Informed Consent Template – SIMPLE

Informed consent is required to provide potential subjects or their legally authorized representatives with the information necessary for them to make a decision about participating in research. We recommend the use of this template to create informed consent documents.

This SIMPLE informed consent template should be used only for research that meets the following criteria:

* An initial summary of important information about the research is not required because the research does not involve numerous research procedures that will require more than a 2-3 page consent document
* NIH Certificate of Confidentiality will not be issued for the research
* The PI is not a mandatory abuse reporter or reportable information will not be collected
* The research does not involve the collection of biospecimens or genetic analyses
* The research is not an NIH clinical trial and will not be registered on ClinicalTrials.gov
* There is no financial cost to participants
* There is no conflict of interest for the PI or Stetson University
* The research is not an international study (data collected outside the US)
* The research does not involve interventions to treat or improve a condition or disease
* The research does not involve prisoners, pregnant women, human fetuses, neonates, children, or adults who are not competent to give their consent to participate

Information in the consent document must be organized to facilitate comprehension. Consent documents should be written in plain language, generally at the 8th grade reading level. For information on plain language go to <https://www.plainlanguage.gov>. The reading level can be higher if the target population tends to have a higher literacy rate than the general population.

INSTRUCTIONS

* Text in [brackets] represents information about your study that you must add.
* A backslash indicates that you must make a selection depending on the procedures for your study (e.g., “will/will not” or “I/we”).
* Additional instructions or sample text are provided in boxes.
* Before you upload your consent document to the MentorIRB application, delete this cover page, brackets, boxes, and any sections not relevant to your research. The finished document should reflect what you will give to the subject.
* Save the file as a PDF file and use a file name that clearly identifies type of consent and for which subjects it is intended (e.g., AdultConsent.pdf).

For questions about informed consent, please contact the IRB at [irb@stetson.edu](mailto:irb@stetson.edu).

Adapted by permission from the University of Michigan Health Sciences and Behavioral Sciences IRB

**Consent to be Part of a Research Study**

**Project Title**

[Title of the project]

**Invitation to be Part of a Research Study**

You are invited to participate in a research study. In order to participate, you must be [eligibility criteria; e.g., age, gender, language, etc. – please specify an age minimum of at least 18 years old, otherwise your protocol may require full-board review]. Taking part in this research project is voluntary.

**What is the study about and why are we doing it?**

The purpose of the study is [describe the study purpose, be clear and concise – do not copy from a research proposal].

**What will happen if you take part in this study?**

If you agree to take part in this study, you will be asked to [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)]. We expect this to take about [duration, number of interactions]. [Indicate if information collected will be linked to other data (e.g., research data, protected health information, or administrative data such as US Census data).] Identify any procedures that are experimental in this section. Indicate the approximate number of subjects involved in the research study.

For projects involving the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas that are involved.

If applicable, include a statement about whether clinically relevant research results will be shared with the subject and under what conditions. For example:

“We may learn information about your health/mental health as part of the research. We will/will not share this information with you [how/why not].”

**How could you benefit from this study?**

Although you will not directly benefit from being in this study, others might benefit because [insert details]. **[OR]** You might benefit from being in this study because [insert details].

**What risks might result from being in this study?**

There are some risks you might experience from being in this study. They are [describe specific risks and indicate what the study team will do to minimize those risks]. **[OR]** We don’t believe there are any risks from participating in this research but there may be risks that are unknown.

Primary risks include physical, psychological, or informational risks. For informational risks (e.g., those involving breach of confidentiality), describe what you will do to protect the data during collection, while stored or during transmission of the data in the section below. Psychological risks (e.g., those associated with the completion of a particularly sensitive survey or interview) could be mitigated by providing subjects with contact information for counseling resources.

For research posing more than minimal risk to subjects include the following text:

“Please tell the researchers if you have any injuries or other problems related to your participation in the study.”

**How will we protect your information?**

I/We plan to publish the results of this study. To protect your privacy, I/we will/will not include any information that could directly identify you.

If you wish to use identifying information in a publication or presentation, including photographs, audio or video recordings, include the following, as appropriate:

“The results of this study may be published or presented at a scientific meeting. The researchers will ask for separate written permission to include your name [or pictures, recordings] or other information that could identify you.”

I/We will protect the confidentiality of your research records by [explain]. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**. [OR]** [Describe limitations to confidentiality, if any.]

It is possible that other people may need to see the information we collect about you. These people work for Stetson University, [the study sponsor, if any], or government offices that are responsible for making sure the research is done safely and properly.

**What will happen to the information we collect about you after the study is over?**

I/We will/will not keep your research data to use for [future research or other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project. **[OR]** Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

I/We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.] **[OR]** [We will not share your research data with other investigators.]

Sample text:

“Data collected as part of this research will be provided to the [name] repository for future use by other researchers. This data will not contain information that could directly identify you.”

Note:

If research data kept for future research or shared with other researchers will be directly identifiable, you must use the Broad Consent Form.

**How will we compensate you for being part of the study?**

You will receive [nature and total amount of incentive/compensation] for your participation in this study. [Describe how compensation will be determined if the subject withdraws from the research before the end of the study.]

**Your Participation in this Study is Voluntary**

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time without penalty or loss of benefits to which you are otherwise entitled. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, [provide details about disposition of data]. [Describe anticipated circumstances, if any, under which the subject’s participation may be terminated by the PI without the consent of the subject]. [If applicable, add: “Any significant new findings developed during the course of this research that may affect your willingness to continue your participation will be provided to you.”]

**Contact Information for the Study Team and Questions about the Research**

If you have questions about this research, you may contact**:**

Principal Investigator: [**Name**, **email**, **phone,** credentials, institutional affiliation,]

Co-investigator: [Name, credentials, institutional affiliation]

Faculty Advisor: [Name, credentials, institutional affiliation]

Study Sponsor: [If any]

Name, email, and phone number of the PI above should be in bold font.

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

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Michael Eskenazi

IRB Chair

UNIT 8321

Stetson University

421 N. Woodland Boulevard

DeLand, FL 32723

Email: [irb@stetson.edu](mailto:irb@stetson.edu)

Phone: 386-822-7398

**Your Consent**

Required for projects obtaining a signature only – delete this paragraph for projects that will request a waiver of documentation. The document must be dated by the person signing.

For projects involving a waiver of documentation, include the following statement:

“Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records [or you can print a copy of the document for your records]. If you have any questions about the study later, you can contact the study team using the information provided above.”

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

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Printed Subject Name

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Signature Date

You may also need to obtain dated consent for specific activities when those activities are **optional.** Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:

**Consent to be Audio/Video Recorded**

*I agree to be audio/video recorded.*

**YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_**

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

Signature Date

**Consent to be Contacted for Participation in Future Research**

*I give the researchers permission to keep my contact information and to contact me for future research projects.*

**YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_**

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

Signature Date

**Resources**

Should you feel any distress during or after completing the study, you are encouraged to contact professional help. Stetson students may call Stetson University’s Counseling Center at 386-822-8900. Services at the Counseling Center are free for currently enrolled students. If you are experiencing an mental health crisis, you should contact Volusia County Crisis Response Team at 386-822-8740 or The National Suicide Prevention Lifeline at 800-273-8255, which has trained counselors available 24/7.

Revise the information here as appropriate for your study and add any other relevant resources.

Delete the Stetson Counseling Center information if you are not recruiting participants from Stetson.