Consent Form: Example 1 (Reconsent for a Genome-wide Association Study with Broad Data-Sharing)

Important note: *This example consent form was modified from the reconsent form that was developed for the Nurses Health Study (NHS)*[1] *for a reconsent process with study participants to use their previously collected DNA and questionnaire data for an NIH-funded genome-wide association study (part of the Genes, Environment, and Health Initiative (GEI) Genetics Program). This form was kindly provided by Dr. Frank Hu (Harvard School of Public Health; Principal Investigator of the diabetes component of the NHS).*

This example consent forms contains multiple checkboxes. It is possible that the inclusion of multiple checkboxes could result in consent forms that are less understandable to subjects and unnecessarily long. Whenever possible, the consent form should only include information that is pertinent to the study and should not include multiple unchecked boxes.

Protocol Title: [Insert title]
Principal Investigator: [Insert PI name]

About this consent form

Please read this form carefully. It tells you important information about a research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form. If you have any questions about the research or about this form, please ask us. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a copy of this form to keep.

Why is this research study being done?

We are requesting your participation in a study involving previously collected DNA samples and questionnaire data to study how genes interact with environmental factors to influence the development of diseases such as cancer, cardiovascular disease, diabetes and glaucoma.

What will happen in this research study?

If you agree to participate, this project does not involve any additional time commitment on your part. You have already made valuable contributions to our research by providing a blood or cheek cell sample. We have kept your sample on file and for some of you analyzed it for a fixed set of markers associated with disease risk.

The human genetic library contains millions of genetic markers; only a minority of these is associated with disease. Technology has advanced such that we can now search the entire human genetic library for all possible genetic markers that might be related to a specific condition. This approach to finding the cause of complex diseases such as diabetes and glaucoma is very exciting but costly. The

[1] http://www.channing.harvard.edu/nhs/

National Institutes of Health (NIH) will fund such an approach. An outside lab designated by the NIH will search the entire human genetic library of markers using your DNA sample in order to reduce the number of possible markers associated with disease from several hundred million down to about 2,500. Then we will perform more analyses to deduce which of those markers are actually associated with disease. Your coded medical information and information from more detailed analysis of your coded samples will be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from an NIH Data Access Committee.

As is standard practice for [Insert Study Name], an annual newsletter will be mailed to you and will include general information about grouped results. No individual information will be reported in the newsletter. You will not be provided with individual results.

What are the risks and possible discomforts from being in this research study?

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 or have access to the code linking samples to you.

What are the possible benefits from being in this research study?

This study will not provide direct benefits to you. However, your participation will contribute to a better understanding of the factors that influence health.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone number is listed below. Ask questions as often as you want.

Please contact the study office by calling [Insert Contact Name and Phone Number] if you have any questions about the study.

If you want to speak with someone **not** directly involved in this research study, please contact [Insert Institutional Contact (e.g. IRB office)]. You can call them at [Insert appropriate Phone Number].

You can talk to them about:

- Your rights as a research subject

- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires [Insert Institution Name] and researchers to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as "health information.

If you decide to take part in this research study, your health information may be used within [Insert Institution Name] and may be shared with others outside of [Insert Institution Name], as explained below.

We have marked with a ☒ how we plan to use and share your health information. If a box is not checked ☐, it means that type of use or sharing is not planned for in this research study.

We will also give you the [Insert Institution Name] Notice for Use and Sharing of Protected Health Information. The Notice gives more details about how we use and share your health information.

- **Health Information About You That Might be Used or Shared During This Research**

  ☐ Information from your hospital or office health records within [Insert Institution Name] or elsewhere, that may be reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside [Insert Institution Name], you will be asked to give permission for these records to be sent to researchers within [Insert Institution Name].

  ☒ New Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study

- **Why Health Information About You Might be Used or Shared with Others**

  The reasons we might use or share your health information are:
  - To do the research described above
  - To make sure we do the research according to certain standards – standards set by ethics and law, and by quality groups
  - For public health and safety - for example, if we learn new health information that could mean harm to you or others, we may need to report this to a public health or a public safety authority
  - For treatment, payment, or health care operations

- **People and Groups That May Use or Share Your Health Information**

  1. **People or groups within** [Insert Institution Name]

     ☒ Researchers and the staff involved on this research study

     ☒ The [Insert Institution Name] review board that oversees the research

☒ Staff within [Insert Institution Name] who need the information to do their jobs (such as billing, or for overseeing quality of care or research)

2. **People or groups outside** [Insert Institution Name]

☒ People or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers

☒ Federal and state agencies (such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health and/or the Office for Human Research Protections) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research

☒ Organizations that make sure hospital standards are met

☐ The sponsor(s) of the research study, and people or groups it hires to help perform this research study

☒ Other researchers and medical centers that are part of this research study

☐ A group that oversees the data (study information) and safety of this research study

☒ Other: Qualified researchers approved by Data Access Committee at NIH.

- **Time Period During Which Your Health Information Might be Used or Shared With Others**

  - Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

- **Your Privacy Rights**

  - You have the right not to sign this form permitting us to use and share your health information for research. If you don't sign this form, you can't take part in this research study. This is because we need to use the health information of everyone who takes part in this research study.

  - You have the right to withdraw your permission for us to use or share your health information for this research study.

    If you chose to discontinue your participation in the study, there will be no penalty or loss of benefits to which you are entitled. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

    If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to take part in this research study.

  - You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study.

- **If Research Results Are Published or Used to Teach Others**

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

The alternative to participating is not to participate, and **the decision about whether to participate is completely up to you.** If you decide not to sign this form, it will not affect any benefits to which you are entitled and will not involve any penalties.

Consent/Assent to take part in this research study and authorization to use or share your health information for research

Statement of Subject or Person Giving Consent/Assent

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other options for treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.

If you understand the information we have given you, and would like to take part in this research study, and also agree to allow your health information to be used and shared as described above, then please sign below:

Signature of Subject:

_____ _____

Adult Date/Time