**Instructions for Completing the Parental Permission Form Template**

January 2019

IMPORTANT - Please review the following as you prepare the Parental Permission 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.**
* **IMPORTANT: If the participant is younger than 7 years old, written assent is not appropriate. If the child is between 7-11 years old and it is appropriate to obtain signed assent, prepare a separate assent form for the participant to sign. If the child is between 12-17 years old, the child signs and dates an assent signature line on the parental permission form and a parent or guardian also signs the form..**
* 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 form 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. It must also be written in the second person (e.g., *your child* is invited to participate). The IRB has tips on writing for lay audiences (<http://www.irb.uconn.edu/wording.html>) and Microsoft Word has a tool to assess readability. DO NOT use language copied from the protocol or a grant proposal and 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 validation stamp.
* Parental permission form pages must be numbered and should follow the following format “page X of X.” When amending the 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 parental permission 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 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 (i.e. a letter containing the elements of consent).

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

Parental Permission 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. ]

[**Suggested statement**. “You are being asked to provide permission to allow your child to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Your child may say yes or no. Your child may change his/her 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.”]

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

[**Suggested statement**. Participation will involve approximately XX hours of your child’s time per/XXXX over the next XX years.]

[**Examples of procedures to include**. “Your child will be asked to complete surveys about XXX, be interviewed about XXX, be in a focus group about XXX with XXX, provide a blood sample, complete physical testing,.]

[**Suggested statement**. The most severe risks of XXX are XXX. The most common risks of XXX are XXX. Because XXX is investigational there may also be risks that are not yet known,. Some of the questions on the surveys or interview may also cause your child to feel upset. Risks are described in more detail later in this form.]

[**Suggested statement**. There may also be benefits from participation. If XXX is effective your child 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 XXXsocietal benefitXXX.]

[**Suggested statement** if 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. There are alternate assignments that you may wish to complete.}

A more detailed description of this research follows.

Introduction

[As indicated in the revised Common Rule: 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 subject’s … understanding of the reasons why one might or might not want to participate.”]

[**Required statement** to begin section: “Your child is invited to participate in a research study to …” then continue with the following **suggested statement**: “Your child is being asked to participate because he/she is…”] [Note that instead of the phrase “your child” the IRB will also consider use of alternates such as “your son/daughter” or “your children” or “you and your child.”]

[For biomedical studies or studies that are more than minimal risk, include the following **suggested statement**, “This permission form will give you the information you will need to understand why this study is being done and why your child is being invited to participate. It will also describe what your child will be asked to do to participate and any known risks, inconveniences or discomforts that your child may have while participating. We encourage you to take some time to think this over and to discuss it with your child, other family members, friends and, if applicable, your child’s 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, your child may be asked to sign the form (if age appropriate, see instructions on page 1) and it will be a record of your permission to allow your child 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.]

# 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 parents 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 my child 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 give permission for your child to take part in this study, he/she will be asked to ….” or “There are two parts to the research study. In the first part your child will be asked to …”]

[Describe the procedures to be used in the study in sequential order. 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 videotape. 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]

[Describe procedures to obtain the child’s assent to participate prior to the start of study procedures. For longitudinal studies, procedures to obtain assent during each phase of the research should be explained.]

[Explain if the child will be given breaks during the procedures and indicate that procedures will stop when the child becomes fussy, uncooperative or asks to stop.]

[Explain if parents will be allowed to stay with or watch their child during experimental study procedures.]

[As indicated in the Revised Common Rule: 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 parents. If applicable, include a statement about whether the research project might include whole genome sequencing in lay terms.”]

[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.]

[For biomedical research, the following statement is strongly **suggested**, “Another available option is > **describe as applicable** <. Your child 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 child’s condition, it is possible that choosing not to participate may be beneficial.”]

What are the risks or inconveniences of the study?

[Inform parents of any risks (e.g. physical, emotional, social) to the child 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.]

[Inform parents of any inconveniences (e.g. the amount of time required to complete procedures, abstention from food, length of time the child 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 to your child because of his/her participation in the 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 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 child 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 the child is not expected to directly benefit, then use the following **suggested statement** for this section: “Your child may not directly benefit from this research; however, we hope that your child’s participation in the study may …(describe societal benefits).”]

Will my child 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 to you and your child for participating in this study. Your child will not be paid to participate in this study.”]

[Describe any cash payment, gifts, etc. to participants 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.]

[Indicate when parents and the child can expect to receive the compensation.]

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

[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 or your child to share in the economic benefit.”]

How will my child’s information be protected?

[Explain procedures to protect the child’s and family’s privacy and the confidentiality of study records and, if applicable, of audio or videotapes. If the study involves use of the internet, e-mail or electronic record keeping, 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 and who will have access to them. If participants are audio or videotaped, describe who will transcribe or view the tapes. Please note: study records may be kept indefinitely, as long as the data has been stripped of identifiable information and described as such in the parental permission form.]

[Indicate whether data will or will not be shared with parents, school officials, teachers, etc. and explain the circumstances under which data will or will not be shared. If study data is to be released, describe the person(s) or agency to whom information will be provided, the nature of the information to be furnished, the purpose of the disclosure and whether the participant’s name will be used. 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.]

**[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 the data collected from your child. The researchers will keep all study records (including any codes to your child’s data) locked in a secure location. Research records will be labeled with a code. The code will be derived from your first and last initial followed by a \*\*\*\*\* [insert coding procedures specific to your study (e.g. “sequential 3 digit code)] \*\*\*\*\* number 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 audiotapes 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 child’s identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and your child will not be identified in any publications or presentations.”]

[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 your child 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 your child but we cannot guarantee 100% confidentiality. Your child’s 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. 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 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 your child 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 child’s name, address or phone number. There will be a code to link your child’s data [data/biological materials] with his/her name and other personal information.” 2 – “[Data/biological materials] that we collect from your child may be shared with other researchers in the future, but only after your child’s 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://gds.nih.gov/pdf/GDS_Policy_Guidance_Grant_App_Contract_Proposals.pdf). 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" \l "hs) or [Frequently Asked Questions – Data Sharing](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm" \l "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 parent decides to withdraw the child from the study. For biomedical studies indicate that all data collected up to the point of withdrawal will be kept.]

[For applicable clinical trials subject to FDA oversight, 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 web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.”]

[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 subject; or, that the participant’s information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.”]

**[**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](mailto:eciesielski@uchc.edu), 860-679-6004) in Research Compliance Services.**]**

[**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 child’s 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 my child is injured or sick because he/she 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 your child becomes sick or injured during the course of the research study, immediately notify the principal investigator or a member of the research team. If your child requires medical care for such sickness or injury, your child’s care will be billed to you or to your insurance company in the same manner as your child’s other medical needs are addressed.

However, if you believe that your child’s illness or injury directly resulted from the research procedures of this study, you may be eligible to file a claim on behalf of your child 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 my child stop being in the study and what are my and my child’s rights?

[**Required statement** to begin section: “Your child does not have to be in this study if you do not want him/her to participate. If you give permission for your child to be in the study, but later change your mind, you may withdraw your child at any time. There are no penalties or consequences of any kind if you decide that you do not want your child 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 allow your child 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: “your child does not have to answer any question that he/she does not want to answer.” Explain procedures to inform the child of this during the course of the study.]

[For certain cases it may be necessary to expand upon the “no penalty” statement. For example, if parents are recruited through their child’s doctor include a statement indicating that the services they receive from their doctor “will not be taken away or changed” if they decline to participate.]

[If applicable, inform parents that their child may be withdrawn from the study at any time. Describe conditions for such a withdrawal (e.g. missed appointments, non-adherence to procedures, disruptive behavior, adverse reactions).]

[If applicable, describe plans to reconsent participants when they reach 18 years of age. Explain how contact information will be kept secure.]

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

[Include the following **required statement** on the parental permission form 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 child’s rights as a research participant, you may contact the University of Connecticut Institutional Review Board (IRB) at 860-486-8802.”]

Parental Permission Form for Participation in a Research Study

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Return Slip

**Principal Investigator:**

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

**Study Title:**

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

**Documentation of Permission:**

[Use the following **required statement** and format for this section: “I have read this form and decided that I will give permission for my child to participate in the study described above. Its general purposes, the particulars of my child’s involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw my child at any time. My signature also indicates that I have received a copy of this parental permission form.”] Please return this form to the child’s teacher by (insert date).

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

Child Signature: Print Name: Date:

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

Parent/Guardian Signature: Print Name: Date:

Relationship to Child (e.g. mother, father, guardian): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Signature of Person Print Name: Date:

Obtaining Consent