For IRB Use– Protocol #

**Broad Consent for Future Research Uses of Identifiable Information and Identifiable Biospecimens (and Storage or Maintenance for such Secondary Research Use) for which Broad Consent is Required**

[Instructions for use: The Broad Consent Template is intended to comply with federal government requirements administered by the HHS Office for Human Research Protections and the Food and Drug Administration.  It is also intended to meet the requirements of a HIPAA authorization for use and disclosure of PHI for future research purposes.

The institution, health care provider or researcher offering this broad consent is responsible for ensuring that the Broad Consent Form meets applicable federal and state laws, as well as institutional policies.]

**Research with Private Information and Biospecimens**

Research using personal health information (such as information about your health status, medical test results, and what medical conditions you have), and biospecimens (for example, blood or other body tissues) has led to important advances in medicine, science, and other areas.  As explained in this form, we hope to make it easier for researchers to use your information and biospecimens in the future.

The rules for how information and biospecimens originally collected for one purpose (such as for your medical care or another research study) can be used for new research depend on whether the information and biospecimens identify you personally, or whether things that identify you – such as your name, address and medical record number – have been taken off of the information and biospecimens. When all of the details that could reasonably be used to identify you have been removed from your information and biospecimens, we say they are “de-identified.” Federal and state law allows researchers to use de-identified information and biospecimens without asking anyone for permission. This has been true for a long time, and research with de-identified information and biospecimens has benefited patients in many ways.

When your information and biospecimens can still be linked to you, we say they are “identified” or “identifiable.”  Research with identifiable information and identifiable biospecimens can be even more helpful to science and medicine, because it allows researchers to put together a lot of information about a person and understand even more about medical conditions and if and how treatments work.  However, research with identifiable information and identifiable biospecimens bears more risk to people’s privacy, and therefore, there are strict rules for this kind of research. When researchers ask you to say “yes” to allow your identifiable information and identifiable biospecimens to be used in a wide range of different types of research studies in the future, t**his is called “broad consent,” and it is what we are asking you to agree to in this form.**

**What are we asking you to do?**

This form asks you to make an important choice about the use of your identifiable information and identifiable biospecimens.  It asks you to decide if you are willing to give your broad consent now to the future research use of your identifiable information and identifiable biospecimens.

If you say “yes,” researchers in the future may use your identifiable information or identifiable biospecimens in many different research studies, over a long period of time, without asking your permission again for any specific study covered by this form.  This could help science.

**IRB PROTOCOL #**

**IRB Authorization: \_\_\_\_\_\_\_\_**

If you say “no,” researchers in most cases will have to ask your permission to use your identifiable information or identifiable biospecimens in any future research study.  Because this may be difficult or impossible, it could make scientific studies harder to do.

This form explains in more detail what saying “yes” or “no” to this broad consent will mean to you.  If you don’t choose either “yes” or “no” after reading this form and talking to our research staff, your identifiable information and identifiable biospecimens might still be used for some low risk research without your consent.  It is better if you say “yes” or “no” on this broad consent form, so that your choice is clear.

Remember, this form applies only to research with identifiable information and identifiable specimens.  Researchers can always use de-identified health information and de-identified biospecimens for research, without getting any person’s consent and without asking an ethics committee for permission.

Please ask us about anything in this form that you do not understand, and only make a decision if you have had all your questions answered and have had enough time and opportunity to consider whether to agree to give this broad consent.

**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

**IRB PROTOCOL #**

**IRB Authorization: \_\_\_\_\_\_\_\_**

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.

[If applicable: “The following types of research will **not** be conducted using your identifiable biospecimens and identifiable information: (List any types of sensitive or genetic research that will not be conducted).”]

[If applicable: “At least the following types of research (as well as other types not listed here) **will** be conducted using your identifiable biospecimens and identifiable information: (List any types of known research activities not covered by the above list).”]

**Are There Risks of Harm?**

The main risk in saying “yes” is that your privacy could be violated. We will do our best to protect your information from going to people who should not have it, including by removing information that could be used easily to identify you. The risk that your identifiable information or identifiable biospecimen will go to someone who should not get it is very small.

Another risk is that if you say “yes,” your identifiable information or identifiable biospecimens could be used in a research project to which you might not agree, if you were asked specifically about it.  The examples listed above should give you a good idea of the kinds of research projects that might be done.  Also, a research ethics committee will make sure that this broad consent covers the research studies planning to use identifiable information or identifiable biospecimens from you.

**Privacy and Your Protected Health Information**

The personal information that can identify you is protected by federal privacy and security regulations issued under the Health Insurance Portability and Accountability Act (“HIPAA”).  This section of this form advises you on your rights under these regulations.

If you say “yes” in this form, we may share your identifiable information and identifiable biospecimens with researchers in the future, as described above.  We may also share your identifiable information with regulatory authorities that oversee research, including the Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP), and with committees and people here at [institution/entity] and in other places whose job is to review and oversee research.

Your medical information and records, once given to parties who are not bound by laws – such as the HIPAA regulations –that protect your identifiable information may no longer be protected from being used and shared without your consent.

This permission will last as long as we have a scientific and research need to use and share your identifiable information (including identifiable health information) and identifiable biospecimens.

If results are published of studies done with your identifiable information or identifiable biospecimens, your name will not be used in those publications.

**Are There Any Benefits?**

You will not personally benefit from saying “yes” in this form. Research with your identifiable information and identifiable biospecimens may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

 **IRB PROTOCOL #**

**IRB Authorization: \_\_\_\_\_\_\_\_**

**Are There Alternatives to this Broad Consent? Is There a Choice?**

You are free to say “no” to the use of your identifiable information and identifiable biospecimens.  Saying “yes” to this broad consent is voluntary.  If you say “no,” you will not lose any access to health care or benefits to which you are otherwise entitled, and saying “no” will not change your relationship with your health care providers. No matter what you decide, your decision will not affect your rights to obtain medical care or other services.

 [If applicable: “If you say ‘no,’ you will not be able to participate in the primary study.”]

**Can You Change Your Mind and Reverse Your Decision to Give this Broad Consent?**

If you say “yes” now, you can later change your mind, but there are some limits.  If you change your mind, contact [Name or office] at [Phone Number]. [Repository/Biobank/Institution/Institutional Department or Division] will not begin new research uses of your identifiable information or identifiable biospecimens, but those specimens will continue to be used in studies that started before you changed your mind. If your identifiable information and identifiable biospecimens have already been given to another researcher, person, institution, or company, it may not be possible to limit their continued and new uses.

If you change your mind, [Repository/Biobank/Institution/Institutional Department or Division] [may de-identify your information and biospecimens and use them in the future] OR [will not use your identified or de-identified information and biospecimens for future research].

**Will it Cost Anything?**

Whether you say “yes,” “no,” or do not respond to this form, there are no costs to you.

**Is There Any Payment or Compensation for saying “yes”?**

If you say “yes,” your identifiable information and identifiable biospecimens may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are [no plans] [or insert plans] to tell you, or to pay you, or to give any compensation to you or your family.  Most uses of biospecimens or information do not lead to commercial products or to profit for anyone.

Regardless of whether you say “yes” or “no” on this form, or whether you don’t respond at all, if your de-identified information and de-identified biospecimens are used to create products or deliver services, there are no plans to pay you or give any compensation to you and your family.

**If You Say “Yes,” Will You Learn More about Your Health?**

Because this is a broad consent, there are no plans to tell you about any specific research studies that might be done with your identifiable information or identifiable biospecimens, and there are no plans to give you any results from these studies.

Most tests done on biospecimens in research studies are only for research and have no clear meaning for health care.  If future research with your identifiable information or identifiable biospecimens gives results that do have meaning for your health, the researchers may – but are not required to – contact you to let you know what they have found.  If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results.   If this happens, then

 **IRB PROTOCOL #**

 **IRB Authorization: \_\_\_\_\_\_\_\_**

you may  want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

**Options For Responding to this Request for Broad Consent: What Will Happen?**

As explained above, the law allows de-identified information and de-identified biospecimens to be used without permission.  Therefore, this form is asking only about the future use of your identifiable information and identifiable biospecimens.

If you give a definite and clear “Yes” or “No” to this broad consent, then researchers now and in the future will have a clear idea about what they are allowed and not allowed to do with your identifiable information and identifiable biospecimens.  Not giving any answer will also have implications, as described below.

**IF YOU SAY “YES”**

• Your identifiable information and identifiable biospecimens will be stored, used and shared for the kinds of future research described in this broad consent form, without anyone asking your permission for each new study.

• Identifying information may also be removed from your information and biospecimens, allowing them to be used for any future research or other purpose.

**IF YOU SAY “NO”**

• The researchers and institutions identified above will not store, use or share your identifiable information and identifiable biospecimens for the research described in this broad consent form.

• [However, identifiers may be removed from your information and biospecimens, allowing them to be used for any future research or other purpose.] OR [The researchers and institutions identified above will not use your de-identified information and biospecimens for future research.]

• Researchers could come to you again later and ask to store, use and share your identifiable information or biospecimens for research.

**IF YOU DO NOT SAY “YES” OR “NO”**

• If you do not mark “yes” or “no” on this form (if you do not return it, or leave it blank), then it will be the same as if you were never asked to make a choice.

• This means that your identifiable information and identifiable biospecimens may be used for future research if:

o The researchers ask you to say yes to a specific research study, and you agree.

o An IRB allows your identifiable information or identifiable biospecimens to be used in a study that is low risk to you without asking for your consent.

o Another legal exception applies.

• Identifiers may be removed from your information and biospecimens, allowing them to be used for any purpose.

• Researchers could come to you later and ask again for your broad consent.

**IRB PROTOCOL #**

**IRB Authorization: \_\_\_\_\_\_\_\_**

[NOTE:  A chart of the various options and their implications may be inserted here, for clarity.]

**Questions**

If you have any questions about this broad consent, please contact [Name] at [Phone Number].

If you want to report or have questions about an injury that you believe you or others have suffered as a result of your agreeing to this broad consent, please contact [Name] at [Phone Number].

You may discuss your rights as a person who has agreed to, refused, or declined to respond to an offer of broad consent with [Name] at [Phone Number].

Please ask us to explain anything in this form that you do not clearly understand. Please think about this broad consent and/or discuss it with family or friends before making a decision to say “Yes” or “No.”

**STATEMENT OF AGREEMENT**

I say yes. The broad consent has been explained to me, and I agree to give my broad consent to the future research uses of my identifiable information and identifiable biospecimens.  My participation is voluntary, and I may withdraw at any time without any penalty or loss of benefits to which I am entitled.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legally Authorized Representative’s Printed Name (if applicable)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your Signature or Signature of Legally Authorized Representative

­\_\_\_\_

Date

  **STATEMENT OF REFUSAL**

I say no. The broad consent has been explained to me, and I **do not agree** to this broad consent.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legally Authorized Representative’s Printed Name (if applicable)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your Signature or Signature of Legally Authorized Representative

\_\_\_\_\_\_

Date