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## **Broad Consent for Storage and Future Research Uses of Identifiable Information and Identifiable Biospecimens**

**IRB Approval Date: xx/xx/xxxx**

**Principal Investigator:**

**IRB Protocol #:**

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[Suggested language]

### **Introduction**

Research using personal health, social or behavioral information, and biospecimens has led to important advances in science, social service, legal provisions, 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 a multi-purpose survey you completed for children's services to support decision making 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 health records– 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 individuals and society 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 researchers, because it allows them to put together a lot of information about a person and understand even more about health, social and behavioral conditions and if and how treatments or interventions 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, this is called “broad consent,” and it is what we are asking you to agree to in this form.

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## 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 in order to advance knowledge in science and services.

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

Remember, this form applies only to research with identifiable information and identifiable biospecimens. Researchers can always use de-identified health information and de-identified biospecimens for research. If you were to provide broad consent now but later you withdraw it, investigators may continue to use your collected and stored data and biospecimens so long as the data and biospecimens have been subsequently stripped of identifiers so as to not be subject to the human subjects regulations or state privacy laws.

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?

**Suggested Language:** If you say “yes” in this form, [Name of School of Social Service Administration or Chapin Hall, Center for Children] will store, use and share your identifiable information and/or identifiable biospecimens, and may do so for the purpose of future research studies 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?

**Required Element:** A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient

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information such that a reasonable person would expect that the Broad Consent would permit the types of research conducted and the way subjects' information will be used if they agree to have their data stored and used for future secondary research studies.

Example:

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....
- Developing and testing methods to analyze.....
- Whole genome sequencing (meaning that your entire personal genetic code will be identified)....
- If you might share videotapes, then detail how you should make that clear.
- Add here any statements required by applicable state law to conduct research in applicable areas.

**Required Element:** Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies

Example:

- List any types of known research activities not covered by the above list.

## How long will my identifiable information be Stored?

**Required Element:** A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).

## Are There Risks of Harm?

**Required Element:** A description of any reasonably foreseeable risks to the subject.

Examples:

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.

AND/OR

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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.

### **How will my data be kept confidentiality?**

**Required Element:** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

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

Example:

*Your data will remain confidential during storage, maintenance and future uses.... Access to data will be limited to staff whose duties specifically require access to such data in the performance of their assigned duties and consistent with the secure methods to transmit and store data in accordance with the data security requirements at the University [or Chain Hall]. State who will be the gatekeeper of the data and responsible for the secure environment.*

### **Are There Any Benefits?**

**Required Element:** A description of any benefits to the subject or to others that may reasonably be expected from future secondary research studies.

Examples:

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 ...; *however, these studies will be designed to learn more about [insert purpose/topic of study].*

**OR**

*The possible benefits to you from future studies include...*

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

**Required Element:** A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

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 any service or existing relationship to which you are otherwise entitled, and saying “no” will not change your

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relationship with your social service, university professors or 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.

**Required Element:** A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

**Required Element:** When appropriate, a statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

**Required Element:** When appropriate, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);

**Required Element:** Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject.

**Required Element:** An explanation of whom to contact for answers to questions about the subject’s rights and about storage and use of the subject’s identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Example:

Who can I contact if I have questions or concerns about providing a broad consent? If you have questions, you are free to ask them now. If you have questions later, you may contact the principal investigator at [\[add your contact information, including name, telephone number, and email address\]](#).

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If you have any questions about your rights as a participant in this research, you can contact the following office: School of Social Service Administration and Chapin Hall Institutional Review Board

University of Chicago

969 East 60th Street

Chicago, Illinois 60637

Telephone: (773) 834-0402

Email: [ssairb@uchicago.edu](mailto:ssairb@uchicago.edu)

## 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 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.

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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:

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- 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.

[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.

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Your Printed Name

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Legally Authorized Representative's Printed Name (if applicable)

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Your Signature or Signature of Legally Authorized Representative

#### 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

I am a *[faculty member]* at the University of Chicago, in the School of Social Service Administration *[or Chapin Hall Center for Children]*. I am asking for your consent to store and use your identifiable research data for future secondary research projects.

#### 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

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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.