**Instructions for Completing the Parental Notification Amendment Form Template**

IMPORTANT - Please review the following as you prepare the Parental Notification Amendment 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 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* will complete…). DO NOT use language copied from the IRB 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, etc.
* Parental notification 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 and advisors must be listed for studies involving students. Official university eamils must be used for contact information.
* 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 notification amendment form (formatted as shown with proper headings) are **required**. The format of the template is appropriate for many 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 protocol amendment application at the time of submission and submit an alternative version (i.e. a letter containing the elements of notification).



**Parental Notification Form Regarding Amendment to a Research Study**

**Principal Investigator:**

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

**Faculty Advisor:** [Remove if n/a]

**Study Title:**

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

**Introduction/Why is this study being done?**

[**Suggested statement** to begin section: “Researchers from Texas A&M University-Central Texas have made revisions to a research study at your child’s school. You are receiving this form because you previously consented to your child participating in the study. This form will give you the information you will need to decide if you **DO NOT** want your child to continue to participate. We encourage you to take some time to read about the study revisions 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 continue to participate, no further action is required. However, if you decide that you **DO NOT** want your child to continue 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). Your child will be asked if he/she would like to continue to participate in the study before he/she continues in the study.

[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 ….”]

Your child has been asked to participate in a research project studying [insert specific statements outlining the major points about the study]. The purpose of this study is to [explain research questions and purpose in lay language]. She or he was selected to be a possible participant because [explain how participant was identified]. *Note that the updated Common Rule requires the consent form to include “a concise and focused presentation of key information that is most likely to assist a prospective participant or legally*

*authorized representative to understand the reasons why someone might or might not want to*

*participate in the research. This part of the informed consent must be organized and presented in*

*a way that facilitates comprehension”. Some of that specific information can be included in the 3 sections below this one.*  This study is being sponsored/funded by [name sponsor/funding source]. \**If research is not sponsored/funded, do not include this sentence.*

**What are the original study procedures compared to amended procedures? What will my child be asked to do?**

[Note: List all original procedures. Select whether the procedure is unchanged, deleted or changed. Provide description of changes, if applicable.]

[Explain what amended data is being collected about the child, if applicable.]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Description of Original Procedure(s) | Procedure Unchanged | Procedure Deleted | Procedure Changed | Description of Changes (if applicable) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

[List and describe any additional procedures below. Provide description of procedure. Be sure to explain what data is being collected about the child.]

Additional Procedure(s):

|  |  |
| --- | --- |
| Procedure(s) | Description of Procedure(s) |
|  |  |
|  |  |
|  |  |

[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 and the topics covered. Please note that some surveys and questionnaires require signed parental permission according to the Protection of Pupil Rights Amendment (PPRA). See the following webpage for additional information – <http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html>]

[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 continue to participate, what will he/she do instead?**

[Describe alternate procedures or tasks for children whose parents do not want them to continue 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: if there are risks to participants then this study may not be eligible for a waiver of parental permission and it will be necessary to use the parental permission form.**]

**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 Texas A&M University-Central Texas Institutional Review Board (IRB) and the Office of Research Compliance may inspect study records as part of its post-approval monitoring 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 continue in this study if you do not want him/her to participate. If you decide to allow your child to continue 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 [or faculty advisor], (insert name, email address and phone number) or the student researcher (insert name, email address and phone number).”]

**Whom do I contact about my child’s rights as a research participant?**

[Include the following **required statement** on all consent forms, “This research study has been reviewed by the Institutional Review Board at Texas A&M University-Central Texas. For research-related problems or questions regarding your child’s rights as a research participant, you can contact Walter Murphy, Research Compliance Officer, at (254) 519-5761 or murphyw@tamuct.edu.”]



**Parental Notification Form Regarding Amendment to a Research Study**

**Principal Investigator:**

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

**Faculty Advisor:** [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 continue 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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_