharing/informed-consent-for-GDS>; <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent>; https://nda.nih.gov/contribute/contribute-data.html#infocon) and modify and expand this section as appropriate.

# WHAT DOES MY PARTICIPATION IN THIS STUDY INVOLVE?

This study involves obtaining a sample from you, as well as collecting information on your medical history from you and your medical records. The samples will be studied directly or reprogrammed prior to further study.

# HOW WILL I GIVE SAMPLES FOR THIS STUDY?

[*Instructions to investigators: Include and/or check options appropriate for study and instruct the participant to initial next to the box(es) checked to indicate their acknowledgement. NIMH genetic studies will typically involve blood draws and iPS cell studies will likely involve skin punches.*]

With this consent form, you are asked to provide blood, skin biopsies, or hair samples as indicated in the checked boxes below. Please initial on the line to indicate that you agree to the procedure.

* Blood Donation: Blood will be drawn through a needle in your arm. We will draw no more than [ ] teaspoons (or [ ] cups) of blood at one time. [note: protocols vary with regard to volume; confirm amount with protocol].
* Skin Biopsy: A small area of skin will be washed with iodine and alcohol. We will inject a local anesthetic to numb the area. Then we will remove a 1/4-inch piece of skin with a biopsy tool. After the biopsy, the site will be covered by a dressing. You will receive instructions on how to care for area. [include if applicable]
* Hair Sample: We will remove a few hairs from your head at the root by pulling sharply. [include if applicable]
* [*Other, if applicable:* ]

[*Include if applicable; will vary by institution/study*: If you are having a biopsy or other surgery, we will ask for your permission to use a part of the blood or tissue samples being removed to create iPS cells for research. We will only use this blood or tissue for research if it is not needed for your care or treatment.]

# COLLECTION OF MEDICAL INFORMATION

# *Instructions to investigators:* The below consent language is provided to assist in the development of consents for biomaterial submissions only. For consent language examples covering the collection of more detailed phenotypic and/or genetic information, please refer to other available NIH and NIMH guidance (<https://www.genome.gov/about-nhgri/Policies-Guidance/Genomic-Data-Sharing/informed-consent-for-GDS>; <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent>; https://nda.nih.gov/contribute/contribute-data.html#infocon) and modify and expand this section as appropriate.

We will interview you about your medical history. We will review your medical records. We will ask about your family’s racial and ethnic background and where they came from. We will provide anonymized medical information about you, such as your sex, age at the time of sample donation, symptoms and diagnosis to the repository and to other researchers along with cells and samples.

# HOW MANY VISITS ARE REQUIRED?

Obtaining these samples usually requires one outpatient visit. We will obtain the samples during a visit scheduled for another reason whenever possible.

# WILL I BE RE-CONTACTED BY THE RESEARCHERS?

We may want to contact you in the future.

* We may contact you to obtain additional samples or to request updates on your health. If we ask, keep in mind you are under no obligation to donate additional samples or provide additional information.
* At the present time, research on your cells is not likely to provide any information on your personal health. In rare cases, it may be possible that researchers could identify new information that they believe is urgently related to your health. In this very unlikely event, we may contact you to give you a choice about whether or not to learn the information.
* We may contact you if we discover that the cells made from your sample could be useful for research that is not covered by this consent form, and that we want to get your permission to do. This might include research on sperm and egg cells, reproduction, and infertility. It might include some research using new techniques or for new purposes that we simply cannot predict at this time.
* We may send periodic notifications about the types of research being done with your samples, and about the scientific and medical progress that has been made.
* Please remember to update [*institution name*] or the research team with your contact information if it changes. Otherwise, they may not be able to find you.
* You will never be contacted directly by a researcher at another institution who has received your samples or medical information. Only our research team may re-contact you.

Remember that you can re-contact the research team at any time, now or in the future, and ask any questions you have.

With this consent form, you are asked to agree to be re-contacted by the researchers in the future for a variety of reasons. However, if you do not wish to be re-contacted, please indicate your preference below:

* Check and initial here if you DO NOT agree to be re-contacted in the future by the research team for any reason.

# ARE THERE LIMITS ON HOW MY CELLS WILL BE USED?

All research on your cells must comply with all applicable laws and policies. The reprogrammed cells generated from your tissue samples will never be used to clone (known as "reproductive cloning") or to otherwise create an entire human being. Research with human cells may involve transplanting or testing them with animals, within the limits imposed by laws and regulations.

The repository being used to store samples from this study is not the same as for storing umbilical cord blood or other stem cell storage services. You will not be able to retrieve your donated samples or cells from the researchers for personal use.

# CAN I PLACE OTHER LIMITS ON THE USE OF MY CELLS?

By agreeing to be in this study, you agree to the terms and limitations described in this consent form. We are not able to honor personal restrictions. For example, you may not place restrictions on who may or may not be treated with your cells or resulting medical products. You also may not place limits on the types of research that may be conducted with your cells. If you have questions about these terms, please feel free to ask us.

# WHAT ARE THE RISKS OF THE STUDY?

* Blood Donation: You may have some discomfort and bruising at the site of needle entry. There is a very small risk of fainting. Infection in the area of the needle insertion is rare.
* Skin Biopsy: There is usually not much pain at the biopsy site. Bleeding and infection are rare. Biopsy wounds usually heal with a very small, nearly unnoticeable scar, but there may be a

raised scar or visible lump. We will take the biopsy from a place on your body that is not easily seen.

* Emotional Risks of Research on Your Sample: Emotional and psychological risks are also possible with the donation of samples for reprogrammed cells. We may publish results of this research study in the medical literature. When we publish results, we do not use names or personally identifiable information. However, it is possible that you or family members could be recognized because of the rarity of your disease or based on your DNA sequence. It would be very difficult to identify any individual based on such published data, but it is a potential risk. While there is a small risk that your personal information could be released inadvertently, risk could arise if your genetic information is released and misused. For example, if research results suggested a serious problem with your health, someone could try to use this information to make it harder for you to get or keep a job or insurance. There are laws in place that make it illegal for an employer or health insurance company to discriminate against an individual based on their genetic information. More information about this is available through The Genetic Information Nondiscrimination Act (GINA) of 2008 that protects Americans from discrimination based on their genetic information in both health insurance and employment (https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination).
* Group Risks: Information on your ethnic and geographic background will be included with other medical information about you in the database as part of the repository. Research on the samples you provide may lead to results which are upsetting to you and others in your group, which you may disagree with, or which could be stigmatizing for your community.

# HOW WILL MY IDENTITY BE PROTECTED?

Your person information will not be given to the repository or to anyone else. We will take the following steps to ensure anonymity. Your name, birth date, and other personally-identifying information will be removed from your data and samples. They will be linked to your sample only by code number. The code key for the samples will be stored in password-protected database under control of the [*institution name*] investigators. Medical information, samples, and cells that are shared with others will be coded and will not include identifying information (name, address, telephone number, or personal identification number). Only the original investigators will be able to trace your samples and information to you. [*Instructions to investigators: If you are using GUIDs and submitting data to NDA, please refer to the plain language description of GUID operation provided by NDA.]*

The results from the analysis of your DNA will not be released or shared in any way with your relatives, with insurance companies, or any third party not involved in research. The researchers have obtained a Certificate of Confidentiality from the Federal Government which will help them protect your privacy, unless you consent in writing to the release of research information. However, if they learn that you or someone else is in serious danger of harm, they may make disclosures to protect you and/or the other persons. Information collected in this study may be reviewed by authorized individuals from the Food and Drug Administration (FDA), the National Institutes of Health (NIH), or other agencies for the purpose of making sure that proper systems, procedures, and regulations are being followed.

#

# ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

[*Instructions to investigators: this section text can vary but should inform subjects that they are unlikely to directly benefit from the study.*]

Although you personally will not receive any direct benefit from this study, individuals who might develop [*medical condition*] in the future, their family members, and future generations may benefit if we can determine what causes such disorders or predict responses to different medications. We do not expect to discover any information of direct clinical relevance during the next few years. Because the meaning of research results are not usually fully understood, these results generally are not made available to subjects or their doctors. If later on, diagnostic tests or new ways to treat your condition are discovered, this information should be obtained from properly licensed clinical labs or clinics and will not come from the research team.

# WHAT ARE MY OTHER OPTIONS?

Taking part in research is entirely voluntary. You do not have to participate in this study if you do not want to do so. Your decision about whether or not to participate will in no way affect your present or future medical care at [*related hospital/clinical center, as applicable*], your participation in other research studies at the [*institution name*], or your relationship with the research team.

# WHAT IF I CHANGE MY MIND?

[*Instructions to investigators: this section text can vary but should inform subjects that the NIMH repository will destroy our banked samples and records if consent is withdraw but cannot retrieve samples/data that have already been distributed to the research community.*]

You have the right to leave the study at any time without giving any reason, and without penalty. If you wish to leave the study, contact [*PI’s name*]. We will use your anonymous code number to tell the repository to remove your health information, cells and genetic material. The repository can use this code number to remove your health information, cells and genetic material, without ever knowing your name or other personal information. Your cells and genetic material will be destroyed and no new research can be initiated with your samples. However, research which has already been initiated with the samples cannot be stopped, and data collected from such research and deposited in databases cannot be purged.

# WILL I RECEIVE PAYMENT FOR BEING IN THIS STUDY?

[*Instructions to investigators: Indicate whether or not participants will be paid for their participation in this study. For example:* "You will not be paid for taking part in this study" or “You will receive a modest payment of $ for your participation”. *Also include the following text to indicate that materials and de- identified data may be used by for-profit entities*.]

Your cells, DNA and health information will be used by research scientists, including those from private companies. Such companies have a financial interest in using information found from studying patient samples. This includes developing commercial products that may later help others by improving diagnosis and treatment of various medical problems. These companies may patent products or sell discoveries based on this research. Your cells or derivatives from your cells may be sold or used to make commercial products. There are no plans to provide any compensation to you or your heirs should this occur.

# PROBLEMS OR QUESTIONS

If you have any questions about the study, you may contact [*PI’s name*] at [*PI's telephone number*]. If you have any questions about your rights as a research subject, you may contact [*chairperson of IRB committee*] of the IRB Committee on Research Involving Human Subjects, at [*PI's sponsoring institution*]. You will get a copy of this consent form to keep. If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study. If you are a minor, we must have your parent or legal guardian sign on your behalf.

**SIGNATURES [*per institutional format*]**