Additional Considerations for Future Use of Data and Specimens Collected During a Research Study

Some researchers may wish to store data or specimens collected during a research study for use in future research. The following elements should be incorporated into the Protocol Template and Informed Consent Form for such requests:

Protocol Template

Section 5F:

- Describe what data/specimens will be collected for future use as specifically as possible.

Section 5H:

- Include a description of how the data/specimens will be stored, including whether they will be stored in an identifiable manner (e.g., direct or indirect identifiers are linked with them).
- Include a description of where the specimens will be stored and the security protections in place to minimize the risk of breach of confidentiality.

Section 12:

- Indicate whether consent to data/specimen banking is contingent upon participation in the study.
- Describe what limits will be placed on intended future use, if any. If you intend to make data/specimens available for future unrelated research, indicate this here.
- If participants will be be able to opt out of data/specimen banking, or use of their data/samples in future unrelated research, indicate this here.

Informed Consent Form

Under Purpose

If the goal of the study is to create a biobank, the following language is suggested for the Purpose section.

> *The purpose of this research project is to collect and store human samples (such as blood) and health information. Researchers can then use the stored materials in future studies. Through such studies, they hope to find new ways to detect, treat, and maybe even prevent or cure health problems. Some of these studies may be about how genes affect health, or how genes affect response to treatment. (Genes, which are made up of DNA, have the information needed to build and operate a human body.) Some of the studies may lead to new products, such as drugs or tests for diseases.*

Under Description

The following future use language can be inserted into the informed consent document under “Description of What's Involved” to obtain consent for data/specimen banking. Not all of this language will be appropriate for every study. The following language does not pertain to mandatory banking as

part of the protocol for analyses necessary for the conduct of the study.

The researchers would like to ask your permission to keep specimens (like blood, tissue, hair, or any other body matter) collected from you during this study to use them in future research studies. They would also like to know your wishes about how they might use your specimens in future research studies. You should also know that it is possible that products may someday be developed with the help of your specimens, and there are no plans to share any profits from such products with you.

***(1)** Will you allow the researchers to store your specimens to use in future research studies?*

> *Yes_____ No_____ If no, please stop here. If yes, please continue to the next question.*

***(2)** The researchers can keep your specimens stored in one of two different ways: one way will store your specimens in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your specimens anonymously (no one will know who the information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have your specimens stored anonymously, you will not be able to change your mind to ask for your specimens to be destroyed at a future date.*

> *How would you like your specimens stored? Please initial **ONE** choice:*
> *I would like my specimens stored with a link to my identity_____*
> *I would like my specimens stored anonymously _____*

***(3)** Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your specimens might be used, or to discuss possible participation in another research project? Please initial your choice:*

> *Yes_____ No_____*

***(4)** Do you give the researchers permission to keep the specimens indefinitely and use them for future studies that are **directly related** to the purpose of the current study? Please initial your choice:*

Yes_____ No_____

***(5)** Do you give the researchers permission to keep the specimens indefinitely and use them for future studies that are **not related** to the purpose of the current study (for example, a different area of research)? Please initial your choice:*
Yes_____ No_____

> ***(a)** If the future research in a different area can be done without having to know that the specimens came from you personally, that will be done.*
>
> ***(b)** If the future research in a different area requires that it is known specifically who the specimens came from, then one of the following will be done:*
>
> > ***(i)** If you allowed the researchers to contact you in the future, they will be able to*

contact you to explain why your specimen is needed and what will be done with it. Your permission will be asked to use your specimens in that research project.

(ii) *If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical, for example, because you have moved, your specimens may still be used. Either all links to your identity will be removed from the specimens, or an Institutional Review Board will be asked for permission to use the specimens linked to your identity. The Institutional Review Board (IRB) is a committee of doctors and scientists and non-scientists and people not associated with this hospital or medical school whose job it is to protect people who participate in research. The IRB can give permission for researchers to use and share health information connected to specimens that are linked to people's identities, but only if it determines that doing this will not be more than a minimal risk to people or their privacy.*

(6) *Do you give permission to have portions of the specimens* ***given to other researchers*** *at Mount Sinai or other institutions for use in research that is either related or not related to the purpose of this study? Please initial your choice:*

Yes_____ No_____

Under "Ending Participation in this Research Study:

- Describe the procedures for withdrawing consent for future use of any data/specimens. Describe if and how data/specimens can be withdrawn or destroyed.
- Explain what withdrawal means, (e.g. the sample will be returned, destroyed, anonymized, or no new information will be collected).

If future research may involve genetic testing:

- Under "Description" indicate whether or not the results of genetic testing will be shared with participants. If they will be, describe how these results will be shared. Please note that only tests performed in a CLIA-certified lab can be shared with participants if the tests are approved by the FDA or New York State.
- Under "Risks," include the following statement regarding the GINA Act:

  There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most large
  employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Additional Considerations for Genome-Wide Association Studies (GWAS) and Similar Large Genetic Sequences Going into a Public Repository

Are you conducting a GWAS study?

According to the National Institutes of Health, a GWAS study is any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the present or absence of a disease or condition.

To whom does the NIH GWAS policy (effective 1/25/08) apply?

- Investigators who receive ANY NIH money for genome-wide analysis of tissue specimens
- Investigators who voluntarily submit genotype or phenotype data to the NIH GWAS repository

What are the requirements if you are submitting data to the NIH GWAS repository?

The IRB must verify that the following items have been addressed:

- Submission of the data is consistent with the informed consent form of study participants from whom the data was initially obtained
- De-identification of the data sets is consistent with the GWAS standards (HIPAA standards for de-identification)
- Risks to individuals, their families and groups or populations associated with the data submitted has been considered and
- Genotype and phenotype data to be submitted were collected in a manner consistent with the Common Rule (federal law governing human research protections)

What are the implications for my IRB submission?

In order for the IRB to verify that the above items have been met, address each of the following in the listed documents.

Protocol Template

Section 5G:

- Describe what genotype/phenotype data is being submitted to the NIH GWAS Repository
- Describe the method(s) used for coding the data
- Describe how the link will be maintained with the assertion that it will not be shared with the NIH

Informed Consent Form

Include the following suggested language in each of the labeled sections of the consent form in addition to the language suggested for studies involving the collection of data/specimens for future research. The following language has been extracted from the model consent form proposed by The Electronic Medical Records and Genomics (eMERGE) Network Consent & Consultation Workgroup (12/15/09).

Under Description

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by [institution], some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, 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. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Under Risks

Group Risks

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

Privacy Risks
Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, 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. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.