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 World Health Organization's 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:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and **must not be included in your consent forms**.
   - 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:
   - 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.
   - Language used throughout form should be at the level of a local student of class $6^{th}/8^{th}$
   - Use reader-friendly formatting so that your document *looks* easy to read (i.e. wide margins and bullet points).
   - 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 key information that is most likely 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 comply with presentation/organization of "key information". 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 ≤ 4 pages 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 study may help us to develop some target treatments for GI complications in children with IBD.

Participants in this study will have a blood sample collected and a small piece of tissue removed from their intestine during their clinically scheduled procedure. The comparison of tissue from IBD and healthy children will be done in the laboratory after collection of the tissue. Parents of participating children will also be asked to complete a questionnaire. Your child's participation is complete once the medical record and questionnaire have been reviewed, and the tissue and blood sample have been collected.

There is a risk of bleeding after the tissue from the intestine is removed. Risks of taking the blood sample are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting are also possible.

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

IS MY PARTICPATION VOLUNTARY AND CAN I WITHDRAW?

Indicate clearly that they can choose to participate or not. Explain that they can stop the study at any time and provide instructions on how to notify the research team on their desire to discontinue.

Example:
Your participation in this research is voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for disease Z, and you will be told more at a later time. You may change your mind later and stop participating even if you agreed earlier. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the [drugs or intervention] can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

If applicable, include anticipate circumstances under which the PI without regard to the participant's consent may terminate the patient's involvement.

Example:
You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

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 ABOUT?

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Example:
Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as in the past. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason the research is being done is to find out if the new drug ABX is better than drug XYZ which is currently being used.

Type of Research

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

Example:
This research will involve a single injection in your arm as well as four follow-up visits to the clinic

It is required by regulations to include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the participant and if so, under what conditions.

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

When you are finished taking [drugs or interventions]:
Explain the follow-up tests, procedures, exams, etc. required, including the timing of each and whether they are part of standard cancer care or part of standard care but being performed more often than usual or being tested in this study. Define the length of follow-up.

List tests and procedures as appropriate. Use bulleted format. Omit this section if no tests or procedures are being tested in this study or required for safety monitoring.

Example:
You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body.

- Blood draw- 2 tablespoons
- Questionnaire

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event. Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision. List known risks in bullet format with the percentage of frequency.

Example:
- Swelling 5%
- Rash <1%

As already mentioned, this drug can have some unwanted effects. It is possible that may also cause some new problems not listed. However, you will be followed closely and keep track of any unwanted effects or any problems. Other medicines may be used to decrease the symptoms of the side effects or reactions. Or the use of one or more drugs may be stopped.

Reproductive risks: If appropriate, insert language that cautions against becoming pregnant while on this study.

Example:
The drugs or procedures in this study may harm a fetus or an infant. You should not become pregnant, breastfeed, or cause a pregnancy while on this study. If you are able to become pregnant, you will have a pregnancy test at set times during the study. If sexual activity could

lead to a pregnancy, you and your partner must use contraception while you are in the study. You may also need to use contraception for a period of time after the study. The study team will describe what kind of birth control methods to use and how long to use them. If you think you may be pregnant or may have caused a pregnancy at any time during the study, tell the study staff right away.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

Example:
If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. There may not be any benefit for you but your participation is likely to help find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned. The total number of participants expected to enroll in the study should be listed.

Example:
You are being invited because you are an adult with malaria who attend clinic Z to participate in the research on the new malaria drug. A total of 100 participants will be asked to join this study.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Clearly list what the patient or their insurance will be responsible for. List what, if anything, will be paid for by the Sponsor. State clearly what you will provide the participants with as a result of their participation. You are required by University policy to include a statement, if applicable, that explains that any compensation over $600 within a calendar year will require a W9 to be completed and will be considered reportable income. This compensation may affect any benefits they currently receive.

Example:
You or your insurer will be billed for the costs of any standard medical care you receive during your participation in the study and you will be responsible for any associated co-payments and deductibles. There is a possibility that your medical insurance company may not cover these costs because you are in a research study. If this happens you might have unexpected expenses from being in this study, such as the costs associated with treating side effects.

You will be compensated for time and travel. You will receive $20 at the end of each completed visit for a possible total of $700. Since you could be compensated over $600 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.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

Example:
Talk to your doctor about your choices before you decide if you will take part in this study.

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- An FDA approved drug called XYZ
- Getting no treatment
- If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given…

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

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 for 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.

HOW WILL MY INFORMATION BE PROTECTED?

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician, but would now be available to the entire research team.

Example:
The information that is collected from this research project will be kept confidential. Information about you that will be collected during the research will be stored and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and that information will be stored under lock and key. Information will be shared only with the groups outlined in the **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES** section.

Additionally, the informed consent document must contain a statement about the future use of the subject's identifiable private information and identifiable biospecimens.

Example:
The coded or unidentifiable information collected about you for this research project, including biospecimens (blood, urine, tissue, etc.), may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

-or-

The coded or unidentifiable information collected about you for this research project will not be used or distributed for future research studies.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

List all appropriate contact information.

Example:
Before you decide whether you would like to participate in this study, please ask any questions that come to mind. Later, if you have questions about the study, you can contact [Principal Investigator] at [phone number] or [email address], or [Co-Investigator] at [phone number] or [email address].

WILL I BE TOLD ABOUT ANY NEW INFORMATION?

Include the following language if applicable.

If there are significant new findings during the course of the research that could impact your willingness to continue participating, you will be informed.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Explain the use of the IRB as well as provide the contact information.

Example:
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.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

The following items should be included as applicable to the study.

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. By law, the language cannot be altered in any way, and must remain a standalone paragraph.

Required Language, if applicable:
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.

Source of Funding:
If a member of the study team has a personal financial interest in the outside entity funding the study or other personal financial interests in entities that might reasonably be affected by the research, a financial interests statement is required. The following language must be included, if applicable.

Required Language, if applicable:
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:

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.

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 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 ***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, if applicable:
(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.

Genetics Testing:
The below language is mandatory if your protocol will be dealing with 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.

Required Language, if applicable:
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

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

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, if applicable:

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
o

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
- The University of South Alabama Health System to include [the site will 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 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:

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.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

This section should have a statement similar to the one below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. This section should avoid statements that have "you understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Additionally, **the language around the Bill of Rights is required per institutional policy.** The Bill of Rights is a separate handout that is given prior to the informed consent process. This document can be found in IRBNet Forms and Templates.

You have read the foregoing information, or it has been read to you. You have had the opportunity to ask questions about it and any questions that you have asked have been answered to your satisfaction. You consent voluntarily to participate as a participant in this research.

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

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 _____