**BROAD CONSENT FORM FOR FUTURE RESEARCH BEING CONDUCTED UNDER THE AUSPICES OF**

**THE UNIVERSITY OF TULSA**

**INTRODUCTION:** You have had identifiable private information or identifiable bio-specimens collected for non-research purposes or collected for a different research study that [*Insert name(s) and title(s) of the researcher(s)].* [*If a faculty sponsor is involved, also insert faculty mentor name and title*], at The University of Tulsa is asking your permission to let it be stored, maintained and used for the purposes of [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]. This document defines the terms and conditions for consenting to this request.

**[In all sections: Change the language to specify identifiable private information or bio-specimens.]**

**WHAT KIND OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIO-SPECIMENS DO YOU WANT TO STORE, MAINTAIN AND USE IN SECONDARY RESEARCH AND WILL YOU BE SHARING IT WITH OTHER RESEARCHERS OR OTHER RESEARCH INSTITUTIONS?** *[Specifically describe or list the identifiable information or bio-specimens that you want to store/maintain/use for research and what types of researchers or research institutions might conduct research with their data.]*

**WHAT ARE THE TYPES OF RESEARCH THAT MIGHT USE YOUR IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIO-SPECIMENS?** *[Give a brief, general description of the types of research that may be conducted with their data. Include enough information that a reasonable person would expect that this broad consent would permit to cover.]*

**WILL YOU BE GIVEN ANY INFORMATION ABOUT POSSIBLE RESEARCH STUDIES THAT MAY USE YOUR IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIO-SPECIMENS?**  *[\*If the subject or legally authorized representative will be provided details about specific research studies, list them below* **OR** *use the following statement below. ]*

You will not be informed of the details of any specific research studies that might be conducted using your identifiable private information or identifiable bio-specimens, including the purposes of the research. Therefore there may be research studies that use your identifiable data that you might not have otherwise chosen to participate in.

**WILL YOU BE GIVEN ANY RELAVANT CLINICAL RESEARCH RESULTS, INCLUDING YOUR INDIVIDUAL RESEARCH RESULTS?** *[\*If it is known that clinically relevant research results, including individual research results,* ***will be*** *disclosed to the subject in all circumstances, make a statement to that effect* **OR** *use the following statement:]*

You will not be informed of any clinical research results, including any individual clinical research results.

**HOW LONG IS THE RESEARCHER ASKING TO STORE, MAINTAIN AND USE YOUR IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIO-SPECIMENS?** *[Describe the period of time that the identifiable data may be stored, maintained and used for research purposes (which the period of time could be indefinite)]*

* ***What will happen to your identifiable information or bio-specimen after that time period?*** *[Explain if you will destroy it after that time period?* **OR** *Will you remove all identifiers and keep the de-identified data indefinitely?]*

**WHAT POSSIBLE RISKS AND BENEFITS CAN YOU EXPECT FROM ALLOWING THE USE OF YOUR IDENTIFIABLE PRIVATE INFORMATION OR BIOSPECIMEN?** [*Briefly explain any foreseeable risks or any direct or indirect benefits to the participants or others that may reasonably be expected.]*

**DO YOU HAVE TO ALLOW THE STORAGE, MAINTENANCE AND USE OF YOUR IDENTIFIABLE PRIVATE INFORMATION OR BIO-SPECIMENS? WHAT IF YOU AGREE AND LATER CHANGE YOUR MIND?** *[Specify identifiable private information or bio-specimens]*.Your decision to allow for the storage, maintenance and use of your identifiable \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is completely voluntary. Refusal to participate or if you later change your mind and request to no longer allow the storage, maintenance and use of your\_\_\_\_\_\_\_\_\_\_\_\_ , will involve no penalty or loss of benefits to which you are otherwise entitled.

**HOW WILL YOUR IDENTIFIABLE PRIVATE INFORMATION OR BIO-SPECIMENS BE PROTECTED?**

* ***Will researchers assign your data/bio-specimen a research ID code to use instead of your name?*** *State “no” or explain.*
	+ ***If yes, will researchers create a list to link names with your research ID numbers?*** *State “N/A” or explain.*
	+ ***If yes, how will researchers secure the link of names and research ID codes? How long will the link be kept? Who has access? Approx. destroy or de-identify date (removal of any identifying info.)?***  *State “N/A” or explain. Answer each question.*

**CAN YOUR INFORMATION COLLECTED FROM THIS STUDY BE SHARED OR USED BY OTHERS?**

***Pick 1 of the 2 statements below that apply to your study and delete the other.***

 **(1)** Once identifiers (name, address, etc.) are removed from the identifiable private information or identifiable bio-specimens collected for this study, the de-identified information or bio-specimens could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from you or your legally authorized representative.

**Or**

 **(2)** Your identifiable information (name, address, etc.) or identifiable bio-specimens collected for this research study will ***not*** be used or distributed to other investigators for future research studies, even if your identifiers are removed.

**WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS OR IF YOU LATER CHANGE YOUR MIND ABOUT THE STORAGE, MAINTENANCE, AND USE OF YOUR IDENTIFIABLE PRIVATE INFORMATION OR BIO-SPECIMENS?**

You should contact the principal investigator, [Insert name of the PI and contact email address and phone number and (if applicable) add Faculty Mentor name and email address]. \*If you change your mind about the storage, maintenance and use of your identifiable private information or bio-specimen the researcher will only be able to remove your data before the de-identification date of­­­­­­­ **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**.

**WHO CAN ANSWER QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT?**

You should contact researchcompliance@utulsa.edu, 918-631-3310 or the researcher listed above.

**\*[*PARTS OR ALL of this section can be deleted if not applicable to your study*]**

**\*ADDITIONAL ELEMENTS OF INFORMED CONSENT THAT YOU NEED TO KNOW: *[If either of the 2 items below are applicable to your study, you are required to provide additional information below. Delete all items that are not applicable and provide information about any items that are applicable to this study. If neither item is applicable you can delete this whole section titles, “Additional Elements of Informed Consent”.]:***

* A statement that the subject’s bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
* For research involving bio-specimens, 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).

**PARTICIPANT’S RIGHTS**

* You have been given an opportunity to read and discuss the informed consent and ask questions about this study;
* You have been given enough time to consider whether or not you want to participate;
* You have read and understand the terms and conditions and agree to the storage, maintenance, and use of your identifiable private information or identifiable bio-specimens;
* You understand your participation is voluntary and that you may stop participation at any time without penalty.

**Your signature means that you understand your rights listed above and agree to the storage, maintenance, and use of your identifiable private information or identifiable bio-specimens.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant or Legally Authorized Representative Date