

## RESEARCH PARTICIPANT INFORMED CONSENT

### Open Data Access to ENCODE Data

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**1. Purpose of research.** The National Institutes of Health's Human 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 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 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.

Fred Hutchinson Cancer Research Center and University of Washington researchers are working together to develop this resource. 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>.

Fred Hutchinson Cancer Research Center is recruiting some of the participants. In order to take part, you must:

- be willing to give a sample of your blood so that researchers can read out your genetic information from it;
- be willing to have your 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;
- be willing to have all of your de-identified (see definition below) genetic information 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.

Your sample will be given a unique code and completely de-identified before provision to the ENCODE researchers. **De-identification means your name, your address, or Social Security number will not be available to the researchers, nor will any other health related information.** The only general information provided along with the sample will be age, sex, ethnicity (if you provide this information), and that you are a normal healthy donor at the time of sample collection. This de-identified information will be available to anyone on the Internet as part of the ENCODE Project.

If you think you 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. If you agree to participate after reading this form, please consent by signing at the bottom of this document.

**2. What will happen with the sample?** The sample will be processed and stored by Fred Hutchinson Cancer Research Center. As part of that processing, all donor information will be de-identified, and a unique code assigned to your sample. The only information we will provide with the sample is your age, sex, ethnicity, and that you are a normal healthy donor at the time of sample collection.

The Fred Hutchinson Cancer Research Center and University of Washington 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 sample with other participants of the ENCODE Project for additional studies to find all of the genes and switches in the genome;
- put all the data in open access (public) scientific databases on the Internet at <http://www.encodeproject.org>; <http://www.ncbi.nlm.nih.gov/geo>; <http://www.genome.ucsc.edu>;
- 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. Fred Hutchinson Cancer Research Center does not allow anyone who receives samples to sell them. However, some of the research done with your 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 will not benefit personally from giving a sample for this project. However, your 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?** Although we will collect your name as part of your formal consent, we will take many measures to protect your privacy (see #6: *How will you protect my privacy?*); we will collect general information about you, as described in #1 and we will generate lots of genetic information from your 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.

**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.

Other risks have been provided in the protocol 985.03 consenting documentation, which will be reviewed with a physician during the consenting process. This documentation only refers to the ENCODE Project.

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

Your signed consent form will be kept in a secured location; only a small sub-set of the study team at Fred Hutchinson Cancer Research Center and University of Washington will have access to this file.

People studying the samples will not have access to any information about you except your age; sex; ethnicity; health status at the time of sample collection.

**7. 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 give 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.

**8. 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.

If you agree to participate after reading this form, please consent by signing below.

I, the undersigned, agree to participate as a research donor in the National Institutes of Health's Human Genome Research Institute's Encyclopedia of DNA Elements, or ENCODE, project.

\_\_\_\_\_  
Research Participant's Name

\_\_\_\_\_  
Today's Date

**FHCRC IRB Approval**

**SEP 25 '14**

**AUG 14 '15**

Consent Released Date

Consent Expiration Date