## Title of [registry/repository] or Name of Institution/Department/Division: ***[insert title of the registry or repository for the storage and maintenance of identifiable private information or identifiable biospecimens here with protocol number, if applicable or insert the name of the institution/department/division that is specifically requesting broad consent]***

## Investigator: ***[insert name of principal investigator]***

## What is broad consent?

Many researchers use personal health information (such as information about your health status, medical test results, and what medical conditions you have), and samples (also called “biospecimens” that include things like blood or other body tissues) to help answer important questions in medicine and science and look for possible cures.

Sometimes the health information or samples that are from your medical care can be used for research. When the information that could be used to identify you (like your name, address and medical record number) has been removed, we say the information/samples are “de-identified.” When the identifying information has been replaced with a random set of numbers or letters, we say the information/samples are “coded” and the key that links this code with your identity is usually kept by a separate group and they are not allowed to share the key with anyone. Researchers are allowed to use de-identified and coded information and samples without asking your permission. This has been true for a long time, and research with this information and these samples have benefited patients in many ways.

When your information and samples contains information that can identify you, we say they are “identified” or “identifiable.” Research with identifiable information and samples can be very 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 samples bears more risk to people’s privacy. In this form, we are asking you if you will allow your identifiable information and samples to be used in a wide range of different types of research studies in the future. This is called “broad consent.”

## Why am I being asked to provide broad consent?

We are asking you to provide broad consent for the storage, maintenance, and future research use of your identifiable private information and identifiable samples as described below. Unlike other research studies, where information and samples are collected to answer a specific question or, for example, to study a particular new drug, we are asking you to give your permission to store and maintain your information and samples for future research which has not yet been defined.

You are being asked to provide broad consent because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition for why they are being asked to provide broad consent.] As researchers identify topics they want to study, they may be able to use your identifiable information or samples, and your permission here would allow them to do so. If you say “yes” and give your broad consent in this form, we may share your identifiable information and samples with other research, academic, and medical institutions, other researchers, drug and device companies, biotechnology companies and others.

## What should I know about broad consent for future research with my information or samples?

1. Someone will explain broad consent for future research to you.
2. Whether or not you agree up to you.
3. You can choose not to agree.
4. You can agree and later change your mind.
5. Your decision will not be held against you.
6. You can ask all the questions you want before you decide.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the registry/repository team].

This ***[registry/repository/request for broad consent]*** has been reviewed and approved by an Institutional Review Board (“IRB”) (an ethics committee that reviews and approves research studies). You may talk to them at (215) 728-4002 or Sophia.sabina@fccc.edu if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the ***[registry/repository]*** team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research subject.
5. You want to get information or provide input about this research.

## What types of future research may be conducted with my information or samples?

We are asking for your permission to store, maintain, and use for future research identifiable information such as:

[Describe the identifiable private information that might be used in research***. Examples include:***

* Medical information such as diagnosis, medical treatments and procedures
* Medical history
* Date of birth]

We also want to store, maintain, and use identifiable samples such as:

[Describe the identifiable biospecimens that might be used in research***. Examples include:***

* Blood
* Buccal swabs
* Tissue samples]

There are no plans to tell you about any of the specific research that will be done with your identifiable information and samples. Possible future research may include, for example:

[Give the subject a ***general description of the types of research that may be conducted with the information or biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted. Examples include:***

* 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 samples 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

***Include the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.]***

## How are my identifiable information or samples protected?

Your identifiable information and samples will be stored at ***[name of institution/location]***. We may share your identifiable information and samples 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. 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 samples.

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

## How long will my information or samples be stored, maintained, and used for future research?

We expect that your identifiable information and samples will be stored and maintained for \_\_\_\_\_\_\_ [hours/days/months/weeks/years/until a certain event/indefinitely]. When we share your information and samples with other researchers, we will instruct them to \_\_\_\_\_\_\_ ***[discard them after a certain period of time/return any leftovers to the registry/repository after a certain period of time/use them indefinitely/other]***.

## Will I be told the results of the research using my information and samples?

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 samples, and there are no plans to give you any results from these studies.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If future research with your identifiable information or samples 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 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.

## What happens if I do not want to provide broad consent?

Having your identifiable information or samples stored, maintained, and used for future research as described above is completely voluntary. You can decide to agree or not to agree.

If you give a definite “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 samples. Not giving any answer will also have implications, as described below.

IF YOU SAY “YES”:

* Your identifiable information and identifiable samples 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 samples, 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 samples 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 replace with “The researchers and institutions identified above will not use your de-identified information and biospecimens for future research” if applicable.]***
* 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 (or 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 samples may be used for future research if:
* The researchers ask you to say “yes” to a specific research study, and you agree.
* An IRB allows your identifiable information or identifiable samples to be used in a study that is low risk to you without asking for your consent.
* Another legal exception applies.
* Identifiers may be removed from your information and samples, allowing them to be used for any purpose.
* Researchers could come to you later and ask again for your broad consent.

Regardless of your decision, 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. Your decision will not affect your rights to obtain medical care or other services.

## What happens if I say yes, but I change my mind later?

You can ask us to stop storing and maintaining your identifiable information and samples at any time. However, once we share your information and samples with other researchers, we will not be able to stop them from being used for the types of research described above.

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 samples, but that information and those samples will continue to be used in studies that started before you changed your mind.

If you change your mind, your identifiable information and samples can still be de-identified and uses for future research. ***[ or replace with “will not use your identified or de-identified information and samples for future research” if applicable]***.

## Is there any way being in this study could be bad for me?

We are asking to use your information and samples that have already been collected for other reasons. As part of this [registry/repository], we will not be conducting additional procedures physical procedures on you. The primary risks for the storage, maintenance, and research use of your information and biospecimens are those associated with maintaining confidentiality. [Describe each of the following risks, if appropriate as they relate to a breach of confidentiality. If known, describe the probability and magnitude of the risk.]

* [Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks]

Another risk is that your identifiable information or samples could be used in a research study 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.

## Will being in this study help me any way?

You will not personally benefit by agreeing to this broad consent. Research with your identifiable information and samples 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.

## What else do I need to know?

Your information and samples (both identifiable and de-identified) 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 replace with plans when using identifiable information/samples] to tell you, or to pay you, or to give any compensation to you or your family.

[Include for sponsored registry/repository. Otherwise delete.] This research is being funded by [Insert name of sponsor].

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent.]

**Signature Block for Capable Adult**

|  |
| --- |
| Please check one of the following choices:[ ]  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 samples. My participation is voluntary, and I may withdraw at any time without any penalty or loss of benefits to which I am entitled.[ ]  The broad consent has been explained to me, and I **do not agree** to this broad consent. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | IRB Approval Date |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the broad consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Adult Unable to Consent**

Please check one of the following choices:

[ ]  The broad consent has been explained to me, and I agree to give broad consent on behalf of the named subject to the future research uses of his/her identifiable information and identifiable samples. Participation is voluntary, and the subject may withdraw at any time without any penalty or loss of benefits to which s/he is entitled.

[ ]  The broad consent has been explained to me, and I **do not agree** to this broad consent on behalf of the named subject.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | IRB Approval Date |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the broad consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Children**

Please check one of the following choices:

[ ]  The broad consent has been explained to me, and I agree to give broad consent on behalf of the named child to the future research uses of his/her identifiable information and identifiable samples. Participation is voluntary, and I may withdraw at any time without any penalty or loss of benefits to which s/he is entitled.

[ ]  The broad consent has been explained to me, and I **do not agree** to this broad consent on behalf of the named child.

|  |
| --- |
|  |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
|  |  |  |
| Signature of parent |  | Date |
|  |  |
| Printed name of parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

 ***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | IRB Approval Date |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the broad consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |