



**OFFICE OF RESEARCH SUBJECT PROTECTION (ORSP)**

**SAMPLE CONSENT LANGUAGE BY TOPIC**

*Updated 9/29/16*

*NOTE: Below are examples of consent form language addressing a variety of topics. They are samples from actual consent forms, and therefore institution and study-specific information has been redacted. They are provided for purposes of illustration only; please adapt as needed for your particular study. In general, a consent form's literacy level should be in the 6-8<sup>th</sup> grade range. If you become aware of other examples that might be useful to include in this list, please contact the Broad Institute's Office of Research Subject Protection at [orsp@broadinstitute.org](mailto:orsp@broadinstitute.org).*

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## Cell Lines

1. Your tissue sample may be used to create 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.
2. Your tissues may be stored in ways that allow the cells to grow and multiply. These may give rise to what is called a cell line. Cell lines can be used for multiple future studies, and these cells may be kept alive for many years.

## Data Sharing: Inter-institutional, dbGaP, and Publications

1. Your [tissues/data] may also be shared with collaborators at other institutions in a confidential manner, without the use of your name or any information that directly reveals your identity.
2. Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease.
3. We may share your sample and/or research data with outside researchers who have an interest in the genetic cause(s) of [x]. In this case, your sample and/or research data would be released with the unique code only and not with your name or other identifying information. If at any time you would like to have your sample removed from storage in our laboratory, please let us know and it will be destroyed.
4. In order to allow researchers to share results, the National Institutes of Health (NIH) and other organizations have developed special data/information banks that collect and analyze DNA samples and results of whole genome studies. If provided to them, these central banks would store your genetic information and sample(s) and give them to other researchers to do more studies. These databases will be accessible by the Internet. Anonymous information from the analyses may be put in a completely public database, available to anyone on the Internet. Your coded medical information and information from more detailed analyses of your coded samples may be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from a Data Access Committee. *Please note that traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into either the public or controlled-access databases for this project.* We do not think there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. There are many safeguards in place to protect your information and sample(s) while they are stored in these banks and used for research.
5. The stored [x] may be used for any scientific purposes involving this or any other project.
6. By signing this consent form you agree to allow your genetic and clinical information to be released into one or more scientific databases. This will help advance medicine and medical research by allowing other researchers to use this information to help solve questions about disease and to compare results from many studies. These databases may be maintained by medical, academic, government, or private entities. If you agree, only your genetic information and some basic information about your medical history will be released into these databases. Since certain genetic information is unique to you, there is a small chance that someone could trace the information back to you. The risk of this occurring is presently very small, but may grow in the future as technology advances. Medical researchers who access your genetic information have a professional obligation to protect your privacy and maintain your confidentiality.

7. We will send your study information and/or samples to research collaborators at [collaborating site]. We will label all your study materials with a code instead of your name. The key to the code connects your name to your study information and samples. The study doctor will keep the key to the code here at [x] and will not share it with our research collaborators. No one outside of [x] will know which study information or samples are yours.
8. Data and DNA will be distributed to qualified researchers interested in the genetics of [x]. The researchers will be given the DNA without any potentially identifying information. Information gained from research on your DNA may be used for the development of diagnostic procedures or new treatments for major diseases. Your DNA will not be sold to any person, institution, or company for financial gain or commercial profit. However, neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide.
9. Your specimens and health information will be available to researchers at [x] who have approval from their Institutional Review Board to use your samples and health information for research that is conducted under this study. In addition, if you agree, we will share your results with central data repositories (such as the National Institutes of Health). Your name or other directly identifiable information would not be provided to these central repositories.
10. Rapid progress in understanding and treating [x] will occur when some of the molecular information derived from your tissues and blood can be shared with other researchers. In particular, the National Institutes of Health (NIH) and other organizations have developed special data (information) repositories that analyze data and collect the results of certain types of genetic studies. These central banks will store your genetic information and samples and give them to other researchers to do more studies. Therefore, we are also asking your permission to share your results with these special banks. Your information will be sent with only a code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research. We do not think that there will be further risks to your privacy and confidentiality by sharing this information with these banks. However, we cannot predict how genetic information will be used in the future.
11. The results of this research study may be published. You will not be identified in publications without your permission.

### **GDS Policy- Sample Consent Language**

If you will need to deposit data into dbGaP (either because of funding or certain publisher requirements) AND your samples were collected after January 25, 2015, your consent form is required to reference future use, broad sharing, and whether individual level data will be shared through an unrestricted or controlled access repository.

1. Sharing and Future use  
Your samples, genomic data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.
2. Repository language  
Your individual genomic data and health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify

you. Researchers approved to access information in the database will agree not to attempt to identify you.

More information can be found on the genome.gov website: <http://www.genome.gov/27559024>

### **Definitions Related to Genes and Genetic Research**

1. We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to [x].
2. Body tissues are made up of cells. Cells contain DNA, which is your unique genetic material that carries the instructions for your body's development and function. Many diseases can result from changes in a person's genetic material that causes cells to not work properly. Currently, researchers and doctors know some of the genetic changes that can cause disease, but they do not know all of the genetic changes that can cause disease. The [x] is designed to identify [y]. Therefore, we would like to study the genetic material from you as part of the [x]. We will compare the DNA from people with certain diseases to the DNA from people without those diseases to find the differences that exist.
3. The samples we will analyze are comprised of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine characteristics such as hair and eye color. Genes are composed of DNA letters that spell out these instructions. DNA is the material that makes up your genes. We plan to do research on how genes influence the behavior of [x]. This will be done by performing analyses on your tissues, blood, or other body fluids such as saliva or urine.
4. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are composed of DNA letters that spell out these instructions. Studies of the DNA molecules that make up the genes are called "molecular" analyses. Molecular analyses are ways of reading the DNA letters to identify errors in genes that may contribute to an increased risk of [x] or to the behavior of [y]. Some changes in genes occur only in [z]. Others occur in the genes that are passed from parent to child. This research study will examine both kinds of genes.
5. We are a group of doctors and scientists from [x] studying the possible genetic causes of [y]. This means that we want to study genes that can help us understand the cause of [y]. Genes are passed down or "inherited" from parents to their children. They determine things such as our hair color, blood type, height and how our bodies grow and develop. Genes can also determine whether someone develops certain medical conditions.
6. Researchers will be looking for biomarkers. Biomarkers are tiny molecules including those called protein, ribonucleic acid (RNA), and deoxyribonucleic acid (DNA). Genes are made from DNA and are the basic "instruction book" for people. Everyone's genes are a little different. These differences explain some of the variation between people, like eye color, hair color, and blood types. They also partly explain why some people, but not others get certain diseases. Information about these differences among people can help researchers discover new tools to diagnose and treat disease.
7. We plan to do genetic research on the DNA in your tissue sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.
8. The samples we will analyze are comprised of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine characteristics

such as hair and eye color. Genes are composed of DNA letters that spell out these instructions. DNA is the material that makes up your genes. We plan to do research on how genes influence [x].

9. Genes are the packets of information in the cells of our bodies that parents pass along to their children. Genes determine traits such as eye color, height, and blood type. Previous research has shown that certain changes in genes can increase a person's risk of developing common diseases like cancer, heart disease, diabetes, and Alzheimer's disease. How changes in genes affect the risk of having these diseases, however, is poorly understood.

### Discarded Tissue

1. If your doctors have plans to remove tissue from you (e.g. surgery or biopsy) we are asking your permission to retrieve a sample of the tissue, in order to establish a specimen bank for [x] research. This is tissue that would otherwise be discarded and in no way impacts on your doctors' ability to diagnose or manage your disease. However, there is no guarantee that we will bank your tissue since all of your tissue may be required by your doctor to make a diagnosis or the specimen may not be acceptable for tissue banking purposes. Agreeing to provide tissue is completely voluntary, and you may decline to do this but participate in the rest of the study.
2. There are risks to taking part in any research study. While on study, you are at minimal risk for side effects resulting from the study itself. You are not being asked to undergo a separate procedure for this tissue collection. The pathology department at the hospital where you had your surgery will be asked to share some of the tissue that was or will be removed during surgery. If you are having your [x] removed, this may be tissue that would otherwise be discarded, or tissue that is usually saved by the pathologist for further follow-up information if needed. We will use a small part of this tissue, and will return the remainder to the hospital from which it was obtained. This does not entail any additional risks to you. We will look for genetic changes within your [x]. Because some of these genetic tests are investigational, it is unclear how the results will affect your treatment. These tests could provide information to your doctors now or in the future that may have an impact on identifying conventional approved treatment.
3. If you have [x] tissue removed as part of your clinical care, we would like to obtain a piece of this tissue. This tissue would be stored in the specimen bank of the repository for use in [y] research. If you are ever scheduled to undergo surgery to remove [x] tissue, we will ask the pathology department at the hospital where you are scheduled for surgery to provide us with a piece of the tissue that is removed. This is tissue that would otherwise be discarded. Allowing us to obtain a piece of this tissue for the repository will not affect your doctor's ability to diagnose or manage your disease.
4. No additional surgical procedures are required to obtain tissue samples for this study since only left-over tissues will be used for this study. Researchers do not influence or designate techniques for removal of tissues or collection of biomaterials.

5. This will be done by performing analyses on your tissues (obtained from biopsies or surgery), blood, or other body fluids such as saliva or urine. Importantly, we will use tissue specimens that have already been collected and stored as part of your clinical care. Analyses will be performed on material only after all necessary clinical tests have been performed. No additional procedures will be required.

### **Genetic Research Risks (Primarily Related to Privacy)**

1. One of the potential risks of this study is to your privacy. We take careful measures to protect your privacy and confidentiality. Methods used to strictly preserve your confidentiality include: using the special ID code, passwords, and restricting access to research databases. However, in spite of all of the safety measures that we use, we cannot guarantee that your identity will never become known. Although the risk is extremely low, it is possible that knowledge of your genetic information could lead to problems with insurance or employment. Governmental protections combined with the privacy measures followed by our research team as part of this study ensure that the chance that this study could lead to problems with insurance or employment is extremely low.
2. A possible risk is the loss of confidentiality about your medical information. A related possible risk is disclosure of genetic results where insurance or employment could be discriminatory. We will take steps to protect your privacy. These include:
  - DNA samples will not be labeled with your name or other easily identified numbers like social security numbers.
  - Your samples will be coded (assigned a unique study number) which will allow the researchers to link your sample to the other information that you provide through questionnaires or other study activities.
  - The key to the code linking you to your DNA samples will be maintained in confidential files with standard security precautions. The key is used only to connect other information you provide to your DNA sample. The key to the code will never leave [Insert Study Name/Institution Name].
  - Some of the tests performed on your samples may be done by affiliated researchers or laboratories outside of [Insert Institution Name], but they will never know who you are nor have access to the code linking samples to you.
3. You should also be aware that there might be social and economic disadvantages, which can be associated with the gathering of genetic information. You should understand that our testing might find an inherited defective gene, which puts you/your child at risk for a genetic disorder in the future. Genetic information divulged to the wrong source, could affect you and your family (if an insurance company or employer acquired this genetic information). However, results from this research study will not be available to anyone and will not be placed in your medical record. Thus, it is extremely unlikely that an insurance company or employer would ever learn of such results.
4. There is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. If you do not share information about

taking part in this study, you will reduce this risk. We will not place information about the study or the results of genetic tests in your medical record.

5. The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. However, we will take the following steps to protect your privacy:
  - We will store your samples only with a code.
  - The tissue bank database will use the code to connect your sample to certain limited health information about you.
  - The tissue bank database will be password protected. Only the tissue bank staff will know the password.
  - Information that could be used to identify you will only be shared with researchers within [x] who have approval of the [x] ethics board. The ethics board is a group that independently reviews and watches over all research studies involving people at [x]. The board follows state and federal laws and codes of ethics to make sure that the rights and welfare of people taking part in research studies are protected.
  - Information that likely could be used to identify you will never be shared with researchers outside [x].
  
6. Learning that your DNA contains a variant that is associated with an increased risk of a disease could cause depression, anxiety, anger, or fear of future events. This information could affect your relationship with family members. Some insurance companies might consider an inherited, disease-associated variant to be a “pre-existing condition” and you might be obligated to disclose this information prior to obtaining new health or life insurance. We think that the chance of this happening is small. A national law, the Genetic Information Non-Discrimination Act (GINA), provides protection against genetic discrimination in by health insurers and employers. If you already have or have had [x], any new genetic testing is unlikely to make insurers view your risk of underwriting as being any worse than it already is. Furthermore, research genetic tests such as the ones being performed in this protocol are not placed into your medical record. No one, including insurers, would have access to this information without your explicit written consent.

The laboratory studies may find no [x] abnormalities in your specimens. In that case, you might have gone through this testing process and not learned anything about your [x]. Current technologies are not able to find and identify every possible variant that might be related to [x]. You may still have genetic or other variants that are related to your [x] but the tests we performed may not be able to detect them.

Family members may be upset to learn that they may be at risk for [x] or other diseases and that they learned this through your participation in this study.

We will not inform you about test results regarding diseases for which there are no effective monitoring or treatment strategies. Therefore, you may be falsely reassured about your health or risk status if we do not report specific findings to you.

All testing methods have an error rate and it is possible that a result we report to you or your doctor may have been an error. We attempt to reduce this possibility by monitoring our testing and trying to reduce the error rate. In addition, we will only report results that have been

generated or reproduced in a laboratory that is certified by the government for its consistency and accuracy (called a CLIA laboratory).

7. Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future. If this information was shared with your family members, it could affect them as well because genes are inherited within families.

### Research Results May Be Returned

1. If you agree to let us tell your doctor about the results of these tests, he or she may tell you about them and offer genetic counseling if you wish to have it. It is possible that some tests will reveal non-[x]related information. If so, we will provide this information to your doctor only if it is associated with a risk to your health and there is something that doctors can do about it. We will not provide this information if there are no actions that doctors can take to reduce your health risks.
2. In general, we do not plan to contact you about the results of this study. However, a small number of the analyses we perform may have clinical importance. For example, they might uncover characteristics known to make [x] responsive to specific therapies. In addition, some of the analyses that currently have no clinical importance may later be discovered to have some. Therefore, we are asking you to consider whether or not you would like us to inform your doctor about the results of these molecular analyses and to contact you in the future about additional research studies that may be appropriate for you.
3. The tests being performed on your tissues or fluids are designed to look for changes that might be associated with [x]. Some of these changes could be genetic. If you agree to allow us to give these results to your doctor, then he or she may give the results to you. Genetic counseling would be provided if you want it.

Some of these tests might discover unexpected changes that are associated with diseases other than [x]. These changes are known as “variants.” We would tell your doctors and you about these variants if they are medically significant and medically actionable. This means that the variants are associated with a significant health risk AND there is a proven method that your doctors could use to keep you healthy or improve your health despite this risk. For example, a medically significant finding would be one that increased your risk of serious heart disease. This finding would be “actionable” if your doctors could help you avoid heart disease by monitoring you or altering your diet or giving you medication. This kind of result would be made available to your doctor and you, and we would offer genetic counseling.

In contrast, although a variant associated with a serious neurologic disorder might also be medically significant, it would not be “actionable” unless there was some treatment that was proven to treat that disorder. This type of result would not be made available to your doctor or to you. You may also decline to receive some or all of the results from this study.

4. In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

### **Research Results Will Not Be Returned**

1. Neither you nor your study doctor will be given information obtained from the research conducted with your samples and data.
2. The research we are doing is only a stepping stone in understanding [x]. Therefore, information from this research will not be returned to you or your doctor. Tests done for research using your samples will not be useful in directing your medical treatment. This information will not be placed in your medical records.
3. Genetic information that results from this study does not have medical or treatment importance at this time. We will not report any genetic test results to you or your doctor.
4. These studies are being done to add to our knowledge of how genes and other factors affect [x]. We are gathering this knowledge by studying groups of people, and the study is not meant to test your personal medical status. For that reason we will not ordinarily give you the results of our research on your samples unless there is clear evidence of actions that could benefit your health as described in more detail below.

### **Withdrawal**

1. If you participate in the study, you can change your mind later and decide that you don't want to participate anymore and you do not want your [saliva/blood/etc] to be used in this study. Please let us know and we will destroy the sample. If your sample has already been tested at the time you change your mind, your results and other data may have already been shared with other investigators. In that case, we will not be able to destroy this data. Data that has already been used will remain part of the study database and may not be removed in order to maintain the integrity of the research. However, any identifiable information will be destroyed so that no one can tell the data belonged to you.

### **Tissue Banks**

1. As part of your routine care, your doctor will obtain [x] from you for testing. After the tests for your medical care are completed, part of your samples may be left over. Normally these leftover samples would be thrown away. We are asking you to allow us to collect and store this leftover [x] in a research tissue bank.

If you agree, the leftover samples will be frozen and sent to the bank. We are also asking for your permission to store some of your health information with your samples so that your samples will be more useful for research. We plan to continue to review your medical record to update your health information in the tissue bank computer database.

2. The purpose of this research tissue bank is to collect, process, and store samples until researchers need them to do research. Tissue samples in this bank will be used mainly for research on [x]. Research tissue banks collect and store many types of samples, such as blood, urine or other bodily material. Our research tissue bank is located at [y]. There is no set limit to the number of individuals who provide samples to this bank. The more samples and health information that we can collect, the more useful the tissue bank will be for research.
3. Some of your specimens and the material generated during the analysis of your specimens may be useful for future study. We are asking your permission to store these specimens and materials

in secure storage facilities (called “repositories” or “banks”) for possible later use.

4. Research tissue banks collect and store many types of samples, such as blood, urine or other bodily material. The purpose of this research tissue bank is to collect, process and store blood samples until researchers need them to do research on [x]. Tissue banks have rules about which researchers can get samples and what kind of research they can do using the samples. Researchers can use samples and information from this bank to study medical questions related [x]; for example, what causes and what helps prevent, treat, or cure this disease, and how it may be passed on in families. We are asking you to allow us to place your blood samples in a tissue bank. If you agree, your blood samples will be frozen and stored. We are also asking for your permission to store some of your health information with your samples so that your samples will be more useful for research. Our research tissue bank is located at [y]. We hope to collect [z] samples.

Your samples and information will be used to study [x]. The long-term goals of the research are to learn how to better understand, prevent, diagnose or treat [x]. It is not possible to list every research project. Also, we cannot predict all of the research questions that will be important over the next years. As we learn more, new types of research and new research questions related to diabetes and heart disease may be worked upon.

Your samples will be made available for researchers at [x]. The bank will usually provide samples with very limited information that does not identify you (for example, your age and diagnosis). The bank will only provide identifiable information (such as your medical record number) to researchers whose study has been approved by the ethics board. In the future, these researchers or bank staff may review your medical records to collect additional health information about you.

5. Some of your specimens as well as some of the material generated during the analysis of your tissues or blood may be useful for future study. We are asking your permission to store these specimens and materials in a secure storage facility for possible later use.
6. If your specimen is stored in a tissue bank or biorepository, then a designated group of clinicians and scientists who oversee the bank will release your specimen only if they think that the research being performed justifies the use of your material. This step is designed to help ensure that your specimens are being used for the best possible scientific purposes and to help minimize the possibility that your material will be used up.

### **iPS Language**

1. *Why are we doing this research?*

The purpose of this study is to grow stem cell lines from a sample of your [tissue] for research. Cells are the building blocks of all living things. Each type of cell plays a different role in the human body. A stem cell is a special type of cell. The stem cells we will grow, called induced pluripotent stem (iPS) cells, can form many different types of cells in the human body when grown under specific conditions. Your cells, and the iPS lines grown from your cells contain genes made of DNA. Nobody else in the world has the same DNA as you, unless you are a twin. Your blood sample, and any stem cell lines grown from your sample will contain your DNA.

2. *What will happen in the study?*

[If applicable] Your blood samples will be routinely screened for HIV (the virus that causes AIDS) and hepatitis (causes diseases of the liver). If either of these tests comes back positive, we will contact you. We will help and refer you for follow up.

3. *Who will have access to my samples and information?*

The sample collected (your blood) and the cell lines created from that sample will be an important research tool. Though the original samples are a limited resource, any cell lines created may be kept and grown for research use for many years, perhaps longer than your lifetime. The researchers intend to put them into a cell bank. In that bank, the material collected and the stem cell lines produced by this study will be kept so that they can be shared with researchers at other universities, hospitals, research institutes, and companies that do scientific research around the world. The material and cell lines will be shared so that other researchers can do other kinds of scientific work, including studying the biology of stem cells, the causes of and possible treatments for many human diseases and conditions, and other clinical or research questions that are not yet known. The iPS cell lines created during the study, or derivatives of the cells, may also be used in human transplantation research. If so, you will not be able to place any restrictions or provide any direction as to who will receive the iPS cell lines or their derivatives, for human transplantation or other purposes. The material and cells lines and/or their derivatives may also be used in research involving genetic manipulation of the cells, the mixing of human and animal cells, or the introduction of iPS cells into human or animal embryos.

Your samples may be used to make new products, tests, or findings. These may have value and may be developed and owned by the study staff, [relevant institution(s)], and/or others including for profit companies. If this happens, the researchers or [relevant institution(s)] may make money from this research, but there are no plans to provide money to you.