

# Sample informed consent language for open data access to ENCODE data

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(for public distribution)

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**1. Purpose of research.** The National Institutes of Health's genome institute established the Encyclopedia of DNA Elements, or ENCODE, project to identify all the functional parts of the human genome, from genes to the switches that turn genes on and off. Genes are the basic "instruction book" for the cells that make up our bodies. Genes are made out of DNA, and all of the DNA in each cell is called the genome. Different genes are turned on in different types of cells; for example, liver and kidney cells work differently because different genes are "on" in each. Sometimes changes in genes and their switches can lead to disease by changing the activity of the genes. So understanding all of the parts of the genome is important to understand human health and disease.

We invite you [your family member] to be a part of the Encyclopedia of DNA Elements (ENCODE) Project, whose goal is to find all of the genes and switches in the genome. We are doing this by studying DNA from hundreds of different types of human cells; many samples are needed because some parts of the human genome sequence only work in specific tissues or organs, such as blood or liver. The project puts all of this information in scientific databases available to anyone on the Internet. These scientific databases will be kept for a long time, and many researchers around the world will use them in many future studies. We anticipate that most of these studies will be related to health and disease, but there may be other uses as well. Sharing information from ENCODE widely may benefit the public, by helping researchers make discoveries more quickly.

Researchers are working together to develop this resource, including [institution]. This work is being funded by the National Human Genome Research Institute, a part of the U.S. National Institutes of Health. You can learn more information about the organization of this project at <http://www.genome.gov/ENCODE>.

[Institution] is recruiting some of the participants. In order to take part, you [you, on behalf of your family member] must:

- be willing to give a sample of [specific tissue, cells, organ] so that researchers can read out your [your family member's] genetic information from it using a process called ["sequencing" OR insert other assay here];
- be willing to have the [sample] and genetic material shared with other researchers within the ENCODE Project who are carrying out different types of experiments needed to find all of the genes and switches in human DNA;
- [optional if iPS cell line will be generated] be willing to have your [your family member's] sample [specify tissue(s)] treated so that it grows forever and can be studied for many years. The tissue may be stored indefinitely. Cells from the tissue can also be transformed into different kinds of cells. For example, skin cells could be transformed into nerve cells. These transformed cells are important to medical research; however, they would not be transplanted into anyone;
- be willing to have all of your [your family member's] genetic information (without your [your family member's] name or other traditional identifying information, such as address, or Social Security number) put in scientific databases that will be publicly available on the Internet; and
- be willing to have many researchers around the world study the data from the sample for a long time for any purpose, and to have the information they learn put in scientific publications and databases on the Internet.

**We will not collect your [your family member's] name. However, we will collect general information about you [your family member], including age, sex, and health status at time of sample collection, and if applicable, cause of death, that will be shared with people who study the material and data made from the project's samples.**

**This is a research project, not medical care.** You should see your health care provider for any scheduled visits or if you have a health problem or medical question.

If you think you [you, on behalf of your family member] might want to be part of this project, please read the rest of this form and take as much time as you need to ask questions.

**The decision about whether to participate or not is completely up to you.** [The following sentence is optional but may be required by some IRBs.] If you decide not to sign this form, it will not affect any benefits to which you are entitled.

**2. What will happen with the sample?** The sample will be processed and stored by [institution]. The only information we will include with the sample is your [your family member's] age, sex, and health status at the time of sample collection, and, if applicable, cause of death.

The [Institution] researchers may:

- extract materials from the sample and analyze the sample, by reading out the genetic information to find the genes and switches in it;
- share your [your family member's] sample with other participants of the ENCODE Project for additional studies to find all of the genes and switches in the genome;
- [optional, for possible creation of iPS cell line] treat your [your family member's] tissue so that it grows forever, stored indefinitely, may be transformed into a different type of tissue, and can be studied for many years;
- put all the data in open access (public) scientific databases on the Internet (at [e.g., <http://www.encodeproject.org>; <http://www.ncbi.nlm.nih.gov/geo>; <http://www.genome.ucsc.edu>; cite other URLs for website(s)] through which the data can be accessed); and
- study the genes and switches in the genome from data from all the samples.

**3. What are the costs and payments?** It will not cost you anything to participate in this project. [Institution] does not allow anyone who receives DNA or [tissue] to sell them. However, some of the research done with your [your family member's] samples or the information in the scientific databases may eventually lead to the development of new predictive or diagnostic tests, medicines, or other commercial products. If this happens, you will not receive any of the profits from those products, or any discounts on or special access to the products.

**4. Are there any benefits to participating in the project?** You [Your family member] will not benefit personally from giving a sample for this project. However, your [your family member's] participation will help researchers around the world understand more about how the human genome functions and how it relates to health and disease. This may benefit the general public by leading to a better understanding of health and disease.

**5. What are the risks of participating?** You may have some brief pain and bruising when we [insert procedure here, e.g., draw your blood]. There is also a small chance that you may get an infection, have excess bleeding, become dizzy, or faint from the [insert procedure here, e.g., blood draw]. [needs to be adapted for the specific procedure and will likely be covered in the other part of the consent document.]

Although we will not collect your [your family member's] name and we will take many measures to protect study participants' privacy (see #7: *How will you protect my privacy?*), we will collect general information about you [your family member], as described in #1 and we will generate lots of genetic information from your [your family

member's] sample that will be shared with researchers who study the material and data from the project's samples. This information will be put in open access scientific databases, available on the Internet to anyone who wants to look at it. Although only experts will know how to interpret this information, there is a chance that somebody could connect you [your family member] with the information from the study of the sample you give. The information could potentially be used to discriminate against you or your family members. In the US, there are State laws and a Federal law, the Genetic Information Non-discrimination Act, that provide some protection against this type of discrimination by making it illegal for most employers and health insurers to use information about your genes to discriminate against you or your family.

**We cannot always foresee the results of research, so new risks may come up in the future that we cannot predict now.** We believe that the benefits of learning more about how the human genome works and how it relates to health and disease outweigh the current and potential future risks, but this is something that you must judge for yourself.

**If you believe you have been injured because of this research, please contact [contact person].** Decisions about payment for medical treatment for injuries relating to your participation in research will be made by [institution].

**7. *How will you protect my privacy?*** We will protect your privacy in several ways:

- We will store your signed consent form in a locked file; only members of the study team at [institution] will have access to this file.
- We will not collect your [your family member's] name or any other traditional identifying information (such as address, or Social Security number) that could directly identify you [your family member].

People studying the samples will not have access to any information about you [your family member] except your [your family member's] age, sex and health status at the time of sample collection, and, if applicable, cause of death.

**Despite these measures, it is possible that someone may determine that information in the database came from you [your family member] based on DNA sequence and/or other information.**

**10. *Can I change my mind after I decide to participate?*** Because we will not collect any names with the samples, we will not know the identity of the person who gave any particular sample. For this reason, once you [your family member] give[s] a sample, it will be impractical for us to withdraw it from the project. Also, once the sample has been studied, you cannot take the information about the sample out of the scientific databases.

**11. *How can I find out about the results of the research?*** It will probably take a long time for the data from this project to be used to produce health-related information that we will know how to interpret accurately. For this reason, and because we will not know who the individual sample donors are, we will not be able to give you individual results from this research. However, you can check the web sites at <http://www.genome.gov/ENCODE> or <http://www.encodeproject.org> to see how samples are used, and what sorts of results have been found.