11.6 CONSENT FOR SURVEYS

Research studies where the involvement of subjects is limited to completing a survey may meet the criteria for exemption under category 2 - research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. A research study that is limited to surveys does not meet the criteria for exemption under category 2 if the following are applicable:

i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; ***and***

ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption criteria 2 would not apply to surveys that are: 1) conducted with minors (younger than 18), 2) prisoners, and/or 4) more than minimal risk. A survey research study that meets the exemption criteria should be submitted to the IRB via Cayuse IRB and must include a copy of the survey, the information sheet (see below), and the copy of the letter or email that will be used to recruit participants to complete the survey.

Survey research that does not meet the criteria for exemption under category 2 should be submitted to the IRB as an initial submission for consideration for expedited or full board review.

Research studies that involve only surveys may meet the requirements for waiver of documentation of informed consent (per 45 CFR 46.117(c).

When a research study proposes to collect information without obtaining documentation of consent, a statement that contains the following is required to be included with the survey as an information sheet:

- The investigator’s name and the study title
- A statement that completing the survey is voluntary and that any question may be skipped
- An short explanation of the purpose of the study
- How long the survey will take to complete
- If the survey will ask for any identifiers (e.g. name, email address, etc.) or if it will be anonymous
- If required, a statement that indicates subjects must be 18 to complete the survey
- Any anonymous information from the survey, once entered into the study database, cannot be removed
- A statement that describes the risks and benefits
- A statement that describes any compensation for taking the survey
- A statement which tells the participant that by filling out the survey consent is implied

- In the case that the survey will be conducted online, the statement must also indicate that information can only be kept as secure as any other online communication
- Investigator's (or other study team member's) contact information for questions about the study

If no consent documentation is to be obtained, a request for waiver of informed consent/assent documentation must be included in the initial submission. The above information must be presented to the research subjects prior to the start and completion of the survey.

i. Surveys Collecting PHI and Sensitive Information

Sensitive information is defined as information that would cause the respondent to hesitate before providing an answer or not respond at all. Some respondents may stop taking the survey all together because a sensitive question turns them off from the process. Sensitive questions include questions regarding substance abuse, personal experiences of sexual or physical abuse, attitudes towards race, ethnicity, or religion, family planning, mental health history, economic status that includes reporting of income, criminal history, and other possible material.

When a research study proposes to collect individual identifiers (i.e. one or more of the 18 PHI identifiers defined by HIPAA) and sensitive information, all study participants must be consented with an IRB approved informed consent document. When a research study proposes to survey minors and includes sensitive information, whether it is identifiable or not, written parent/guardian/LAR permission and assent must be obtained. In the informed consent document, the following information must be included in addition to the already required elements:

a. A statement that completing the survey is voluntary and that any question may be skipped
b. An explanation which describes how the survey will be linked to the potential identifying or sensitive information
c. A description of how and if their data may be removed from the study database upon completion

In the case where the survey is to be conducted through a website, the IRB requires the PI to obtain a post-approval/pre-implementation review of the internet security arrangements by the Director of Information Technology related to the internet sites in which PHI or sensitive health information is being requested of or entered by or on behalf of the study participants. More information regarding the requirements for internet research can be found in that section of the IRB Policy and Procedure Manual.