**INSTRUCTIONS FOR DRAFTING AN ORAL PARENT PERMISSION FORM**

This Oral Parent Permission template is designed for studies that do not contemplate obtaining a signature from parents permitting their children to participate in the study. You must explain your reason for using an oral consent process in the Research Plan. Your responsibility is to present study information in sufficient detail and to organize the information in a way that facilitates understanding.

Using this template is appropriate if:

* your study involves a minimal risk procedure for which signed consent is not ordinarily obtained, such as a survey or focus group activity;
* you plan to obtain informed consent from a parent over the telephone.
* the information you seek to collect is of such sensitivity that the collection of a signature increases risk to participants
* In international settings, when it is culturally inappropriate to require a signature.

This is a Word Document; remove this instruction page and the all the colored instruction language as you complete your form. **When you type, choose black as your font color.**

As you draft your language, consider the following:

* Use simple words and short sentences. It’s easier for participants to digest single concepts than multiple concepts in a string. Itemizing using bullet points or tables may also be helpful to the person obtaining the consent and to the parent/guardian.
* The language we’ve used is suggested, not mandated. Use language appropriate for your study population.
* Do not present information as a list of isolated facts.
* Think about what you, or one of your family members, would like to know if he or she considered permitting a child to join the study.
* If your study involves study drugs, consider taking out the drug risks from the consent form and describing them on a separate form.
* Use good document control practices to identify your document and its current version.

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**

**ORAL PARENT PERMISSION SCRIPT**

**Study Title:**

**Principal Investigator:**

**IRB No.:**

**PI Version Date:**

 [Greeting]. I am [Data Collector Name] from [Johns Hopkins/Collaborating Organization] and would like to talk to you about [topic of the study].

* We are working to see if [neutral presentation of hypothesis of study w/out bias as to outcome].
* We are asking you to permit your child to join our work/research study because your child [explain why they qualify]. You do not have to give permission, it is your choice. There will be no penalty to your or your child if you decide not to permit your child to join.
* [For most studies, unless the child is too young, assent is required.] We will also ask your child if they wish to join the study. We must have your permission and your child’s assent to enroll your child in the study.
* If your child also agrees, we will ask your child to [describe the study procedures, who will do them, and where they will happen]. It will take [‘x’ amount of time/number of visits to your home…].
* You may [describe risk and reasons why someone would NOT want to permit their child to join the study, for example, the child may be uncomfortable or embarrassed answering some of the questions/feel a prick from the needle/have a bruise]. [Explain how you will minimize those issues.]
* [If your study’s procedures include the risk of breaching a participant’s expectation of privacy, address how you will protect against such a breach. For example, you may need to protect the participant’s privacy when recruiting or collecting research information to make sure other people do not hear your discussion.]
* Your child may [describe direct personal benefit, if any]. We will use the [answers to questions/blood from blood draw – whatever the information is] to [answer our question/find out about…list].
* [We will let the community know about the results of the study" reads instead: "We will let the community know about the results of the study <<by.....>>. This information will not identify participants individually but rather share more general findings from the study.] [If you perform diagnostic tests] If we learn that your child’s test result [is abnormal/suggests you need care, etc.], we will [refer you to care, connect you with services, etc.]
* We will not pay you or your child to join the study. [We will pay you back for any travel costs. We will provide food while you are with us.]

**All NIH funded studies have Certificate of Confidentiality protections that are part of the grant and must include Certificate of Confidentiality language.**

***<<For U.S. based, NIH funded studies that collect personal identifiers, insert the following Certificate of Confidentiality language****: >>*

* Your child’s study information is protected by a Certificate of Confidentiality.  This Certificate allows us, in some cases, to refuse to give out your child’s information even if requested using legal means.
* It does not protect information that we have to report by law, such as child abuse or some infectious diseases.  The Certificate does not prevent us from disclosing your child’s information if we learn of possible harm to your child or others, or if your child needs medical help.
* Disclosures that you make yourself about your child’s study information are not protected.

***<<For international NIH funded studies that collect personal identifiers, insert the following Certificate of Confidentiality language:>>***

* This study is protected by a Certificate of Confidentiality that helps keep your child’s information private when stored in the U.S*.*
* Do you have any questions? [Probe to assess the participant’s understanding.]
* Will you allow your child to join the study?

***[The next two sections are important if the study needs to provide participants with an avenue to obtain help if they need it, or to complain about the study if they feel that they have not been well treated. If working in settings where telephone access is problematic, or IRBs are not easily reached, provide alternatives. You could also provide contact information on a card instead of a copy of the consent form. Describe your plan to the IRB in the research plan.]***

* You may contact [name and study contact info] about your questions or problems with this work.
* Call or contact the <<**Johns Hopkins Bloomberg School of Public Health IRB Office/name of local IRB overseeing data collection**>> if you have questions about your child’s rights as a study participant. Contact the IRB if you feel you or your child have not been treated fairly or if you have other concerns. The IRB contact information is:

 Telephone: <<410-955-3193>> Toll Free: <<1-888-262-3242>>

 E-mail: <<jhsph.irboffice@jhu.edu>>