University of South Alabama

Informed Consent Local Context Language

NOTE! Boilerplate template for NCI IRB Submission

January 18, 2022

Contents

Instructions for Consent Document

This document is a guide for researchers regarding the Informed Consent Form used when using the National Cancer Institute Central Institutional Review Board to oversee their study. 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.

The Informed Consent Form for NCI IRB studies can be found on the Cancer Trials Support Network (CTSU) website. **Sites should <u>not</u> make any changes, deletions, or additions to the ICF pulled from CTSU.**

The following sections, if required, should be used as a separate form in which the subject should sign and date the same as the Informed Consent Form.

HIPAA Authorization

Sites should use the information in the ICF and/or the HIPAA template located in CTSU, as applicable, to complete the HIPAA form for their study. Delete the highlighted instructions once you completed that section.

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

HIPAA TEMPLATE: Fill-in study specific information in highlighted areas
DELETE the highlighted instructions

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]:

- *Example:* Name, Address, Medical Record Number
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The results of this research study might be published in medical papers but no information that identifies you as an individual will be published.

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, that are applicable. Compare against the HIPAA Authorization form located in CTSU for each study. If available, it can be generally be located on the Site Registration tab under Documents.:

- 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 *applicable locations that are selected in* **IRBNet Application Part A wizard**
- 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 Sponsor and/or Co-operative Group any company supporting the study drug now or in the future. This would include any organization helping the company with the study
- National Cancer Institute
- The National Cancer Institute Central Institutional Review Board

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, it may no longer be protected and may be shared without 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.

I agree that my protected health information may be used for the purposes described in this form.

Participant Name: _____

Participant Signature: _____ Date: _____

Person Obtaining Consent Name: _____

Person Obtaining Consent Signature:_____ Date: _____

Include one or more lines for the parent/guardian to print, sign, and date if minors will be enrolled. Include a place for a Legally Authorized Representative (LAR) to print, sign, and date if LARs will be used.

Genetic Information Nondiscrimination Act (GINA)

GINA language is required ***only if*** the study will be using or studying genetic material. **Most NCI studies will have this language incorporated into the ICF template**. However, if the language is not present and the study involves genetic material, the site **must** provide the below language to the subject. The site is not permitted to make any changes to the NCI consent form. Therefore, the GINA language must be on a separate form and given to the subject.

Required Language:

There are risks of loss of privacy, getting insured, being employed, and stigmatization (treated badly due to your genetic testing results). There are some protections afforded by the Genetic Information Nondiscrimination Act (GINA). For a detailed listing of protections, please read the GINA information sheet that has been printed for you and that you have received with this consent. You can also find The Genetic Information Nondiscrimination Act at: http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf