CONSENT FORM GUIDELINES

The following template is provided for use in creating the consent form to be signed by participants of your study. Please insert the details that are specific to your study. In addition, following 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 the 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 Statement on Future Use of Identifiable Data section if your research is not collecting identifiable private information/biospecimens.
* 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 investigator is a student, please include the investigator’s 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 Consent Form With Signature

Title of Research:

Researchers:

IRB number:

You are being asked by an Ohio University researcher to participate in research. For you to be able to decide whether you want to participate in this project, you should understand what the project is about, 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 the research project. It also explains how your personal information/biospecimens will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked to sign it. This will allow your participation in this study. 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 participate in the study. This section should be organized and presented in a way that facilitates comprehension.]***

# Explanation of Study

 This study is being done because…

 If you agree to participate, you will be asked to…

 You should not participate in this study if… ***[List exclusionary criteria, if applicable]***

 Your participation in the study will last…

## Risks and Discomforts

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

No risks or discomforts are anticipated.

## Benefits

This study is important to science/society because…

Individually, you may benefit… **OR**

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

## 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 and/or 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]***

**Future Use Statement**

Identifiers might be removed from data/samples collected, and after such removal, the data/samples may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

**OR**

Data/samples collected as part of this research, even if identifiers are removed, will not be used for future research studies.

**AND, 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]***

Clinically relevant research results will be given to the subject. ***[Describe under what conditions this will happen]***

This research will or might include whole genome or exome sequencing of biospecimens.

## Contact Information

 If you have any questions regarding this study, 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 as a research participant, please contact Dr. Chris Hayhow, Director of Research Compliance, Ohio University, (740)593-0664 or hayhow@ohio.edu.

By signing below, 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]***