**INSTRUCTIONS FOR DRAFTING AN ORAL CONSENT FORM FOR ADULT PARTICIPANTS**

This consent form template is designed for studies that do not contemplate obtaining a signature from adult participants. You must explain your reason for using an oral consent process in the Research Plan.

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 participant 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, it is culturally inappropriate to require a signature. Your responsibility is to present study information in sufficient detail and to organize the information in a way that facilitates understanding.

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 potential participant.
* 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 joining the study.
* If you have multiple types of adult participants, consider drafting a consent form that directly addresses each of their roles in the study. For example, there may be adults, health care professionals, caretakers, teachers, etc. Label your document clearly with the identity of the person who will be providing consent for 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.
* Review the Informed Consent Elements Worksheet that is posted on our website. Include all the sections that are mandatory and select the sections from the “Optional” part of the form that are appropriate to include.
* Use good document control practices to identify your document and its current version.

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**

**ADULT ORAL CONSENT SCRIPT**

**Study Title:**

**Principal Investigator:**

**IRB No.:**

**PI Version Date:**

 <<Greetings>>. I am <<Data Collector Name>> from <<Johns Hopkins/Collaborating Organization>> and would like to talk to you about <<topic of the study>>.

* We are interested in learning <<insert description of study objective.>>
* We ask you to join our study because you <<explain why they qualify>>. You do not have to join, it is your choice. There will be no penalty if you decide not to join.
* If you say yes, we will ask you 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 join the study, for example, 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.>>
* <<For focus groups, if the topics to be discussed may be sensitive, ask that people in the group minimize personal information and that they keep the discussion confidential.>>
* <<For questionnaires>> You do not have to answer all the questions and you may stop at any time. We will record your answers and use them <<explain how you will use the records/information.>>
* There is a risk that someone outside the study will see your information. We will do our best to keep your information safe by <<describe security protections: not writing down your name/using a special code/locking up the information/etc.>> When we share your information with other researchers, we will ask them to use the same protections.
* You 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 hope this knowledge will <<improve care, insert social benefit.>>
* <<We will/will not give you the results of the tests.>> <<If you perform diagnostic tests>> If we learn that your test result <<is abnormal/suggests you need care, etc.>>, we will <<refer you to care, connect you with services, etc.>>
* 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.
* We <<will/will not>> pay you 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 human subjects research studies that collect personal identifiable information 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 study information is protected by a Certificate of Confidentiality.  This Certificate allows us, in some cases, to refuse to give out your 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 information if we learn of possible harm to yourself or others, or if you need medical help.
* Disclosures that you make yourself about your 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 information private when stored in the U.S*.*
* Do you have any questions? [Probe to assess the participant’s understanding.]
* Would you like 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 rights as a study participant. Contact the IRB if you feel you 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>>

* [if yes] May I begin?