

AUTHORIZATION TO USE AND DISCLOSE INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH PURPOSES

**HIPAA TEMPLATE: Fill-in study specific information in areas shaded grey
Updated, March, 2018**

Purpose

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:

[list the kinds of identifiable health information to be collected for the study such as]:

- *demographic information*
- *test results*
- *medical history*
- *diagnostic and medical procedures*

The results of this research study might be published in medical papers but no information that identifies you as an individual will be published.

*Include specific entities / organizations that will utilize data, but **NOT receive PHI**, such as:*

Organizations that may inspect, evaluate study results, conduct data analysis, and / or copy your research records:

- Governmental agencies in other countries where the study drug may be considered for approval
- Representatives of _____
- People and companies with whom the sponsor works; business partners
- Independent committees

Who will use my protected health information and to whom will it be disclosed?

In addition to the study doctor and the research staff, the following individuals may have access to identifiable information related to your participation in this research study:

List study sponsor(s), funding agency, and/or any collaborators, if applicable.

- *The Food and Drug Administration for the purpose of monitoring the accuracy of the research data, if applicable*
- The University of South Alabama Health System to include *[list applicable locations such as University of South Alabama Medical Center, Children's and Women's Hospital, USA Clinic, etc]*
- Your medical insurance carrier, to the extent required for payment purposes, if applicable.
- The University of South Alabama Research Compliance and Assurance Office may review your protected health information for the purpose of monitoring the appropriate conduct of this research study
- The University of South Alabama Institutional Review Board may review your protected health information as part of its responsibility to protect the rights and welfare of research subjects.
- *WIRB Copernicus Group may review your protected health information as part of its responsibility to protect the rights and welfare of research subjects*

Right to refuse authorization for collection of protected health information

If you decline to provide this authorization, you will not be able to participate in the research study. However, your decision to deny authorization will not affect your future medical care.

Does my authorization expire?

This authorization does not have an expiration date.

Right to withdraw permission to use protected health information

At any time, 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 your permission. However, the research team and the University's Institutional Review Board (a panel of 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:

State here whether you are keeping data on a computer that will identify the subjects in the study. (i.e., research database, spreadsheet) If you are, explain how you are protecting this information. Give details: for example, is the computer in a locked room, is it part of a secured network, is a password required for accessing the system, who has access to the data, etc.