**Parent/Guardian 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**

**Parent/Guardian Informed Consent** Print 1st page on College/Department Letterhead

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

Please read this consent agreement carefully before you decide to have your child participate in the study.

An assent (consent) form for your child is attached. Please review the assent form with your child.

**Study Title:**

**Sponsor:**       **(If applicable)**

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

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

You are being asked to allow your child to participate in a research study conducted through Florida Gulf Coast University. Your child’s participation in this study is voluntary. In order for your child to participate in this study, the University requires that **I (we if team)** obtain your signed consent.

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

A short description of the study follows. Please read it carefully. You can ask me (the researcher) any questions you have to help you understand the study.       can be reached at **(telephone number). I (The researcher)** will also explain the purpose and the nature of the study to your child.

**If the consent will be reviewed in person with the parent or guardian state**

**I (The researcher)** will explain to you in detail the purpose of the study, the procedures to be used, the expected duration or frequency of your child's participation, and the potential benefits and possible risks of participation. You may ask **me (the researcher)** any questions you have to help you understand the study.

**OR** **if the consent will be sent home with the child state**

If you choose to have your child participate in the study, please sign the last page of this form and keep the second copy for your files. If your child agrees to participate, please have **him or her** sign or put a check mark on the attached assent form. Please have your child give the signed parental consent form and assent form to      .

**OR** **if the consent will be reviewed in person with the parent or guardian state**

You will be given a copy of this form to keep. If your child agrees to participate, he/she will sign or put a check mark on the assent form.

If you choose not to allow your child to participate or your child does not want to participate in the study, it will not affect any future services you or your child may be entitled to from the University **add any cooperating agencies in the study**. Anyone who chooses to participate in the study is free to withdraw from the study at any time with no penalty.

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 your child to take part in the study because your child      .

**Description of your Involvement**

If your child joins the study, your child will be asked to

**Benefits of Participation**

**I (We)** do not expect this study to benefit your child directly.

**OR**

Being in this study might benefit your child 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 your child joins the study. The activities your child 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 your child if your child joins 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**

Neither you nor your child will be paid to take part in this study.

**OR**

You **and/or** your child will receive       to thank **you/your** child 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 your child joins the study, **I (we)** will take the following steps to keep your child’s information confidential and secure.

* **Explain the procedures to protect participants’ confidentiality. (Section II.H of the IRB application)**
* **Include the procedures that will be followed to ensure security of the data; including examples of who may have access to research records**

**(Draw from IRB application Section II.H, Confidentiality and Data Security**) I (We) will not release information about you or your child 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 or your child 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 your child provides.

**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 or your child. 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 your child provided and the de-identified information or biospecimens may be used for future research.

**OR**

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

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

The use of your child’s biospecimens (even if identifiers are removed) **and/or genomes (if appropriate)** may be used for commercial profit. Neither you nor your child will be compensated for the use of your child’s samples other than what is described in this consent form.

The principal researcher **will or will not** disclose clinically relevant research results, including your child’s 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**

Your child’s participation in this study is completely voluntary. Your child has the right to refuse to participate in the study even though you give your permission to participate. Your or your child’s decision to not participate in the study will not affect any future services you or your child may be eligible to receive from the University **add any** **cooperating agencies in the study**. If your child joins the study, they can freely refuse to answer any question they do not want to answer and refuse to perform a requested task.

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

If you choose to have your child 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 your child 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 child’s rights as a participant in this research, or if you feel your child has 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 this form and I understand it. I understand that if at any time I or my child become uncomfortable with the study I am free to stop my child's participation. I also understand that it is not possible to identify all potential risks in a study, and I believe that reasonable safeguards have been taken to minimize both the known and potential but unknown risks. I agree to allow my child to participate in the research study described above.

Signature of Parent/Guardian Date

Signature of Parent/Guardian Date

Child’s Name, please print

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

**Assent Form for Children Ages 7 - 12 Print on College/Department Letterhead**

**Study Title:**

I have been told that my mother/father /parent/grandparent/guardian (circle one) said its okay for me to take part in a study about       **(insert a simple statement about your study here, Section II.A.I. through II.A.3)**.

I will be asked to       **(briefly describe the task(s) involved and how long participation will take)**.

I am doing this because I want to. I know that it is okay if I want to stop. I know that I can stop at any time if I want to and nothing will happen to me if I stop.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Child’s Signature (or checkmark)/Date Child’s Name Printed

Witness:

In my judgment, my child understands about the study and agrees to be in the study.

Signature of Parent/Guardian Date

**Assent Form for Children Ages 13 - 17 Print on College/Department Letterhead**

**Study Title:**

I have been informed that my parent(s) or guardian(s) has/have given permission for me to participate in a study to **(insert a simple statement about your study here Section II.A.I. through II.A.3)**.

I will be asked to **(briefly describe the task(s) involved and how long participation will take. Section II.G of IRB application)**.

My participation in this study is voluntary. I know that I can stop at any time if I want to and nothing will happen to me if I stop.

If I do not join the study, it will not affect any future services I may be eligible to receive from the University **(add any cooperating agencies in the study)**.

Minor’s Signature Minor’s Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

Witness:

In my judgment, the minor understands the information in this consent form and agrees to be in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature Date