

**HIPAA Compliant Language for Biological Specimen Banking**

**Suggested Sample**

*Due to the establishment of HIPAA Regulations in 04/14/03, it was necessary to modify the informed consent language for tissue and blood repositories. Changes to broad consent was necessary because HIPAA does not allow subjects to give authorization for* ***unspecified*** *future uses of protected health information. The suggested language in this sample is the one approved by the IRB. Those subjects who have signed a consent form with the previous language before 04/14/03 do* ***NOT*** *have to be re-consented, unless they are being re-consented for other reasons. The signed consent before 04/14/03 remains valid for future uses protected health information specifications.*

*On January 19, 2017, the U.S. Department of Health and Human Services (HHS) and 15 other Federal Departments and Agencies promulgated regulations (the Final Rule) to revise the Federal Policy for the Protection of Human Subjects in Research (the Common Rule). Enacted in 1991, the Common Rule codified the ethical framework for the conduct of medical research involving human subjects conducted or supported by the federal government. The Final Rule establishes, among other things, a framework for “broad consent,” a new type of consent specifically defined in the regulation that is intended to serve as a substitute for traditional informed consent in certain circumstances. While the research community has relied on broad consent forms in a general sense for many years to allow institutions to collect, store, and use subjects’ data and identified biospecimens for unspecified future research, the Final Rule creates a new regulatory pathway for the use of broad consent and its legal implications. Specifically, the Final Rule establishes (i) two new exemption categories for the storage, maintenance, and research use involving identifiable information and biospecimens under which broad consent is a condition for the exception, and (ii) a regulatory pathway to obtain broad consent in lieu of traditional informed consent for non-exempt storage, maintenance, and research use involving identifiable information and biospecimens.*

**TITLE OF STUDY:** [Insert title]

**PROTOCOL NUMBER:**

**SPONSOR:**

**PRINCIPAL INVESTIGATOR(S)**[Name]

[Department]

[Address]

[Phone]

[Email]

What is the Purpose of a Broad Consent?

If you say “yes” in this form, [Name of Repository/Biobank/Institution/Institutional Department or Division] will store, use and share your identifiable information and/or identifiable biospecimens, and may do so for the purpose of medical, scientific and other research, now and into the future, for as long as they are needed for this purpose [or specific a shorter period]. If you say “yes” and give your broad consent in this form, we may share your identifiable information and identifiable biospecimens with other research, academic, and medical institutions, other researchers, drug and device companies, biotechnology companies and others.

What Types of Research May be Done?

If you say “yes” in this form, there are no plans to tell you about any of the specific research that will be done with your identifiable information and identifiable biospecimens. Possible future research may include, for example:

• Studying the causes and progression of different diseases and conditions

• Developing and testing methods to diagnose and treat different diseases and conditions

• Whole genome sequencing (meaning that your entire personal genetic code will be identified)

• Specific genetic research looking at diseases and medical conditions that are passed on in families and among populations larger than families

• Research that creates cell lines by growing cells from your biospecimens in a laboratory – including cells that can be used to create different types of tissue

• Research that includes changing the genes in cells or putting human cells into animals

• Research about drug abuse and alcoholism diagnosis and treatment

• Research about mental health diagnosis and treatment

• Research about developmental disabilities

• Research about HIV and sexually transmitted diseases

• Research about induced termination of pregnancy [abortion]

• Family planning and reproductive health research

[add here any statements required by applicable state law to conduct research in the categories above]

The results of research done on your identifiable information and identifiable biospecimens will not be put into your medical records. It is possible, but unlikely, that testing on your biospecimens could show that you have a medical condition (like tuberculosis or HIV), that the laws in your state say must be reported to public health departments, with information that identifies you. This is required anytime someone is found to have a condition that must be reported, whether this is found in medical care or in a research study.

The researcher 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 it is possible that products will 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 researcher 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 ways that it is linked to your identity (using a code that can indicate the information came from you personally) and the other way will store your specimen 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 your specimens to be destroyed at a future date.

How would you like your specimens to be stored? Please place your initial in **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 researches 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? Place initial your choice:

 Yes \_\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4- Do you give researchers the permission to keep the specimen indefinitely and use them for future studies that are directly related to the purpose of the current study?

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)? Place initial in your choice:

Yes \_\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. If the future research in different area can be done without having to know that the specimens came from you personally, that will be done.
2. 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:
3. 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.
4. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical due to change of phone number or contact information, your specimens may still be used. In that case, all links to your identity will be removed from the specimens or permission will be asked to the IRB for the use of identified specimens. The IRB is a committee of doctors, scientists and non-scientific members whose job is to protect people who participate in research. IRB may give permission to the researcher on the use of specimens that are linked to people identities, only if they determine that by doing so this will not be more that a minimal risk to people or their privacy.

6- Do you give permission to have portions of the specimens given to other researchers at (institutions name) or other institution for use in research that is either related or not related to the purpose of the study? Place initial on your choice:

Yes \_\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**STATEMENT OF CONSENT**

I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study. (To be signed and dated by the subject)

Print name of subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Day/month/year

**PERSON TAKING THE CONSENT**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Print Name of person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Day/month/year

\*A copy of this consent form will be given to the participant\*