University of South Alabama
Informed Consent Boilerplate Language

This document contains language that is required to be in the informed consent by the University of South Alabama. Each section lists the circumstances in which that language is required.

No deletions or modifications can be made to the US/h8 (h)2.9mc0g-2 (eN8SaA g-2 (L004 (u/)Tj 0..h)

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Instructions

This document is a guide for researchers using language that is required to be in the informed consent form. Review each section to see if your study requires that language. If you have any questions about what should be included in the consent form, please contact the Office of Research Compliance and Assurance at 251-460-7573 or 251-460-6308.

Keep in mind the following items when reviewing this document:

blue. It is noted above the language (in black) if that language is an example or mandatory.

cannot be altered in anyway.

red is study specific and must be changed in accordance to your study.

This is not a comprehensive list of everything that needs to be included in an informed consent. Please refer to the templates and checklist provided on the Informed Consent section of the Office of Research Compliance and Assurance website for additional requirements.

IRB Contact Information

Contact information for the IRB of record must be included in the consent form. If utilizing USA IRB as the IRB of Record, the below office name and contact information must be used. The surrounding language is an example and may be altered.

Example Language:

You have rights as a research participant. All research with human participants is reviewed by a committee called the Institutional Review Board (IRB) which works to protect your rights and welfare. If you have questions about your rights, an unresolved question, a concern or complaint about this research you may contact the University of South Alabama IRB office at 251-460-6308, toll-free at 866-511-6509 or via email at irb@southalabama.edu

NIH Certificate of Confidentiality

When a researcher obtains a certificate of confidentiality from NIH, the research subjects must be told about the protections afforded by the certificate and any exceptions to those protections. Below is example language and may be altered.

Example Language:

injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. If you think you have a research related injury, please call your study doctor.

-or-

(Option 3 Sponsor does not pay for injury)
If you are injured by being in this study, treatment is available. The study site and/or your study doctor have not set aside money to pay for treatment of any injury. You and/or your insurance will be billed for the treatment of these injuries. Before you agree to take part in this research study you should find out whether your insurance will cover an injury in this kind of research. You should talk to the study doctor or staff about this. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. If you think you have a research related injury, please call your study doctor.

Biospecimens and Biological Materials

A statement is required re removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

Example Language

The biospecimens (blood, tissue, body fluid, hair, etc.) that are collected from you for this research study will not be used for commercial profit.

A statement is required by regulations to inform the subject if the research using biospecimens will include or might include whole genome sequencing.

Example Language:

Testing done on your biospecimens (blood, tissues, body fluid, hair, etc.) will include genome sequencing. Genome sequencing is a method that figures out the total DNA sequence of a sample at one time. This method means that your genetic material be studied.

Storage of Biological Materials

The following language is required by institutional policy to be included in the consent form if biological specimens will be stored *at the University of South Alabama.* If specimens are being stored at a non-USA location, then this language is not required. This language cannot be altered. Institutional Biosafety Committee review and approval is required.

Required Language:

(Option 1): Researchers will use your specimens to conduct this study. Your specimens will be used only for this study. They will not be shared with other researchers for future research even if all identifying information has been removed. Your samples will be discarded or destroyed once they have been used for the purposes described in this consent.

-or-

(Option 2): Researchers will use your specimens to conduct this study. Once the study is done using your specimens, we may use them for other studies in the future. Future use may include [complete as it applies to your study]

Option 2 Investigator received consulting or other payments:

Payments are made to the University of South Alabama and its affiliates and the funds are used to cover expenses of the study and related academic and research activities of the institution. The investigator, Dr. (full name), personally receives consulting, or other payments from the company which is paying for the study. If you require further information regarding financial arrangements described in this

Federal privacy laws protect the use and release of your identifiable health information, which is called protected health information (PHI). Under these laws, your protected health information cannot be used or disclosed to the research team for this research study unless you give your permission. Study records that identify you will be kept confidential as required by law.

What protected health information will be used or disclosed?
The information that will be used and/or disclosed for this research study includes:

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At anytime, you may cancel this authorization in writing by contacting the principal investigator listed on the first page of the consent form. If you withdraw permission, you will be removed from the study. However, information gathered before the cancellation date may be used if necessary in completing the research study or any follow-up for this study.

Potential for re-disclosure

Your protected health information will not be used or disclosed to any other person or entity, except as required by law. Your PHI may also be disclosed for authorized oversight of this research study by other regulatory agencies or for other research for which use of your PHI has been approved by the Institutional Review Board. Please be aware that once protected health information is disclosed, we are unable to take back anything we have already done or any information we have already shared with f doctors, scientists and community advocates who have the job of making sure the rights and welfare of study participants are protected) are careful to protect your privacy and limit the disclosure of identifying information about you.

Will access to my medical record be limited during the study?

[Remove this section if research is a non-clinical study]

In accordance with the USA Health System Privacy Notice document, you are permitted to obtain access to your protected health information collected or used in this study. However, to maintain the integrity of this research study, you may not have access until the end of the study.

Data Security:

Information about your participation in this study is stored in a computer; we will take the following precautions to protect it from unauthorized disclosure, tampering or damage: