**Consent Form Template** Print 1st page on College/Department Letterhead

Limited instructions shown in ( ) and blue font. Delete these prior to printing.

**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.

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

Study Summary Box this section, provide a concise summary

The purpose of this study is to      . The information we learn from this study may help us      .

Participants in this study will      .There is a risk of      .

If you are interested in learning more about this study, please continue to read below and ask me (or 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** **section** 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      .

**Description of your Involvement**

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

**Benefits of Participation**

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

or

Being in this study might benefit you by

or

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

**Risks and Discomforts of Participation**

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

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

or

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

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

**Compensation for Participation**

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

or

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      . 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 [Clinical Trials.gov](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 the following 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.

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 you choose to join the study, please sign the last page of this form in front of me (or 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-      . If you have any questions about this study, please contact       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.