

**Informed Consent Form Template & Instructions**

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.**
* Please include the “Key Information” (Summary) section at the beginning of the Informed Consent Form.
* Please select an easily readable font (e.g. Palatino, Times New Roman, or Arial) and use 12 point font size.
* Please use language consistent with the lowest educational level of the repsondents.
* Please refrain from using technical jargon.
* The use of data collection process bulleted lists and/or tables may be helpful to explain study procedures, timelines, inclusion/exclusion criteria, etc.
* Please include full names of all acronyms mentioned.
* **Please review the completed consent forms to ensure that it is inclusive of the following:**

\_\_description of the project

\_\_statement of right to withdraw

\_\_statement of confidentiality

\_\_explicit statement of consent

\_\_contact information

\_\_statement of risks/benefits

\_\_description of any costs, credits, or payments

\_\_ IRB Training Certificate ([Secured here](https://phrp.nihtraining.com/index.php))

\_\_a line for signature and date

Unless noted otherwise 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]

|  |
| --- |
| **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 the respondent decides to be in this study, he or she will be one of [insert the total number of subjects] participants in this research study.

**DURATION OF THE STUDY**

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

**PROCEDURES**

If the respondent agrees to be in the study, the following will be required:

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**

Participation in the study could lead to the following potential risks for respondents: 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**

Participation in the study will lead to the following benefits for respondents: [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 the respondents 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 respondents’ willingness to continue participation will be provided *(required statement only if the study will have more than one measurement or interaction with the participants).*

**CONFIDENTIALITY**

All respondent data will be coded and presented in aggregate to ensure for confidential. Records will be kept private and will be kept in a secure location, and only key research team personnel will have access. The records will be kept for seven (7) years and then shredded or permanently deleted from electronic storage devices. Any dissemination of data or results stemming from this study will not include any identifiable information.

[Explain any additional confidentiality procedures here].

The U.S. Department of Health and Human Services (DHHS) may request to review and obtain records of this study *(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 records of this study *(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 website will not include identifiable information, but could include a summary of the results. Respondents can access this website at any time. *(Include this paragraph only if the project is a clinical trial).*

**USE OF RESPONDENTS 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:*

* Respondent personal identifiers will be removed from the identifiable private information [and/or identifiable biospecimens – if applicable] and, after such removal, the information [and/or biospecimens – if applicable] can be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the respondent or his or her legally authorized representative; or
* Respondent personal 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):*

* Respondents’ biospecimens may be used for commercial profit and respondents’ 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**

Respondents will receive a payment of [include payment or reimbursement information here] for 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 is no cost to respondents 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).*

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 a respondent becomes ill or injured as a direct result of participating in this study, he or she should contact regular medical provider. If the respondent has insurance, the insurance company may or may not pay for these costs. If the respondent does not have insurance, or if his or her insurance company refuses to pay, he or she 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**

Respondent participation in this study is voluntary. Respondents are free to participate in the study or withdraw consent at any time during the study. Respondents will not lose any benefits, if they decide to withdraw from the study early. The investigator reserves the right to remove respondents without consent at such time that he/she feels it is in the best interest of the study.

**RESEARCHER CONTACT INFORMATION**

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

**IRB CONTACT INFORMATION**

If respondents would like to speak about their rights or ethical concerns regarding this research study, they may contact the STU Institutional Review Board by phone at 786.417.9300 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 had the opportunity to ask any questions 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 had the opportunity to ask any questions 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.

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

Signature of Participant Date

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

Printed Name of Participant

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

Name & Signature of Person Obtaining Consent Date