Informed Consent Template – LONG

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 document(s).

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. For child assent documents, the reading level and complexity of the information provided should be appropriate for the age level of the child.

Regulations now require that federally-sponsored research projects contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and must include the following:

* Identification of the project as a research study and that participation is voluntary
* Purpose of the research, duration of participation, and a description of research procedures
* Foreseeable risks or discomforts, if any
* Expected benefits to subjects or others, if any
* Alternative procedures or treatments that might benefit the subject (this requirement applies primarily to clinical research)

Many studies have brief consent documents (2 or 3 pages) that meet this new requirement without the need for a separate key information section. However, if your project is complex or involves numerous research procedures, this summary is required for federally-sponsored projects and strongly recommended for all others.

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, ParentalPermission.pdf, etc.).

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**

**Study 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.

**Important Information about the Research Study**

Things you should know:

* The purpose of the study is to [briefly describe study purpose]. If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].
* Risks or discomforts from this research include [briefly describe].
* The study will [description of potential direct benefits to subjects – or no benefits].
* Taking part in this research project is voluntary. You don’t have to participate and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

This section is required only for research projects involving numerous research procedures that will require more than a 2-3 page consent document. Provide a concise and focused summary of key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. Organize information to facilitate comprehension.

**Delete this section if not necessary for the study.**

**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].

If you have used the summary above, provide additional details in this section. Otherwise, begin with this section.

**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]. There may be other risks that are unknown. **[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/biospecimens 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/biospecimens 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.]

**What are the costs to you to be part of the study?**

To participate in the research, you will need to pay for [Indicate what costs, if any, subjects will have to pay].

**Delete this section if not applicable to the study.**

**Who can profit from study results?**

Where a potential Conflict of Interest (COI) for a member of the study team or Stetson University has been identified, subjects must be informed about the nature of the conflict. Examples include:

* Investigators have an ownership, consulting, or similar financial relationship with a sponsor.
* A company or other organization has an ownership or other financial interest in the product or technology under study and might profit or otherwise benefit from the outcome of the study whose product is being studied, particularly if the company/organization is also the sponsor of the study or has a financial interest with the investigators.
* Stetson University may be paid licensing fees for the investigational technology or could be paid in the future.

When a conflict may exist, the IRB may recommend required language to be included in the consent documents.

Sample text:

“[Name of conflicted individual] is a named inventor on patents or patent applications or is the creator of copyrighted material that is licensed or optioned to company name] that will be used in this research. This means [conflicted individual] could gain financially from this study.”

**Delete this section if not applicable to the study.**

**What other choices do I have if I don’t take part in this study?**

For projects that involve an intervention that might treat or improve a condition or a disease, describe alternatives to participation in the research study. These could include intervention or treatment available outside the research context.

Sample text:

“There may be other ways of treating your condition if you don’t wish to be in this research. Check with your health care provider to discuss other options.”

**Delete this section if not applicable to 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.

For international studies list the name, email and phone of the local collaborator, if any, first. Be sure to include the U.S. calling code and exit number for the country of origin. The number will be in the following format: Phone: XXX+1-734-936-0933.

**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

For international studies list information for the local IRB or Ethics Committee, if any, first. Reformat the phone number for international calls as follows: XXX+1-386-822-7287.

**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

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

Signature Date

**Parent or Legally Authorized Representative Permission**

For more than minimal risk research involving children, signature by two parents may be required. Contact the IRB for more information.

**Delete this section if not applicable to the study.**

By signing this document, you are agreeing to [your child’s **OR** the person’s named below] participation 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 for [my child* ***OR*** *the person named below] to take part in this study.*

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Printed Subject Name

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

Printed Parent/Legally Authorized Representative Name and Relationship to Subject

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Signature Date

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

Printed Parent Name and Relationship to Subject (when 2 signatures are required)

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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.