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 USA IRB Local Context Language. A study sponsor can request additional language, however, the addition cannot duplicate local language. Furthermore, additions can only be inserted before or after local language. Additions cannot be inserted in between local language paragraphs, sentences, etc.

Table of Contents

Instructions 3
IRB Contact Information 4
NIH Certificate of Confidentiality 4
Research Related Injury 5
Biospecimens and Biological Materials 5
Storage of Biological Materials 6
ClinicalTrials.gov Reporting 7
Drawing as Incentive 7
Reportable Income 7
Source of Funding 7
Conflict of Interest 8
Genetic Information Nondiscrimination Act (GINA) 9
Health Insurance Portability and Accountability Act (HIPAA) 9
Statement for Bill of Rights 11

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:

- Information about that section is in standard, black lettering
- Examples/Mandatory language is provided in blue. It is noted above the language (in black) if that language is an example or mandatory.
- Mandatory language **cannot** be altered in anyway.
- Language in 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 by phone at 251-460-6308 or 866-511-6509 (toll-free), email at irb@southalabama.edu, or via online form using the QR or link below.



https://tinyurl.com/USA-HRPP

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:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you give permission. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. This Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The certificate does not stop disclosures required by the federal Food and Drug Administration. This certificate does not prevent your information from being used for other research if allowed by federal regulations.

Research Related Injury

Language regarding research related injury is **mandatory** for studies greater than minimal risk. Insert the appropriate language from the three examples listed below. These three versions have been approved by the University of South Alabama IRB and should not be altered. Special circumstances may require additional information and must be in a separate paragraph.

Required Language:

(Option 1 – Sponsor pays for injury):
If you are injured by being in this study, treatment is available. The sponsor will pay for any necessary medical costs related to the treatment of your injury. 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.

-or-

(Option 2 – Sponsor pays what insurance does not pay for):
If you are injured by being in this study, treatment is available. Your insurance will be billed for the cost of treatment. The sponsor will pay for any necessary medical costs related to the treatment of your injury due to your taking part in the study and not paid by your insurance or any other payor. 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.

-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** by regulations that the subject's biospecimens (even if identifiers are 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].

INSTRUCTIONS TO SITE: Within option 2, you must inform the participant of the types of research that may be conducted on their biospecimens. While examples may be given (e.g., diabetes, cancer, etc.), being overly specific may limit or restrict your future research on these samples. To avoid necessity of reconsent, any type of future use must be included within the consent form.

-or-

(Option 3): Researchers will use your specimens to conduct this study. Once the study is done using your specimens, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

INSTRUCTIONS TO SITE: Option 3 should only be used if you intend to create a biorepository. Please contact the University of South Alabama IRB office for additional guidance.

ClinicalTrials.gov Reporting

The following language is **required** by federal regulations to be in the consent form if the study is registered with clinicaltrials.gov. Information on what type of studies that require registering with clinicaltrials.gov can be found on the Office of Research Compliance and Assurance's website located here. By law, the language cannot be altered in any way, and must remain a standalone paragraph.

Required language:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Drawing as Incentive

If a drawing is being offered for participation in a study, this paragraph must be completed and inserted into the information sheet or consent. The amount of the incentive should be in accordance with the amount of time the participant will spend volunteering for the research.

Required language:

You will be included in a drawing of _____(amount) by _____ (gift card / check) for the completion of _____ (questionnaire / survey / donation of samples). The likelihood of being chosen is dependent on the number of participants and it is expected that _____ (number of questionnaires) will be completed. The drawing will be conducted _____ (location) in the presence of _____ (advisor / staff member / faculty) on _____ (date/time). You will be contacted by / through _____(phone call / email) if you have been selected.

Reportable Income

You are **required** by University policy to include a statement, if applicable, that explains that any compensation over $2,000 within a calendar year will require a W9 to be completed and will be considered reportable income. This compensation may affect any benefits the participant currently receives. The below language is an example and may be altered.

Example language:

Since you could be compensated over $2,000 within a calendar year, you must complete a W9 form as this will be reportable income. Reportable income could affect any benefits you may be receiving.

Source of Funding

If the study receives funding from an outside entity, the following **required** language must be inserted.

Required language:

The University of South Alabama and/or its affiliates are being paid by [sponsor name] to conduct this research study.

Conflict of Interest

Any conflict of interest by the Investigator should be listed in the consent form. It is not required to use these specific provisions. Language should be modified to fit the specific facts and circumstances.

Example Language:

Option 1 – Investigator owns equity:
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), owns equity (stock) of the company which is paying for this research. If you require further information regarding financial arrangements described in this paragraph, you should discuss the matter with the study doctor, phone number, or you may contact the Director, Office of Research Compliance and Assurance at 251-460-6625.

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 paragraph, you should discuss the matter with the study doctor, phone number, or you may contact the Director, Office of Research Compliance and Assurance at 251-460-6625.

Option 3 – Investigator is inventor of drug/compound/device:
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), is an inventor of [**the drug/compound/device, etc.**], for which a patent may be filed by the institution. If the patent is pursued, based on data from this and other research, royalties and other compensation may be received by the institution and the investigator. Thus, the investigator has a potential financial interest in the outcome of this study. If you require further information regarding financial arrangements described in this paragraph, you should discuss the matter with the study doctor, phone number, or you may contact the Director, Office of Research Compliance and Assurance at 251-460-6625.

Genetic Information Nondiscrimination Act (GINA)

The below language is **mandatory** if your protocol will involve genetic testing. Additionally, you must use the information sheet for the Genetic Information Nondiscrimination Act (GINA) which is located in IRBNet Forms and Templates. This document is a handout in addition to the consent. HHS 45 CFR part 46 (March 2009) allows each institution to revise the GINA law as appropriate based on the nature of the study. Sponsor language is to be removed and replaced with the USA IRB template.

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

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA language is **required** if your protocol will be collecting Personal Health Information in a covered entity. Complete the study and site specific information.

Required Language:

Health Insurance Portability and Accountability Act (HIPAA)

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:

INSTRUCTIONS TO SITE: list the specific identifiable health information (PHI) to be collected for the study.
Example:
o Name
o Address
o Medical Record Number

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:
INSTRUCTIONS TO SITE: 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 [remove if not applicable]
- The Sponsor [insert name]
- The University of South Alabama Health System to include [list applicable locations such as University Hospital, 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.
- WCG IRB may review your protected health information as part of its responsibility to protect the rights and welfare of research subjects [Remove if the study is not being submitted to WCG]

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 in this 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:

INSTRUCTIONS TO SITE: State here whether you are keeping data on a computer that will identify the subjects in the study (i.e., research database, spreadsheet) and explain how this information is being protected. 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.

Statement for Bill of Rights

The Bill of Rights is a separate handout that is given prior to the informed consent process. The Bill of Rights is only required for clinical trials. **This handout is located in IRBNet Forms and Templates and must be provided to the subject**. The below language must be included in the informed consent.

Required Language:

You acknowledge receiving and reading the Medical Research Subject's Bill of Rights.