Instructions for Completing the Parental Notification Form Template

(Adapted from UCONN IRB, used with permission)

Last update: August 2024

IMPORTANT - Please review the following as you prepare the passive 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.

Writing and other tips:

- **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 Arial (11pt) or Calibri (12pt) . Make the font one color in the final document. Separate large blocks of text into paragraphs. Text should line up along the 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.

Unless otherwise noted all sections of this form (formatted as shown with proper headings) are **required**. The format of the template is appropriate for most research studies. If you have questions concerning use of the template or need assistance preparing the parental permission form, please contact the IRB at irb@hartford.edu.

UNIVERSITY OF HARTFORD

Parental Notification Form Regarding Participation in a Research

Principal Investigator:
Student Researcher: [Remove if n/a]
Study Title:
Sponsor: [Remove if n/a]

Overview of Research

[In accordance with federal guidelines, 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. This section should include two or three sentences that touch on each of 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,
4) the potential for benefits to the prospective participant or to others that may reasonably be expected from the research;
5) appropriate alternatives procedures or courses of treatment, if any, that might be advantageous to the prospective participant.]

[Below, please find the regulatory required elements for the Overview section. The elements must be included for all studies; however, the in some cases the language can be adjusted according to the nature of the research study.]

[Required statements 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."

[Purpose of research.] "This research is being done to better understand if XXX …"

[Duration of participation.] "Participation will involve approximately XX hours of your time per/day or week over the next XX years."

[Procedures to be followed.] "You will be asked to *[describe research methods, such as "complete surveys about XXX", "be interviewed about XXX", "be in a focus group about XXX with XXX", "provide a blood sample", "complete physical testing".]*

[Risks or inconveniences.] "The main risk of XXX is XXX. The most common risks of XXX are XXX." *[If applicable:]* "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."

[Benefits to the participant or to 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."]

[Alternatives, if available, to the research.] [If applicable:] "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 participant pool, like the psychology department pool:]* "There are alternate assignments that you may wish to complete."

"A more detailed description of this research follows."

Introduction/Why is this study being done?

[**Suggested statement** to begin section: "Researchers from the University of Hartford are conducting a research study at your child's school. This form will give you the information you will need to understand why this study is being done and what you need to do if you DO NOT want your child to participate. We encourage you to take some time to read about the study and to discuss it with your child. We also encourage you to ask questions now and at any time. If you decide to allow your child to participate, no further action is required. Your child will automatically be enrolled in the study. However, if you decide that you DO NOT want your child to participate or if you decide later that you would rather not have your child's data be used in the study, please sign the attached form and return it to your child's teacher by (insert date).

[Note that instead of the phrase "your child" the IRB will also consider use of alternates such as "your son/daughter" or "your children."]

[**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?

[**Suggested statement** to begin section: "Your child will complete …." or "There are two parts to the research study. In the first part your child will complete …"]

[Describe the procedures to be used in the study in sequential order. All experimental procedures must be identified as such.]

[Explain what data is being collected about the child.]

[If the research involves questionnaires, surveys or interviews, describe the type of questions that will be asked or the topics covered. Please note that some surveys and questionnaires require signed parental permission according to the Protection of Pupil Rights Amendment (PPRA).

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

If you DO NOT want your child to participate, what will he/she do instead?

[Describe alternate procedures or tasks for children whose parents do not want them to be in the study. Describe if they will be taken out of class while the study is taking place.]

What are the risks or inconveniences of the study?

[Use the following **required 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." Please note: this form cannot be used if there are any risks of participation – active parental consent is needed in those circumstances.]

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).

[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)."]

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. 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. 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 notification 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.]

[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 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."]

[**Required statement** to include last in this section: "You should also know that the University of Hartford 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."]

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 decide to allow your child to be in the study, but later change your mind, you may withdraw your child at any time. Even if your child has completed the study, you may decide NOT to have your child's data used in the study. There are no penalties or consequences of any kind if you decide that you DO NOT want your child 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: "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 school include a statement indicating that their child's relationship with the teacher or the services they receive from their school "will not be taken away or changed" if they DO NOT want their child to participate.]

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, “We will be happy to answer any question you have about this study. If you have further questions about this project 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 Hartford Institutional Review Board (IRB) at 860-768-5365.”]

Parental Notification Form Regarding Participation in a Research Study

Principal Investigator:
Student Researcher: [Remove if n/a]
Study Title:
Sponsor: [Remove if n/a]

Notification of Refusal:
[Use the following **required statement** and format for this section: I have read this form and decided that I DO NOT give permission for my child to participate in the study described above. My signature also indicates that I have received a copy of this parental notification form. Please return this form to the child's teacher by (insert date).

_____
Print Child's Name:

_____ _____ _____
Parent/Guardian's Signature: Print Name: Date:

Relationship (e.g. mother, father, guardian):_____