members and make this information available to the IRB at the time of continuing review.

This clinical investigation must be carried out under a separate IND or IDE, and the application to the FDA must clearly identify that the protocol includes subjects who are unable to consent.

If the IRB determines that the investigation cannot be approved due to the above criteria not being met or due to an ethical concern with the study, the decision will be documented and returned in writing to the investigator.

For research not subject to the FDA regulations, the Secretary of DHHS issued a notice in the Federal Register that waived the general requirements for waiver under §46.101(i). Consistent with this waiver, the IRB may waive the requirement for informed consent for planned emergency research provided the IRB reviews and approves both the activity and a waiver of informed consent and must:

(i) find and document that the research is not subject to 21 CFR 50 regulations, and

(ii) find, document, and report to the OHRP that the conditions listed above have been met relative to the research.

Because of special regulatory limitations relating to research involving fetuses, pregnant women, and human in vitro fertilization, and research involving prisoners, this waiver is inapplicable to these categories of research.

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.

11.7 ALTERNATE METHODS OF CONSENT

For some research studies, consenting participants may require a differing set of methods to including obtaining consent in person or remotely. When alternate methods of obtaining consent are required, the IRB must approve the consent process, the mechanisms of obtaining consent and documentation of the consent discussion.

A. Consenting Participants over the Phone

In order for an investigator to obtain consent or assent over the phone, a full consent and assent form (if applicable) approved by the IRB must be provided to the potential participant/parent/LAR in advance (i.e., via e-mail, fax or mail) to review before and during the consent process.

An information sheet/cover letter may also be included in the documents sent to the subject/parent/LAR during the consent process. An information sheet/cover letter is required if the first introduction to the research study will only be via mail/email or phone call (see also Section 10 regarding subject recruitment).

An information sheet/cover letter should include the following:

- The PI's name and the study title
- The purpose of the study
- How the subject was identified for the study
- That participation is voluntary and that the subject has a right to withdrawal at any time (include specifics about what data may be withdrawn if a subject wishes to discontinue participation)
- A description of when a member from the study team will contact them to discuss the study
- That no documents should be signed prior to talking to a member of the study team

A member from the study team will then need to call the subject/parent/LAR to explain the study in detail and review the informed consent documents with the subject or parent/LAR. If the subject or parent/LAR consents to participate, they will sign his/her copies of the informed