**On-line 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.

## Online Survey 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.

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 if able to.

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 agree to be part of the research study, you will be asked to complete an online survey about      . We expect the survey will take about       (minutes/hours/sessions/etc.) to complete. The survey can/cannot be completed in more than one session.

**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**

(Draw from IRB application Section II.I, Identify the Risks)

Describe the potential risks and discomforts if participate. Include any foreseeable hazards, inconveniences, and risks the participant may undergo and an estimate of their likelihood it/they will occur so far as you know. All risks listed in the protocol must appear in the consent form.

If more than minimal risk to participant state… There is a chance of harm if you complete the survey. The completion of the survey may      . I will       to prevent them or minimize them.

**OR**

If minimal risk for participant state… Your participation will be kept anonymous. However, working with email or the internet has the risk of compromising privacy, confidentiality, and/or anonymity. Despite this possibility, the risks to your physical, emotional, social, professional, or financial well-being are considered to be 'minimal’ by completing the survey.

(Draw from IRB application Section II.J, Risk to participants vs. benefit of study)

**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 make every effort to keep your information confidential and secure by taking the following steps      . However, despite these safeguards, there is the possibility of hacking or other security breaches that could compromise the confidentiality of the information you provide. Thus, it is important to remember that you are free to decline to answer any question that makes you uncomfortable for any reason.

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 results of this study are published or presented at a professional meeting, 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 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 can choose to not answer an individual question or you may skip any section of the survey by       (clicking “Next” at the bottom of the survey page to move to the next question, etc.)

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 or faculty sponsor on the last page so you leave the study in a safe way”.

**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 subject/participant in this research, 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.

**Statement**:

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 I choose.

I understand that it is not possible to identify all potential risks I believe that reasonable steps have been taken to minimize both the known and potential but unknown risks. The submission of the completed survey is my informed consent to participate in the study.

If you would like a copy of the consent form, print a copy before continuing.

**Instructions on how to signify study participation**

Instruction examples:

**I agree to participate in this survey** [link to survey] **OR** **By clicking on the survey link below** you are consenting to participate in this research survey**.**

http://\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**I do not wish to participate in this survey** [returns to FGCU home page for example] **OR** If you do not wish to participate, click the “x’ in the top corner of your browser to exit.

Thank you for your time.

[Name of Investigator(s)]

 This identification number-- xxxxxxxxxx --is a random number generated by the server that you may use to communicate with the researcher if you wish (for example if there is a problem with the Web pages, or if you have any questions, and do not wish to be identified)