**INSTRUCTIONS: Please refer to** [***CUNY HRPP Guidance: Suggested Language for***](http://www.cuny.edu/research/compliance/human-subjects-research-1/hrpp-policies-procedures.html)

[***Informed Consent Documents***](http://www.cuny.edu/research/compliance/human-subjects-research-1/hrpp-policies-procedures.html) **for specific language suggestions.** Information provided throughout this form must be presented in sufficient detail relating to the

research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilities the prospective subject’s understanding of the reasons why one might or might not want to participate.

**THE CITY UNIVERSITY OF NEW YORK**

*<Insert name of PI’s Affiliated CUNY College>*

*<insert name of PI’s Department>*

**BROAD CONSENT FOR FUTURE RESEARCH USES OF IDENTIFIABLE PRIVATE**

**INFORMATION and/or IDENTIFIABLE BIOSPECIMENS**

|  |  |
| --- | --- |
| **Title of Repository:** | <enter title of repository, biobank, database, institutional department/division holding information or biospecimens here> |
| **Principal Investigator:** | <enter name and degree(s) of PI here> |
|  | <enter CUNY title of PI here> |

**Introduction: Research with Identifiable Private Information and/or Biospecimens:** The rules for how identifiable private information and/or biospecimens originally collected for one purpose can be used for future research depend on whether the identifiable private information and/or 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 identifiable private information and/or biospecimens, we say they are “deidentified.” Federal regulations and state laws allow researchers to use de-identified personal information and/or biospecimens without asking anyone for permission. This has been true for a long time, and research with de-identified information and/or biospecimens has advanced science and benefited society in many ways.

When your private information and/or biospecimens can still be linked to you, we say they are “identified” or “identifiable.” Sometimes, it is important for researchers to use identifiable private information and/or identifiable biospecimens because these allow researchers to put together a lot of information about a person, which may be necessary to answer difficult research questions. However, research with identifiable private information and/or 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 allow your identifiable private information and/or identifiable biospecimens to be used in different types of research studies in the future, **this is called “broad consent,” and it is what we are asking you to agree to in this form.**

**Purpose:**

We are asking you to make an important choice about the use of your identifiable private information and/or identifiable biospecimens. We are asking you to decide if you are willing to give your broad consent now to the future research use of your identifiable private information and/or identifiable biospecimens.

If you give your or broad consent, researchers may use your identifiable private information and/or identifiable biospecimens in many different research studies in the future, over a long period of time, without asking your permission again for any specific research study.

If you do not give your broad consent, researchers in most cases will have to ask your permission to use your identifiable private information and/or identifiable biospecimens in any future research study.

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.

If you give your broad consent, <Name of Repository/Biobank/Institution/Institutional Department or Division> will store, use and/or share your identifiable private information and/or identifiable biospecimens for research now and in the future, for as long as they are needed for this purpose <or specify a shorter period>.

If you give your broad consent in this form, we may share your identifiable private information and/or identifiable biospecimens with other researchers and research institutions, including academic institutions, government agencies, private companies and nonprofit organizations.

**Types of research:**

If you give your broad consent in this form, we may use your identifiable private information and/or identifiable biospecimens for many different types of research. We cannot tell you about any of the specific research that will be done with your identifiable private information and/or identifiable biospecimens because we do not know for sure what these might be at this time. Possible future research may include, for example:

**[List any specific types of research areas for which the information or biospecimens may be used]**

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

**Potential Risks:**

The main risk in giving broad consent 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 private information and/or identifiable biospecimen will go to someone who should not get it is very small.

Another risk is that your identifiable private information and/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.

**Potential Benefits:**

You will not personally benefit from giving broad consent in this form. Research with your identifiable private information and/or identifiable biospecimens may benefit our society by helping us advance scientific knowledge.

**Alternatives to this Broad Consent:**

You are free to choose whether to give broad consent to the use of your identifiable private information and/or identifiable biospecimens. Your broad consent is voluntary. Even if you do not allow your identifiable private information and/or your identifiable biospecimens to be stored, used, and/or shared for future research, you will not lose any benefits to which you are otherwise entitled, and saying no will not change your relationship with CUNY.

**Withdrawal of Consent:**

If you give broad consent 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 private information and/or identifiable biospecimens. However, your identifiable private information and/or identifiable biospecimens will continue to be used in studies that started before you changed your mind. If your identifiable private information and/or 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/or biospecimens and use them in the future> OR <will not use your identified or de-identified information and/or biospecimens for future research>.

**Cost**

There are no current or future costs to you, regardless of your decision.

**Payment or Compensation for Participation:**

If you give broad consent, your identifiable private information and/or 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.

Regardless of whether you give broad consent, or whether you don’t respond at all, if your de-identified information and/or de-identified biospecimens are used to create products or deliver services, there are no plans to pay you or give any compensation to you or your family.

**New Information:**

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 private information and/or identifiable biospecimens, and there are no plans to give you any results from these studies.

If future research with your identifiable private information and/or identifiable biospecimens gives results that may be beneficial to you, the researchers may – but are not required to – contact you to let you know what they have found.

**Options for Responding to this Request for Broad Consent:**

On the checklist at the end of this form, please indicate if you would permit the researchers to store and/or share your identifiable private information and/or identifiable biospecimens for future research by putting your initials next to one of the three options provided.

If you make a definite and clear choice in 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 private information and/or identifiable biospecimens. Not giving any answer will also have implications, as described below.

If you do not choose any of the options provided below, or if you do not return a completed copy of this form, then it will be the same as if you were never asked to make a choice. This means that your identifiable private information and/or identifiable biospecimens may be used for future research if:

* The researchers contact you in the future to ask your permission to use your identifiable private information and/or identifiable biospecimens in a specific research study, and you agree.

* An institutional review board (IRB), which is a body that reviews research from an ethical perspective, allows your identifiable information and/or identifiable biospecimens to be used in a study that is low risk to you without asking for your consent.

* Another legal exception applies.

Please note that, if we remove your identifying information from the private information and/or biospecimens, we may use your de-identified information and/or biospecimens for any future research or other purpose without your permission.

**Questions, Comments or Concerns:**

If you have any questions about 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.

If you have questions about your rights as a research participant, or you have comments or concerns that you would like to discuss with someone other than the researchers, please call CUNY’s Senior Research Compliance Administrator at 646-664-8918 or email HRPP@cuny.edu. Alternatively, you may write to:

CUNY Office of Research

Attn: Senior Research Compliance Administrator

205 East 42nd Street

New York, NY 10017

**Participant Decision and Signature:**

\_\_\_\_\_\_ I agree to allow my identifiable private information and/or identifiable biospecimens to be stored and used for the kinds of future research described in this broad consent form by CUNY researchers ONLY, without anyone asking my permission for each new study.

\_\_\_\_\_\_ I agree to allow my identifiable private information and/or identifiable biospecimens to be stored, shared with researchers outside CUNY, and used for the kinds of future research described in this broad consent form by CUNY researchers AND other researchers, without anyone asking my permission for each new study.

\_\_\_\_\_\_\_ I do not agree to the researchers at or outside CUNY storing, using or sharing my identifiable private information and/or identifiable biospecimens for the research described in this broad consent form.

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| Signature of Participant      **Signature of Individual Obtaining Consent** |  | Date |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name of Individual Obtaining Consent |  |  | | |
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| Signature of Individual Obtaining Consent |  | Date | | |