**FGCU Signed Informed Consent Form Model Instructions**

Use this model as a guide to write a consent form using language appropriate for your participants.

**How to use the model…**

* Instructional text is highlighted in yellow.
* Sample text is highlighted in green.
* Recommended/suggested text is in red**.** All other text should be edited according to the needs of your study.
* Fill the gray shaded areas in with text; the box will disappear once text is entered.

**When writing your consent form, remember…**

* Adapt the model for your study. The form should be written for the average person, i.e., written below a 9th-grade reading level or at a level you believe is easy to comprehend by your target population.
* Avoid the use of medical terms, jargon and acronyms when possible.
* Use the word “you” when writing to your audience.
* If the sole researcher, use “I” in place of “the researcher”.
* Use the term participant, not subject or patient.
* The consent form should be typed in 11 point font and kept to 2 pages, if possible.

**Before submitting the consent form to the IRB….**

1. **Delete** the instructional text highlighted in yellow.
2. **Delete** all example text highlighted in green.
3. **Change** the **red text** to black**.**
4. **Perform** final word smithing and formatting.
5. **Do not** indicate the consent is draft when submitting the consent form with the IRB application.

Print the first page of the consent form on your College or Department letterhead

**Consent Form**

**Study Title:**

**Sponsor:**       (If applicable)

**Principal Investigator:**      (Must be full-time faculty or staff)

**Co-Investigator(s):**      (If applicable)

You are invited to participate in a research study conducted through Florida Gulf Coast University. You must be age 18 or older to participate in the study. Your participation in this study is voluntary. The University requires that I (we, if team) obtain your signed consent to participate in this study. If applicable, specify that the research is being done as part of a class or for a degree from Florida Gulf Coast University.

Refusal to join the study will not affect any future services you may be eligible to receive from the University add any cooperating agencies in the study.

Study Summary Box this section

The purpose of this study is to      . (1 - 2 sentences) The information we learn from this study may help us      . (Draw from IRB application Section II.A.1 - II.A.3) using language appropriate for your study population)

Participants in this study will      .

Provide a brief, concise (3 – 4 sentences) description of the research including the expected duration of participation, description of research and/or experimental procedures, the time commitment for the research and/or experimental procedures. The information presented in this section will be expanded later in the body of the consent form.

There is a risk of      .(1 - 2 sentences)

If you are interested in learning more about this study, please continue to read below and ask me (the researcher) any questions you have to help you understand the study.

**Purpose of the Study**

The purpose of this study is to       (elaborate on above explanation **or delete** if additional information is not needed)

**Invitation to Participate in Study**

I/We am/are asking you to take part in the study because you      .

(Draw from Section II.C.4. of your IRB application)

Using lay language; explain all technical terms; avoid jargon and acronyms. Include:

* Why the subject is being asked to participate in the study
* If applicable, anticipated circumstance(s) under which the subject's participation may be terminated by the researcher without the subject's consent.
* If applicable, a statement that significant new findings developed during the research, which may relate to the participant’s willingness to continue participation, will be provided.

**Description of your Involvement**

If you join the study, you will be asked to      .

Draw the study procedures from IRB application Section II.G, Protocol)

* Provide a chronological description of the procedures participants will be asked to do. Include:
	+ total duration of their participation (for example, 3 - 20 minute appointments, for a total duration of one hour)
	+ when and where the study will take place
	+ how the sessions will be scheduled and
	+ any drugs, therapies or devices that will be used.
* If applicable, identify which procedure(s) or treatment(s) are experimental.

**Benefits of Participation**

*(Draw from Section II.J of IRB application)*

If no benefit anticipated for participant state

 I (We) do not expect this study to benefit you.

**OR**

If there are possible benefits for participant state…Being in this study might benefit you by

**OR**

If there are potential benefits for others state…

I (We) hope the information we get from this study will help others who      .

**Risks and Discomforts of Participation**

Describe the potential risks and discomforts if one joins the study. Include any foreseeable hazards, inconveniences and risks the participant may undergo, and an estimate of their likelihood it/they will occur to the best of your knowledge. All risks listed in the protocol must appear in the consent form. (Draw from IRB application Section II.I, Risks)

*If more than minimal risk to participant state…* There is a chance of harm if you join the study. The activities you will do may      . I (We) will       to prevent them or minimize them.

**OR**

If minimal risk for participant state…

There is minimal risk involved with this study. I (We) will       to prevent them or minimize them.

**OR**

If no risk for participant state…

There are no known or anticipated risks to you if you join the study.

If appropriate to the study, include a statement that the particular treatment or procedure may involve risks which are currently unforeseeable

**Compensation for Participation**

(Draw participant compensation from IRB application Section II.D.2, Will the participants be paid or receive other compensation such as course credit?)

If no payment for participating in study state…

You will not be paid to take part in this study.

**OR**

If participants will be paid, Include the amount, the type of payment (check/gift card/student credit, etc.), when it will be given and provisions for pro-rating the payment if a participant’s participation is terminated prior to completion of the study. State

You will receive       to thank you for joining this study.

**OR**

There is a potential for you to incur costs for

**AND** if the study is sponsored, modify the following sentence as appropriate.

You will not receive any proceeds, profits, or other benefits from any commercialization that may result from this study.

**Confidentiality**

If you join the study, I (we) will take the following steps to keep your information confidential and secure      . (Draw from IRB application Section II.H, Confidentiality and Data Security) I (We) will not release information about you unless you authorize us to do so or unless we are required to do so by law. If the results of this study are published or presented, no information will be included that would make it possible to identify you as a study participant.

It is possible that organizations responsible for making sure the research is done safely and properly such as the university, and government offices or the study sponsor, [sponsor name(s), if appropriate] may need to see the information you provide.

If the study will be registered as a clinical trial, include

Public Information about this study 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 site will include a summary of the results. You can search this Web site at any time.

**Storage and Future Use of Data**

Include one of the following statements if private information or identifiable biospecimens are collected in the study.

The identifiers might be removed from the personally identifiable information or biospecimens you provided and the de-identified information or biospecimens may be used for future research.

OR

Your information or biospecimens will not be used or distributed for future research studies even if your identifiers are removed from the information or biospecimens you provided for this study.

Include if appropriate for studies in which identifiable biospecimens or genomes are collected

The use of your biospecimens (even if identifiers are removed) and/or genomes (if appropriate) may be used for commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

The principal researcher will or will not disclose clinically relevant research results, including your individual research results to you. (describe when and under what conditions)

This study will include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Voluntary Nature of Study**

Participating in this study is completely voluntary. Refusal to join the study will not affect any future services you may be eligible to receive from the University add any cooperating agencies in the study. You do not have to answer any question you do not want to answer and you can refuse to perform a requested task.

If you choose to join the study, you can leave it at any time with no penalty. If appropriate, (typically a medical or physical therapy) inform the participant, “If you decide to leave the study, please call the primary investigator on the last page so you leave the study in a safe way”.

If you choose to join the study, please sign the last page of this form in front of me (the person who told you about the study). You will get a copy of this form to keep.

**Contact Information for the Study Team**

I/We do not foresee any medical problems from participating in this study. However, if you believe you experienced a research related injury, please contact       at 239-      . Principal Investigator.

If you have any questions about this study, please contact      Principal Investigator at 239-     .

**Contact Information for Questions about Your Rights as a Research Participant**

If you have any questions about your rights as a participant in this study, or if you feel you have been placed at risk, you can contact the Human Subjects' Institutional Review Board through research@fgcu.edu or Sherry Alexander, Office of Research & Sponsored Programs, at sralexander@fgcu.edu.

**Consent**

I have read or had read to me the preceding information describing this study. All of my questions have been answered to my satisfaction. I am 18 years of age or older and freely consent to participate in the study. My decision to participate or to decline participating in this study is completely voluntary. I understand that I am free to withdraw from the study at any time. I am aware of my option to not answer to any questions or perform any tasks I choose.

I understand that it is not possible to identify all potential risks and I believe that reasonable steps have been taken to minimize both the known and potential but unknown risks.

Signature of Study Participant Date

Signature of Witness Date

*The dated approval stamp on this consent form indicates that this project has been reviewed and approved by the Florida Gulf Coast University Institutional Review Board for the Protection of Human Subjects in Research.*