Informed Consent Form Template Instructions

(This template is for Biomedical or Clinical Research)

Notes to Researchers:

1. Please note that this is a template modified from the : R U O G + H D O W K 2 U J D Q L] D Ethics Research Committee to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. Delete the instruction page prior to IRB submission.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. In this template:
   - x square brackets indicate where specific information is to be inserted
   - x bold lettering indicates sections or wording which should be included
   - x standard lettering is used for explanations to researchers only and **must not be included in your consent forms**.
   - x examples are provided in blue. Some language in blue is mandatory. Instructions for mandatory language is listed in the black standard lettering.

5. When writing the consent form, remember the following:
   - x The consent document is an invitation to participate in a research study that should be composed in second person with complete grammatically correct sentences. Additionally, scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
   - x Language used throughout form should be at the level of a local student of class $6^{th}/8^{th}$
   - x Use reader-friendly formatting so that your document *looks* easy to read (i.e. wide margins and bullet points).
   - x Make sure that a version number and/or date is used

TEMPLATE ON FOLLOWING PAGE

UNIVERSITY OF SOUTH ALABAMA
CONSENT FORM FOR BIOMEDICAL RESEARCH

[Insert title of the study]

[Name of Principal Investigator]
[Name of Organization]
[Address of Organization]
[Contact information of PI]

[Name of Sponsor]

KEY INFORMATION

Per the revised Common Rule, section 45 CFR 46.116(a)(5)(i), requires informed consent to begin with "a concise and focused presentation of the information that a prospective subject or legally authorized representative can reasonably be expected to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research."

This section should include a brief summary of the purpose of the study, study procedures, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study.

Below are examples of language that would be appropriate to begin with in this section. This information is **NOT** required for (i) exempt studies or (ii) consent documents that are four or less pages in length. **If your consent document is four pages or less in length, then you can delete this section.**

Example:
The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of patients with ABC. Participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits to the fitness center three times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. Participants will also be asked to complete a pain diary and have blood draws every 4 weeks throughout the study. Follow-up phone calls from the study team will occur at 4 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months.

The greatest risks of this study include the possibility of injury during the physical therapy program and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

-or-

The purpose of this study is to compare the gastrointestinal (GI) tract in children with Inflammatory Bowel Disease (IBD) and healthy children. The information we learn by doing this

INTRODUCTION

Briefly state who you are and explain that you are inviting them to participate in the research being conducted. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later. It as a federal regulation that you clearly state the study is research and that it is voluntary.

Example:
You are being provided information and are being invited to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask any questions. If you have questions later, you can ask them of me, the study doctor or the staff.

WHAT IS THIS STUDY ABOU

Example:
You will not be given any information about the results of this research study including if you received placebo or XXX

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research. Federal regulations require that the therapies, intervention, procedures, etc. which are experimental are clearly stated. Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Include whether a participant will be at home, in the hospital, or in an outpatient setting.

For randomized studies: explain what randomization is and what treatment is in each arm. List the chance of being placed in each arm.

Example:
You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups similar to flipping a coin. Neither you nor your doctor can choose the group you will be in. You will have an [equal/one in three/etc.] chance of being placed in any group

Before you begin the study:
List tests and procedures as appropriate. Use bulleted format.

Example:
You will need to have the following exams, tests or procedures to find out if you can be in the study.

- Blood draw- approximately 2 tablespoons
- MRI

These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

During the study:
List test and procedures as appropriate. Use bulleted format.

Example:
If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are not part of regular cancer care.

- Ultrasound
- Questionnaire
- Diary entry

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 Biospecimens and Biological Materials:

The following language is **required** by institutional policy to be included in the consent form if biological specimens will be stored

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

- x The Food and Drug Administration for the purpose of monitoring the accuracy of the research data, [remove if not applicable]
- x The Sponsor
- x The University of South Alabama Health System to include [the site will list applicable locations such as Uni Y H U V L W \ + R V S L W D O & K L O G U H Q ¶ V D Q 8 6 $ & O L Q L]F H W F «
- x Your medical insurance carrier, to the extent required for payment purposes, if applicable.
- x 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
- x 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.
- x 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 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

Print Name of Participant

_____

Signature of Participant

_____

Date _____

Print Name of person obtaining consent

_____

Signature of person obtaining consent

_____

Date _____

A copy of this ICF has been provided to the participant.

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness

_____

Signature of witness

_____

Date _____