

**INSTRUCTIONS FOR COMPLETING THE**

**INFORMED CONSENT FORM TEMPLATE**

Important - Please review the following as you prepare your document:

* **PLEASE DELETE this instruction page after you have read the information. Please also delete all information in [brackets] and *italics* from the template in the final document. This information is meant only as a guide for researchers in preparation of the document.**
* You are required to include the “Key Information” (Summary) section at the beginning of your Informed Consent Form.
* You should select a font that is easy to read such as Times Roman or Arial and use a font size no smaller than 12 point. Make the font color black in the final document. Separate large blocks of text into paragraphs. Text should line up along the margin.
* The consent document must be written using lay language, at an 8th grade reading level (similar to the level used in popular magazines and newspapers) that is appropriate for the participant population. The following link provides instructions on how to check the reading level in Microsoft Word:
  + <https://support.office.com/en-gb/article/Test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2>
* Do not use language copied from the protocol or a grant proposal; avoid technical jargon. The form should be written as if the investigator and participant are engaged in conversation.
* The use of language in the first-person tense is not permitted (e.g., "I understand that ...") because it can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Therefore, please use second-person language in the document (e.g., “You understand that…”).
  + Note: The only exception is the last paragraph of the informed consent form template (Participant Agreement), which should remain in first-person tense.
* The use of bulleted lists and/or tables may be helpful to explain study procedures, timelines, inclusion/exclusion criteria, etc.
* All pages must contain a 1 inch margin on all sides to allow for sufficient white space and space for the IRB validation stamp.
* All pages must be numbered and should follow the following format “page X of X.”
* When appropriate, write the full name of all acronyms that are mentioned.

Unless otherwise noted all sections of the informed consent form (formatted as shown with proper headings and STU logo) are required. The format of the template should be appropriate for all research studies.



**INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

[Insert Title of Study]

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| --- |
| **SUMMARY INFORMATION**  *(Note: This summarized key information section needs to be included at the beginning of the Consent Form. The information provided in this section must be brief. More detailed information should be provided later on in the respective areas of the Consent Form).*  Things you should know about this study:   * **Purpose:** The purpose of the study is to [very briefly describe study purpose]. * **Procedures**: If you choose to participate, you will be asked to [very briefly explain what the participant will do]. * **Duration:** This will take about [very briefly describe the period of time]. * **Risks**: The main risk or discomfort from this research is [very briefly describe]. * **Benefits:** The main benefit to you from this research is [very briefly describe – or state there are no benefits]. * **Alternatives:** There are no known alternatives available to you other than not taking part in this study. *(Note: if there are alternatives, then please revise the above statement and briefly list the alternatives)* * **Participation:** Taking part in this research project is voluntary.   Please carefully read the entire document before agreeing to participate. |

**PURPOSE OF THE STUDY**

The purpose of this study is to [insert the purpose of the study].

**NUMBER OF STUDY PARTICIPANTS**

If you decide to be in this study, you will be one of [insert the total number of subjects] people in this research study.

**DURATION OF THE STUDY**

Your participation will involve [insert the duration of the study]. *(Please provide the number of hours, days, weeks, months, etc. for participation)*

**PROCEDURES**

If you agree to be in the study, we will ask you to do the following things:

1. [Explain tasks and procedures]. *(Use short sentences with bullet points to describe the tasks in an 8th grade reading level. Subjects should be told about video or audio taping, assignment to study groups, frequency of procedures, etc. Subjects should also be informed if any of the procedures are experimental.)*
2. [Explain tasks and procedures]. *(Use short sentences with bullet points to describe the tasks in an 8th grade reading level. Subjects should be told about video or audio taping, assignment to study groups, frequency of procedures, etc. Subjects should also be informed if any of the procedures are experimental.)*

**RISKS AND/OR DISCOMFORTS**

The study has the following possible risks to you: First, [list the risk]; Second, [list the risk] *(Risk must be explained, including the likelihood of the risk. Please list physical, psychological, societal, or economical risks.)*

**BENEFITS**

The study has the following possible benefits to you: [list the benefit(s)] *(The benefits to the participant must be stated.*  *If there are no benefits to the participants, state that fact here, and then list the benefits.)*

**ALTERNATIVES**

There are no known alternatives available to you other than not taking part in this study *(otherwise, insert information about any alternative procedures or courses of treatment here**, if applicable)*.Any significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you *(required statement only if the study will have more than one measurement or interaction with the participants).*

**CONFIDENTIALITY**

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the Principal Investigator and Co-Principal Investigator will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

The research records will be stored in a locked container or on password protected electronic storage devices (computers, USB drives, or the cloud). The records will be kept for seven (7) years and then shredded or permanently deleted from electronic storage devices.

[Explain any additional confidentiality procedures here].

The U.S. Department of Health and Human Services (DHHS) may request to review and obtain copies of your records *(required statement if the project is HHS funded or is seeking HHS funds).* The Food and Drug Administration (FDA) may request to review and obtain copies of your records *(required statement if the project falls under Food and Drug Administration regulations).*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at anytime. *(Include this paragraph only if the project is a clinical trial).*

**USE OF YOUR INFORMATION**

*Note: If the study involves the use of identifiable private information and/or biospecimens, then you will be required to include one of the following two statements:*

* Identifiers about you might be removed from the identifiable private information [and/or identifiable biospecimens – if applicable] and that, after such removal, the information [and/or biospecimens – if applicable] could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative; or
* Your information [and/or biospecimens – if applicable] collected as part of the research will not be used or distributed for future research studies even if identifiers are removed.

*Note: If the study involves the use of biospecimens (even if identifiers are removed), then include the following additional statements (if applicable to your particular research project):*

* Your biospecimens may be used for commercial profit and you will *(or will not)* share in this commercial profit.
* The researcher will *(or might)* 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).

**COMPENSATION & COSTS**

You will receive a payment of [include payment or reimbursement information here] for your participation. *(If subjects receive class points or some other token, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdraw. If there is no compensation provided to the subject, state that fact here.)* There are no costs to you for participating in this study. (*If costs are associated, please state them here).*

**MEDICAL TREATMENT**

*(Note: This section is required if the study will have more than a minimal risk for illness, injury or accident due to participation in this research).*

Routinely, STU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

**RIGHT TO DECLINE OR WITHDRAW**

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

**RESEARCHER CONTACT INFORMATION**

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact [name of principal investigator] at [location], [phone number], [e-mail address].

**IRB CONTACT INFORMATION**

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the STU Institutional Review Board Chair by phone at 305-628-6576 or by email at irb@stu.edu.

**PARTICIPANT AGREEMENT**

*(Use this section if the study uses only online data collection tools, i.e. online surveys).*

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. By clicking on the “I Agree to Participate” button below I am providing my informed consent.

***(Insert “I Agree to Participate” Button Here on the Website)***

*(Use this section if the study uses face-to-face or a combination of face-to-face and online data collection tools, i.e. face-to-face interviews and online surveys).*

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

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Signature of Participant Date

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Printed Name of Participant

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Name & Signature of Person Obtaining Consent Date