**Instructions for Completing the Consent Form Template**

January 2019

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 Garamond 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 margin.
* Avoid widows and orphans. A widow is generally a single line of a paragraph appearing at the top of a page and an orphan is generally a single line of a paragraph appearing at the bottom of a page.
* 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.). The IRB has tips on writing for lay audiences (https://www.kpwashingtonresearch.org/about-us/capabilities/research-communications/prism/) and Microsoft Word has a tool to assess readability. 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.
* All pages must leave 1 inch margins on all sides to allow for sufficient white space and space for the IRB electronic validation.
* 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.
* Students may not be listed as Principal Investigator.
* 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 explain why this is the case in the IRB-1 protocol application at the time of submission and submit an alternative version.

If you have questions concerning use of the template or need assistance preparing the consent form, please contact RCS at 6-8802.

Consent Form for Participation in a Research Study

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**Principal Investigator:**

**Student Researcher:** [Remove if n/a]

**Study Title:**

**Sponsor:** [Remove if n/a]

**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 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**.] “This research is being done to determine if XXX …”

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

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

[**Required statement describing risks or inconveniences**.] “The principal risk of XXX is XXX. The most common risks of XXX are XXX. Because XXX is investigational there may also be risks that are not yet known.”[**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**, “If XXX is effective you may experience an improvement in XXX; but this is not guaranteed and your XXX may decline. 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. There are approved drugs to treat your condition and you should review those options with your doctor.” [**Where participants are recruited from a UConn 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…”]

[For biomedical studies or studies that are more than minimal risk, include the following statement, “This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and to discuss it with your family, friends and doctor. We also encourage you to ask questions now and at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form.”]

[If applicable, disclose any financial relationship the PI or member of the research staff has with the sponsor. Such relationships may include serving as an officer/director, paid consultant, stockholder, or close relative of a stockholder.]

[If genetic testing is included in the study, describe how the testing will help to achieve the study’s goals or why it is necessary]

# 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.]

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

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

[**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 …”]

[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. All experimental procedures must be identified as such.]

[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](https://ovpr.uconn.edu/services/rics/irb/irb-templates/)]

[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.”]

[If applicable, include a statement that 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. If applicable, include a statement about whether clinically relevant research results, including individual research results, will be disclosed to participants. If applicable, include a statement about whether the research project 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)”]

[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 biomedical research, insert the following statement, “Another available option is > **describe as applicable** <. You have the option not to participate in this study. The risks associated with this option are >describe accordingly<. The benefits associated with this option are > **describe as applicable** <. Because we do not know if the treatment we are studying is effective in treating your condition, it is possible that choosing not to participate may be beneficial.”

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

[**Suggested statement** for use of GreenPhire to make payments to participants, “For your participation in this research you will receive a total of [fill in] in the form of a prepaid debit card. The amount of [fill in] will be added to the card at visits [fill in]. In order to issue this prepaid card to you, in addition to your name, we will need to know [fill in accordingly]. This information may be shared with people at this institution responsible for financial compliance. If you receive over $600 in a calendar year from participating in research studies, in the form of gift-cards, cash or checks, that money must be reported to the IRS as income.”]

[If the research may lead to development of a commercial product include the following **required statement**, “This research may lead to the development of a commercial product. This product may have economic benefit to UConn (include sponsor, if applicable). If such a product is developed, UConn (include sponsor, if applicable) do not intend for you to share in the economic benefit.”]

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: Regulations require records to be retained for at least 3 years after completion of the research. 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.”]

[If study data is 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?]

[If there is a possibility for future sharing of non-genetic research data/biological materials with other researchers or sharing of data per NIH & NSF data sharing requirements, insert one of the following two **suggested statements,** as appropriate, 1 - “[Data/biological materials] that we collect from you may be shared with other researchers in the future, linked together with other information such as your age, gender and ethnicity. We will share such information, but we will not give other researchers your name, address or phone number. There will be a code to link your [data/biological materials] with your name and other personal information.” 2 – “[Data/biological materials] that we collect from you may be shared with other researchers in the future, but only after your name and all identifying information have been removed.”]

[If there is a possibility for future sharing of Genomic research data with other researchers, refer to sections 1(c) and 2 for specific, **required**, consent form requirements as described in the NIH Guidance for Institutions Submitting Data Under the [GDS Policy](https://osp.od.nih.gov/scientific-sharing/policies/). Investigators funded by the NIH and who plan to or are required to share data are strongly advised to consult the NIH website for important information concerning [Human Participant and Privacy Issues](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#hs) or [Frequently Asked Questions – Data Sharing](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm#923) before the protocol is submitted for review to the IRB.]

[Describe any situations in which confidentiality cannot be guaranteed]

[UConn employees are mandated reporters, the following statement is **required** when research is conducted with minors – “If, during the course of this research study, a UConn employee 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.”]

[If a Certificate of Confidentiality is required, describe the extra protection (and limits to such protection) that is afforded. Refer to the IRB website for a suggested statement to inform participants of this - http://research.uconn.edu/irb/researcher-guide/informed-consent/]

[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](https://urldefense.proofpoint.com/v2/url?u=https-3A__prsinfo.clinicaltrials.gov_ACT-5FChecklist.pdf&d=DwMFAg&c=EZxp_D7cDnouwj5YEFHgXuSKoUq2zVQZ_7Fw9yfotck&r=f2EfCXh3p_HgCMJNGN62xiKjP0VUVs6AhgtQKvGGjcQ&m=uZAYf10dH1fEfem-7SC3kN0svLCP3FIC0bugYhgdac0&s=2Prai3pz73B6B_9xrHRGo8YFuiHxgNFxzASTIeUlIxw&e=), and [NIH supported](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html) 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 studyin 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. [For questions about ClinicalTrials.gov](https://urldefense.proofpoint.com/v2/url?u=https-3A__research.uconn.edu_rcs_clinicaltrials-2Dgov_requirements_&d=DwMFAg&c=EZxp_D7cDnouwj5YEFHgXuSKoUq2zVQZ_7Fw9yfotck&r=f2EfCXh3p_HgCMJNGN62xiKjP0VUVs6AhgtQKvGGjcQ&m=r_rX66QXvviY7xtaFkBrJFoAOJfZn0SrpUMb9wMEO_k&s=cvnNQHxJMi5Ly3rZfjkyKIA8FEBn7ARwYfaKwsG130M&e=), please contact Ellen Ciesielski (eciesielski@uchc.edu, 860-679-6004) in Research Compliance Services.**]**

[If applicable, include one of two statements about the collection of private information or identifiable biospecimens for future research (either that identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the participant; or, that the participant’s information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.”]

[**Required statement** to include last in this section: “You should also know that the UConn Institutional Review Board (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.”]

What happens if I am injured or sick because I took part in the study?

[Only applicable for studies that present greater than minimal risk to participants. Delete if not applicable.]

[**Required statement** for this section: “In the event you become sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If you require medical care for such sickness or injury, your care will be billed to you or to your insurance company in the same manner as your other medical needs are addressed.

However, if you believe that your illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim with the State of Connecticut Office of Claims Commissioner. For a description of this process, contact Research Compliance Services at the University of Connecticut at 860-486-8802.”]

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 longitudinal, interventional and/or treatment studies the following statement is **required**: “You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.”]

[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 UConn 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 living with HIV through a clinic include a statement indicating that the services they receive through the clinic “will not be taken away or changed” if they decline to participate.]

[If applicable, inform participants that they may be withdrawn from the study at any time. Describe conditions for such a withdrawal (e.g., safety/medical concerns, missed appointments, non-adherence to procedures, disruptive behavior during study procedures, adverse reactions, incarceration, etc.).]

[Can participants withdraw consent for use and storage of samples? Is there a point at which withdrawal is not possible of 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 concerning your rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.”]

[For international studies, rather than provide participants with the IRB Office phone number, give participants the general IRB e-mail address – irb@uconn.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.”]

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Participant Signature: Print Name: Date:

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Signature of Person Print Name: Date:

Obtaining Consent