***INSTRUCTIONS: Delete this section before finalizing your consent form to submit with your IRB protocol application. The language should be modified as appropriate for your study. Provide relevant information in the sections below. Delete/replace italicized directions/guidance (anything in this font color) with information specific to your study, and delete/replace/modify sections that do not apply to your research.***

**More information about required components of a consent form can be found on the IRB website and https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html**

The overarching goal of a consent form and the consent process is to allow participants to make as informed of decision as possible about their voluntary participation in research. **It should be written in the simplest language possible.**

The basic required elements of informed consent can be found in the HHS regulations at [45 CFR 46.116(a)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116). Also see [OHRP Informed Consent Tips](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html).

The regulations require that the following information must be conveyed to each participant regardless of study procedures (any exceptions to this must be approved by the IRB):

* a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental
* a description of any reasonably foreseeable risks or discomforts to the participant
* a description of any benefits to the participant or to others which may reasonably be expected from the research
* a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
* a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
* for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
* an explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research-related injury to the participant
* a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
* If you are collecting identifying information or biospecimens, including names and signatures on consent forms or other intake materials, please describe what will be done with the information, how long it will be stored and for how long (including if/when it will be destroyed), how you will protect privacy/confidentiality

The following are required *only when appropriate* *or applicable* depending on study design, participant population, and level of risk; see: 45 CFR § 46.116(c):

One or more of the following elements of information, *when appropriate*, shall also be provided to each participant or the legally authorized representative:

* A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;
* Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant's or the legally authorized representative's consent;
* Any additional costs to the participant that may result from participation in the [research](https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a69c034e956ff0cc9f47d70b63bdea3b&term_occur=999&term_src=Title:45:Chapter:A:Subchapter:A:Part:46:Subpart:A:46.116);
* The consequences of a participant's decision to withdraw from the [research](https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a69c034e956ff0cc9f47d70b63bdea3b&term_occur=999&term_src=Title:45:Chapter:A:Subchapter:A:Part:46:Subpart:A:46.116) and procedures for orderly termination of participation by the participant;
* A statement that significant new findings developed during the course of the [research](https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a69c034e956ff0cc9f47d70b63bdea3b&term_occur=999&term_src=Title:45:Chapter:A:Subchapter:A:Part:46:Subpart:A:46.116) that may relate to the participant's willingness to continue participation will be provided to the participant;
* The approximate number of participants involved in the study (depending on the sensitivity or identifiable nature of the study, this may help participants decide the risk of identification);
* A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;
* A statement regarding whether clinically relevant [research](https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a69c034e956ff0cc9f47d70b63bdea3b&term_occur=999&term_src=Title:45:Chapter:A:Subchapter:A:Part:46:Subpart:A:46.116) results, including individual [research](https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a69c034e956ff0cc9f47d70b63bdea3b&term_occur=999&term_src=Title:45:Chapter:A:Subchapter:A:Part:46:Subpart:A:46.116) results, will be disclosed to participants, and if so, under what conditions; and
* For [research](https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a69c034e956ff0cc9f47d70b63bdea3b&term_occur=999&term_src=Title:45:Chapter:A:Subchapter:A:Part:46:Subpart:A:46.116) involving biospecimens, whether the [research](https://www.law.cornell.edu/definitions/index.php?width=840&height=800&iframe=true&def_id=a69c034e956ff0cc9f47d70b63bdea3b&term_occur=999&term_src=Title:45:Chapter:A:Subchapter:A:Part:46:Subpart:A:46.116) will (if known) 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).

Not provided here are many of the required elements for biospecimens. If you are collecting such information, please refer to 45 CFR § 46.116 d and e.



**INFORMED CONSENT**

**Title of research**:

**Who is conducting the study:** This study is being completed by \_\_\_\_\_, who is a professor in the Department of \_\_\_\_\_\_\_\_\_ at SUNY Old Westbury. [List names and affiliations]

**Purpose of Study:** *Provide a clear, concise explanation in lay language of the purposes of the research, including prominent use of the term "research." (Note: the IRB can waive this element if the study requires deception. In such cases, a debriefing statement should be used to inform participants at an appropriate time after their involvement in the study).*

**Eligibility**: To participate in this study, you must be 18-60 years old and able to complete this survey in private and in one sitting. [Note that this section is not necessary if you do not have particular inclusion or exclusion criteria]

**What you will be asked to do in the study:** *I/We* will ask you to…

*Explain in simple, non-scientific language what will happen to the participant or what s/he will be asked to do in the study. Describe the participant time commitment for each component, as well as the total time for participation. All procedures listed in the IRB application and funding proposal should be described, and any experimental procedures (interventions, manipulations, treatments) specifically noted.*

**Privacy/Confidentiality/Data Security:** *Explain briefly, and in plain language,**how you will protect the participant’s privacy and/or confidentiality.*

* *De-identification of data*
* *If you will de-identify data with identifiers, or keep identifying information separate from research data ( e.g. signed consent forms kept separate from the survey data and the two will not be connected)*
* *If you plan to keep identifying information with the data, state this here*
* *If you are not planning to collect any identifying information at all (as in anonymous surveys).*
* *Physical security of data/research files*
* *Who will have access to identifying information*
* *How will sensitive data be kept secure in an electronic environment*

*If using Qualtrics, include the following statement:*

We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet. Note: if you are asking sensitive information, please elaborate if you are collecting that information (see below)

*If using another survey vendor to administer online surveys, include the following statement:*

Please note that the survey(s) [is/are] being conducted with the help of [company name], a company not affiliated with SUNY or SUNY Old Westbury and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

***When the research involves e-mail communication, include the following statement:***

Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

***For sensitive research data with identifiers, stored in the cloud or on servers, or transmitted via the internet, consider including the following statement:***

**Data may exist on backups and server logs beyond the timeframe of this research project.**

***OR***

**Your confidentiality will be kept to the degree permitted by the technology being used. We cannot guarantee against interception of data sent via the internet by third parties.**

**Sharing De-identified Data Collected in this Research**

*(****If you may share data without identifiers:*** *We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.)*

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**[Future use of Identifiable Data or Specimens Collected in this Research**

***In addition to the recommended data sharing language, above, if you are collecting identifiable data or identifiable biospecimens, you must include one of the following:***

**Identifiers might be removed and the de-identified information or biospecimens used for future research without additional consent.**

**OR**

**Identifiable information might be used for future research with obtaining your consent.**

**OR**

**Your information or biospecimens will not be used or distributed for future research studies.]**

**Risks:**

***In simple, non-scientific and plain language, describe any reasonably possible risks or discomforts:***

* ***Legal risks (e.g., possibility of discovering activities that may require reporting to authorities, possibility of being arrested)***
* ***Physical risks (e.g., nausea, muscle aches, rashes, infection, discomfort, physical irritation)***
* ***Social or economic risks (e.g., loss of confidentiality; effect on financial standing, employability, or insurability)***
* ***Emotional or psychological risks (e.g., feelings of sadness or anxiety)***
* ***Confidentiality: steps taken to protect confidentiality, if any. Include whether there are situations in which you would breach confidentiality.***

***\*\*If there are no known or estimated risks, state: I/We do not anticipate any risks from participating in this research.***

**Benefits: *Describe any probable benefits of participation. Be sure to distinguish between a likely direct benefit (e.g., from therapeutic or intervention research) and a possible indirect benefit (e.g., reflecting on an experience may lead to a better understanding of oneself). If there are no direct benefits, indicate that there are none.***

***\*\*Compensation, financial incentives, learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant are not “benefits” and should not be listed here.\*\****

**Incentives/Compensation:** *Indicate whether the participant will receive incentives/compensation or extra credit for being in the study. If participants will not receive any incentives, state this.* ***If students will receive course credit for participation, ways of earning equivalent credit without participating in the research should be described here.***

**Voluntary participation:** *Explain that the participant's involvement is voluntary, the participant may refuse to participate before the study begins, discontinue at any time, or skip any questions/procedures that may make them feel uncomfortable, with no penalty to them possible, participants should be reimbursed for their time and effort.*

*If there is consequence to compensation, that must be explicitly stated, and that consequence must be reasonable and proportionate (e.g., terminating halfway through results in half of the payment). If completing all research materials (e.g., answering all survey or interview questions; meeting a minimal requirement of entries in a weekly/monthly log) is required for participation, you must make this condition clear to them here. Some crowd-sourcing services may prohibit partial compensation; though this is allowable, it is discouraged to oblige. Consequences to academic standing, record, or relationship with the university or other organization or service that may be involved with the research are prohibited. State that people can choose not to participate if they are uncomfortable with these*

**Right to withdraw from the study:** Taking part in this study is voluntary. You can stop at any time by exiting the survey and closing your web browser. [Withdrawal or refusal to participate will not result in any penalty. Anonymous responses cannot be withdrawn from the study because we will not be able to link the data back to you.] *statements such as these are required but can/should be tailored to your study design. It is possible to combine this and the voluntary participation section above, as long as the information is clear.*

**If you have questions**

***Explain how the participant can contact you with questions or concerns. A standard statement follows:***

The main researcher conducting this study is *[principal investigator’s name]*, a *[professor, graduate/undergraduate student, etc.]* at SUNY Old Westbury. Please ask any questions you have now. If you have questions later, you may contact *[principal investigator’s name]* at *[email address]* or at *[phone number]*.

The Institutional Review Board (the ethical oversight committee for research with humans) at SUNY College at Old Westbury has approved this research activity. If you have any questions, please contact the Old Westbury Institutional Review Board, at IRB@oldwestbury.edu.

**Online Participant consent example**: I confirm that I am at least 18 years old, I agree to participate in this research study, and that I know that participation is voluntary. Please select “Yes” below to continue or you may exit now.

**Statement of Consent *(Include only if you are using signed, written consent.* *Signed consent may not be necessary for most minimal risk social and behavioral research****, and you can instead request a waiver of documentation of consent.*

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature Date

Your Name (printed)

Signature of person obtaining consent Date

Printed name of person obtaining consent

This consent form will be kept by the researcher for five years beyond the end of the study.

If you are using biospecimens or if this is part of a clinical trial, see the information on the following pages.

**Information about use of your biospecimens**

***If you are collecting biospecimens, you must include the following:***

**Specimens collected from you for this study and/or information derived from your specimens *will/may/will not* be used to generate commercial profit. You will/will not share in any commercial value or other compensation from products developed using these specimens.**

***If clinically-relevant research results may be generated, you must include this statement:* You *will/will not* receive any clinically relevant results discovered about you and/or the general participant population.**

***If your study may involve whole genome sequencing, include this statement:* This research *may/will* include whole genome sequencing.**

**Clinical Trial**

***If the IRB informs you that the study is a “clinical trial,” you must include language such as the following, identifying the study as a clinical trial and stating that the study will be listed on ClinicalTrials.gov. For NIH-funded trials this is required; for all others this is strongly suggested:* This study is classified as a clinical trial and will be registered online at http://www.ClinicalTrials.gov. The website will not include any information that can identify you, but will include a summary of results once the research is completed. You can search this publicly-available website at any time.**