CONSENT FORM GUIDELINES

The following consent form template is only for use in creating a consent form to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information and/or identifiable biospecimens. Please insert the details that are specific to your study. Additionally, here are some tips for creating the consent form:

* Keep the language simple. Consent forms should be written at an 8th grade reading level or below. Avoid use of technical terms. When using acronyms or abbreviations, spell out the full meaning the first time they are used.
* Compose the consent form to speak to the participants, not about them. For example, “You will be asked to…” instead of “The participant will be asked to…”
* The title of the study on the consent form need not match the title of the study in the project outline form. Sometimes it is warranted to use a simpler title for the consent form.
* Most sections are required. However, you may remove the compensation section if no compensation is offered to participants. You may remove the “Where Applicable” section if the conditions do not apply.
* To see templates for other consent form models (parental consent, online, etc.), please check the website at [www.ohio.edu/research/compliance](http://www.ohio.edu/research/compliance).
* If the researcher is a student, please include the researcher and advisor’s contact information in the contact information section, and identify the advisor as such.
* Include a version date at the very end of the consent form. If revisions are requested by the board, update the version date when requested revisions are made.

 Ohio University Adult Broad Consent Form

Title of Research:

Researchers:

IRB number:

You are being asked by an Ohio University researcher to provide broad consent for the storage, maintenance, and secondary research use of your identifiable private information and/or your identifiable biospecimens. For you to be able to decide whether you want to participate, you should understand what type(s) of research may be performed, as well as the possible risks and benefits in order to make an informed decision. This process is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks of storage, maintenance, and secondary research use of your identifiable private information / biospecimens. It also explains how your personal information and/or biospecimens will be used and protected. Once you have read this form and your questions about the storage, maintenance, and secondary research use of your identifiable private information and/or biospecimens are answered, you will be asked to provide broad consent. You should receive a copy of this document to take with you.

# Summary of Study

 ***[Provide a concise, focused summary of the research and include key information to assist a potential participant in understanding why one may or may not want to provide their broad consent. This section should be organized and presented in a way that facilitates comprehension.]***

# Explanation of Type(s) of Specified Future Research

***[Use this section to describe either a particular type of specified research or a wider scope of research to be performed in the future. This section must include sufficient information to allow a reasonable person to know what types of research the broad consent would permit and the types of research to be conducted.]***

**Description of Identifiable Private Information/Biospecimens**

***[Use this section to describe the identifiable private information/biospecimens to be stored, maintained, and used in secondary research. Indicate whether or not the information/biospecimens will be shared with other researchers and what the nature of the secondary institutions and investigations will be.]***

**Length of Storage**

Your identifiable private information/biospecimens will be stored and maintained for a duration of… ***[State if the private information/biospecimens will be stored and maintained indefinitely]***

Your identifiable private information/biospecimens may be used for research purposes for a duration of… ***[State if the private information/biospecimens will be used for research purposes indefinitely]***

## Risks and Discomforts

Risks or discomforts that you might experience are… **OR**

No risks or discomforts are anticipated

## Benefits

This secondary research will be important to science/society because…

Individually, you may benefit… **OR**

You may not benefit, personally by participating in this study.

**Disclosure of Secondary Research Studies**

You will be provided the purpose of and/or details about specific studies that may be conducted using your identifiable private information/biospecimens.

 **OR**

You will not be provided the purpose of and/or details about specific studies that may be conducted using your identifiable personal information/biospecimens. Secondary research may include studies that you would have chosen not to consent to.

**Disclosure of Clinically Relevant Research Results**

You will be provided clinically relevant research results. ***[Indicate under what conditions results will be provided or if results will be provided in all circumstances]***

**OR**

You will not be provided with any research results, including individual research results.

**Where applicable:**

Identifiable or de-identified biospecimens may be used for commercial profit. ***[Indicate whether or not the profit will be shared with the participant]***

## Research with biospecimens will or might include whole genome or exome sequencing. Confidentiality and Records

Your study information will be kept confidential by…

Additionally, while every effort will be made to keep your study-related information confidential, there may be circumstances where this information must be shared with:

 \* Federal agencies, for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research;

 \* Representatives of Ohio University (OU), including the Institutional Review Board, a committee that oversees the research at OU;

 *\* [****Insert sponsors of the research, if any, who will have access to identifiable data/biospecimens]***

**Compensation**

As compensation for your time/effort, you will receive…

Please be aware that certain personal information, such as name, address and social security number, may be provided to the Ohio University Finance Office to document that you received payment for research participation. However, your study data will not be shared with Finance.

**OR**

 No compensation will be provided. ***[Or remove the compensation section completely]***

## Contact Information

 If you have any questions regarding the storage, maintenance, and secondary research use of your identifiable private information and/or your identifiable biospecimens, please contact the investigator ***[insert investigator’s name, email and phone number]*** or the advisor ***[insert advisor’s name, email and phone number]***.

 If you have any questions regarding your rights with the storage, maintenance, and secondary research use of your identifiable private information and/or your identifiable biospecimens, or in the event of research-related harm, please contact the Director of Research Compliance, Ohio University, (740)593-0664 or compliance@ohio.edu.

By agreeing to participate in the storage, maintenance, and secondary research use of your identifiable private information and/or your identifiable biospecimens, you are agreeing that:

* you have read this consent form (or it has been read to you) and have been given the opportunity to ask questions and have them answered;
* you have been informed of potential risks and they have been explained to your satisfaction;
* you understand Ohio University has no funds set aside for any injuries you might receive as a result of participating in this study;
* you are 18 years of age or older;
* your participation in this research is completely voluntary;
* you may leave the study at any time; if you decide to stop participating in the study, there will be no penalty to you and you will not lose any benefits to which you are otherwise entitled.

Signature Date

Printed Name

 Version Date: ***[insert mm/dd/yy]***