

## **IMPLIED CONSENT GUIDANCE for Surveys**

If you are doing an **online, paper or telephone survey**, a waiver of the requirement for written informed consent may be requested. If granted, however, an informed consent process is still required, and the components of written informed consent as detailed below are still necessary.

- Online: Typically, these components will be cited on the front page of the online survey and an “I accept” button will then provide participants access into the survey. An example of an online informed consent form is posted at the end of this document.
- Telephone: Typically, these components will be written as the beginning of the “script” and verbal consent will be requested before beginning the telephone survey. A copy of the script must be provided to the IRB.
- Paper Survey: Typically, these components will be written as the beginning of the “script” and verbal consent will be requested before beginning the telephone survey. A copy of the survey must be provided to the IRB.

If you have questions or need assistance, please contact the RH IRB office at (605) 755-9028.

### **PLEASE NOTE:**

- When using the template below, do NOT include anything in brackets (in other words, delete the instructions).
- From the examples provided, select the statements that are appropriate and applicable to your study. You don't have to use all that are listed, and you may write your own text, as appropriate.
- After RH IRB Review and Approval the survey will be stamped with the RH IRB approval. Please be sure this appears in your final document. You may also copy and paste this onto any recruitment flyers.

### **EXAMPLE ONLINE or PAPER SURVEY CONSENT FORM**

[Note: For online surveys, you must also submit the Online Survey Statement of Confidentiality form.]

You are invited to participate in a research project about [subject or project title]. This online survey should take about [x to x] minutes to complete. Participation is voluntary, and responses will be kept anonymous [if you never know the subject's identity] [or confidential if you do know the subject's identity] to the degree permitted by the technology being used.

You have the option to not respond to any questions that you choose. Participation or nonparticipation will not impact your relationship with the Regional Health. Submission of the survey will be interpreted as your informed consent to participate and that you affirm that you are at least 18 years of age.

If you have any questions about the research, please contact the Principal Investigator, [name], via email at [email address] or the faculty advisor [if applicable], Dr. [name] at [email address]. If you have any questions regarding your rights as a research subject, contact the Regional Health Institutional Review Board (RH IRB) at (605) 755-9028.

Please print or save a copy of this page for your records.

\* *I have read the above information and agree to participate in this research project.*

       Enter survey

Referenced: <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

Informed Consent FAQs:

**Can consent or parental permission ever be "passive" or "implied?"**

Terms such as “passive” or “implied” consent are not referenced in the HHS regulations. However, OHRP is aware that these terms are sometimes used by investigators or IRBs to describe a process in which consent or parental permission requirements have been altered or waived, or for which the requirement to document consent or parental permission has been waived.

HHS regulations at [45 CFR 46.116](#) state that no investigator may involve a human being as a subject unless the investigator has obtained the [legally effective informed consent](#) of the subject or the subject's legally authorized representative. However, under conditions specified in the regulations at [45 CFR 46.116\(c\) or \(d\)](#) [an IRB may approve a consent procedure that does not include, or that alters some or all of the elements of informed consent set forth in 45 CFR 46.116](#). In some cases, an IRB also can waive the requirement to obtain consent ([45 CFR 46.116\(c\) and \(d\)](#)). In addition, under conditions specified in the regulations at [45 CFR 46.117](#), an IRB may also waive the requirement for documentation of informed consent. (Note that the regulations at [45 CFR 46.408\(c\)](#) also permit an IRB to waive parental permission.)

For example, a researcher conducting a survey (that does not qualify for an exemption under [45 CFR 46.101\(b\)](#)) mails a survey questionnaire to a random sample of adults. The survey materials clearly state that by responding to the questions and mailing the survey back, the recipients have agreed to participate in the research. However, the materials accompanying the questionnaire do not include all of the elements of consent listed at [45 CFR 46.116\(a\)](#) and do not require that the subject sign a consent form. If the IRB has approved this alteration of the consent process and has waived the need for documentation of consent, then such procedures are permissible under the regulations. By sending back a completed survey the recipient has implied that he or she consents to participate but has not signed an informed consent document. Although some might call this “implied informed consent,” OHRP would consider this to be a permissible informed consent process if the IRB has approved the informed consent alteration and waived the requirement for documentation of informed consent.

The term “passive consent” is sometimes used in research with children to describe situations in which the investigator can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do not want their child to participate. Sometimes this practice is referred to as an opt out procedure, which is not consistent with the regulatory requirement for seeking and obtaining parental permission. If the IRB determines that the conditions for [waiver of parental permission](#) can be met, then the IRB could waive the requirement for parental permission under [45 CFR 46.408\(c\)](#) or [45 CFR 46.116\(c\) or \(d\)](#). Even though not required by the regulations, an IRB may require that parents be given the opportunity to refuse permission even when the IRB has waived the regulatory requirement to obtain parental permission.