

Instructions for Completing the Consent Form Template

(Adapted from UCONN IRB, used with permission)

Updated August 2024

IMPORTANT - Please review the following as you prepare the consent form:

- **DELETE this instruction page and all information in [brackets] from the template in the final document. This information is meant only as a guide for researchers in preparation of the document. Unless otherwise noted, through the use of required and suggested statements, the text within each section may be revised to be appropriate for your study. The required and suggested statements are given in quotation marks to make it easier for you to locate where the statements begin and end. Please DELETE all quotation marks when incorporating these statements.**
- You should select a font that is easy to read such as Times Roman , Arial, or Calibri and use a font size no smaller than 12 point. Make the font one color in the final document. Separate large blocks of text into paragraphs. Text should line up along the left 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. A 5th grade reading level should be used as a benchmark for incarcerated participants. It must also be written in the second person (e.g., *you* are invited to participate, *you* will be asked, etc.). 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 bulleted lists and/or tables may be helpful to explain study procedures, timelines, inclusion/exclusion criteria, etc.
- Consent form pages must be numbered and should follow the following format “page X of X.” When amending the consent form include the revision date in the footer.
- When appropriate, write the full name of the study sponsor (e.g. National Institutes of Health, National Institute of Mental Health).

Unless otherwise noted all sections of the consent form (formatted as shown with proper headings) are **required**. The format of the template is appropriate for most research studies. If you feel that the format of the consent template would not be appropriate for your study, please contact the chair of the IRB at irb@hartford.edu to propose an alternative format.

UNIVERSITY OF HARTFORD

Consent for Participation in a Research Study

Principal Investigator:

Student Researcher: [Remove if there are no students involved in the project]

Study Title: [should be in language the subject can understand without use of discipline specific or technical research jargon]

Sponsor: [Remove if there is no sponsor for the research]

Overview of the Research

[Investigators are responsible for developing/providing this overview section which must include a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the consent must be organized and presented in a way that facilitates comprehension. In general this section should include concise statements that touch on the following: 1) that consent is being sought for research and participation is voluntary 2) the purpose of research, expected duration of participation and procedures to be followed 3) reasonable foreseeable risks or discomforts to the prospective participant, the potential for benefits to the prospective participant or to others that may reasonably be expected from the research; appropriate alternatives procedures or courses of treatment, if any, that might be advantageous to the prospective participant.]

[**Required statement to begin this section.**] “You are being asked to provide consent to participate in a research study. Participation is voluntary.” [then continue with the following **suggested statement:** You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.”]

[**Required statement describing purpose of research.**] “The purpose of this research is XXX ...”

[**Required statement describing duration of participation.**] “Participation will involve approximately XX minutes/hours of your time per/XXXX over the next XX weeks/months/years.”

[Required statement describing procedures to be followed.] “You will be asked to **[describe research methods** e.g. complete surveys about XXX, be interviewed about XXX, be in a focus group about XXX with XXX, provide a blood sample, complete physical testing, etc.]

[Required statement describing risks or inconveniences.] “The principal risk of XXX is XXX. The most common risks of XXX are XXX.” **[if applicable** “Some of the questions on the surveys or interview may also cause you to feel upset. Risks are described in more detail later in this form.”

[Required statement describing benefits to the participant or others.] “There may also be benefits from participation.” **[Describe potential benefits.]** **[If applicable,** “This research may also result in information that leads to an approved XXX or societal benefit XXX.”]

[Required statement, if applicable to the research and appropriate alternatives are available.] “Before making a decision about whether to participate in this research you should know that there are other options available to you.” **[Where participants are recruited from a University research participant pool.]** “There are alternate assignments that you may wish to complete.”

“A more detailed description of this research follows.”

Introduction

[Present information in sufficient detail and organize and present the information in a way that does not “merely provide lists of isolated facts, but rather facilitates the prospective participant’s ... understanding of the reasons why one might or might not want to participate.”]

[Required statement to begin section: “You are invited to participate in a research study to ...” then continue with the following **suggested statement:** “You are being asked to participate because you are...”]

Why is this study being done?

[Suggested statement to begin section: “The purpose of this research study is ...” or “We are conducting this research study to”]

[Describe why you are conducting the study. Provide participants with a clear and accurate statement of the scientific purpose and objectives of the research. Use lay terms. DO NOT repeat the study title or the simplified purpose indicated in the summary.]

What are the study procedures? What will I be asked to do?

[**Suggested statement** to begin section: “If you agree to take part in this study, you will be asked to” or “There are two parts to the research study. In the first part you will be asked to ...”]

[Consider use of bullet points or a chart or table if this would increase the participants’ understanding of the procedures]

[Describe the procedures to be used in the study in sequential order. Indicate how long each will take to complete, where each will be conducted, etc. If participants will be screened, describe screening procedures and major inclusion/exclusion criteria.]

[If the research involves questionnaires, surveys or interviews, describe the type of questions that will be asked or the topics covered.]

[Describe where the research will be conducted, when the research will be conducted and how much time (per session and in total) will be required of the participant and whether or not the participant will be contacted in the future.]

[Describe procedures to audio or video record. Inform participants that they will be asked to sign a Photo/Video release form]

[Describe procedures to re-contact participants at a later date, if applicable]

[If the research involves use of deception or incomplete disclosure, insert the following statement: “Some research requires that the full purpose of the study not be explained before you participate. We will give you a full explanation at the end of the study.” Please note: the last sentence can be further customized to say, “We will give you a full explanation as soon as you complete the study.”]

[Describe collection of genetic data. **suggested beginning statement:** Researchers want to learn about the role of genes (or inherited traits) in health and disease. Genetic research may discover genes, find out how genes work, or help researchers learn how to use what we know about genes to treat or prevent disease. In this study...]

What other options are there?

[If this is not a treatment study, this section may not be required. Delete if not appropriate.]

[For research studies that involve students participating for some type of course credit, describe alternatives to earning research related credit (e.g. attend lecture, write a research paper, etc.), if applicable.]

What are the risks or inconveniences of the study?

[Inform the participant of any risks (e.g. physical, emotional, social, employment) as a result of study procedures. Each procedure should be identified and then the associated risks described. Identify immediate and latent risks and list them in appropriate order, from most likely to least likely to occur. *Identify steps taken to minimize risks.* Indicate if there may be unforeseen risks. The use of a table that states procedure, risk, and steps taken to minimize risk may be helpful for this section.]

[Inform the participant of any inconveniences (e.g. the amount of time required to complete procedures, abstention from food, length of time participants may be required to sit or stand) as a result of study procedures.]

[If there are no known risks, then use the following **suggested statement** in this section: “We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study.”]

[Describe risks associated with the collection of genetic data. Including the risk that, even if samples are anonymous, at some time in the future, it may be possible to determine identity using the sample. Risks to family members. Potential loss of confidentiality. Steps taken to minimize risks including what is stated in the Genetic Information Nondiscrimination Act (GINA) document (to be provided to all participants in studies that obtain genetic data). Inform participants that GINA does not “protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.”]

What are the benefits of the study?

[Describe any direct benefits to the participant that may be *reasonably* expected as a result of the research. Describe benefits expected to accrue to the population the participant represents or to society in general (e.g. advancement of knowledge, health benefits to others). DO NOT include payments for participation or other incentives and gifts as a benefit of participation.]

[If participants are not expected to directly benefit, then include the following **statement** for this section: “You may not directly benefit from this research; however, we hope that your participation in the study may ...(describe societal benefits).”]

Will I receive payment for participation? Are there costs to participate?

[If participants will not receive payment and there are no costs, use the following **required statement** to begin the section: “There are no costs and you will not be paid to be in this study.”]

[Describe any cash payment, gifts, etc. to participants, when participants can expect to receive the payment and the method by which compensation will be paid. Include conditions for

partial payment or no payment for early termination. If compensation will be paid in stages, list amount for each stage and the total amount that could be earned for completion of the study.]

[Describe any costs participants may incur (e.g. parking fees).]

[For research studies that involve students, describe the specific amount of course credit participants can earn for their participation and the method by which this is determined.]

How will my personal information be protected?

[Explain procedures to protect participant's privacy and the confidentiality of study records and, if applicable, digital files and recordings. (Please note that privacy pertains to the individual and confidentiality refers to data). If the study involves use of the internet, e-mail, digital record keeping, or digital audio and video recordings, describe procedures to ensure confidentiality of the electronic data (e.g., stand-alone servers, firewalls, etc.). State how long study records will be kept, where they will be kept (consider long-term storage) and who will have access to them. If participants are audio or video recorded, describe who will transcribe or view the recordings. Please note: Federal regulations require records to be retained for at least 3 years after completion of the research. The American Psychological Association requires 5 years of data storage, so keep in mind that this may be applicable to particular research studies if publication in APA forums is desired. Records may be kept indefinitely, as long as the data has been stripped of identifiable information and described as such in the consent form.]

[**SUGGESTED** Statement to begin section (*be sure to describe procedures specific to your study*):
“The following procedures will be used to protect the confidentiality of your data. The researchers will keep all study records (including any codes to your data) locked in a secure location. Research records will be labeled with a code. The code will be derived from a number ***** [insert coding procedures specific to your study (e.g. “sequential 3 digit code)] ***** that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. The master key and any recordings will be destroyed after 3 years. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.” (Please ensure this section is consistent with the study protocol)]

[For all studies, a statement must be included that confidentiality cannot be guaranteed. Insert the following **required statement**, “We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality.” For web-based

research, include the following **required statement**, “We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.”]

[For studies involving focus groups: Please include in the “Confidentiality” section information about the limits to participants’ confidentiality which are presented by participating in a group discussion. e.g., “All participants will be asked to keep what is said during the group discussion between the participants only. However, complete confidentiality cannot be guaranteed.”]

[If study data are to be released, describe the person(s) or agency to whom information will be furnished, the nature of the information to be furnished, the purpose of the disclosure and whether the participant’s name will be used. This is particularly important for certain vulnerable populations including employees (management access to study data) and student athletes (coaching staff access to study data). For studies involving the use of **supplements, drugs, devices or biologics** (whether marketed or investigational) the consent form must state specifically that the FDA has the right to inspect study records.]

[If de-identified data will be retained indefinitely state so here.]

[Specifically address storage of genetic material – will it be stored anonymously or coded such that the code could be used to link the sample back to the participant. Will the material be shared with internal or external researchers? Will it be anonymized for sharing? How long will the sample be stored? What happens to remaining material? Will the sample be placed in a repository?]

[Describe any situations in which confidentiality cannot be guaranteed]

[If any of the researchers are mandated reporters (ie. health care workers, teachers, etc.), the following statement is **required** when research is conducted with minors – “If, during the course of this research study, a researcher suspects that a minor (under the age of 18) has been abused, neglected, or placed at imminent risk of serious harm, it will be reported directly to the Department of Children and Families (DCF) or a law enforcement agency.”]

[For longitudinal studies, describe what happens to data already collected if the participant decides to withdraw from the study.]

[For applicable clinical trials subject to [FDA regulation](#), and [NIH supported](#) clinical trials, the following specific statement must be included. **Required statement:** “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”]

[The NIH Policy on Dissemination of NIH-funded Clinical Trial Information applies to applications for funding submitted to NIH on or after 1/18/17. NIH defines a clinical trial as a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human participants' biomedical or behavioral status or quality of life. The NIH definition of a clinical trial includes phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g., behavioral interventions.]

[**Required statement** to include last in this section: "You should also know that the University of Hartford IRB and Research Compliance Services may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on your responses or involvement. The IRB is a group of people who review research studies to protect the rights and welfare of research participants."]

Can I stop being in the study and what are my rights?

[**Required statement** to begin section: "You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time for any reason. There are no penalties or consequences of any kind if you decide that you do not want to participate."]

[For interviews, focus groups and surveys, it may be appropriate to inform participants that they are not required to answer each question. Use the following suggested statement: "you do not have to answer any question that you do not want to answer."]

[For certain vulnerable populations it may be necessary to expand upon the "no penalty" statement. For example, if student athletes will be enrolled include a statement indicating that their "standing with the team will not be affected" if they decline to participate. If you are enrolling people receiving medical care or services include a statement indicating that the services they receive through the clinic "will not be taken away or changed" if they decline to participate.]

[Can participants withdraw consent for use and storage of samples? Is there a point at which withdrawal is not possible or feasible?]

Whom do I contact if I have questions about the study?

- [Include the following **required statement** on all consent forms and add contact information as appropriate, "Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this study or if

you have a research-related problem, you may contact the principal investigator, (insert name and phone number) or the student researcher (insert name and phone number). If you have any questions about your rights as a research subject, please contact the University of Hartford Institutional Review Board (IRB) at 860.768.5365. The IRB is a group of people that reviews research studies and protects the rights of people involved in research.”]

[For international studies, rather than provide participants with the IRB Office phone number, give participants the general IRB e-mail address – irb@hartford.edu. Also, if possible, provide a local contact number for the researchers.]

Documentation of Consent:

[Use the following **required statement** and format for this section: “I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.”]

Participant Signature:

Print Name:

Date:

Signature of Person
Obtaining Consent

Print Name:

Date: