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is voluntary and that the subject has a right to withdrawal at any time (include specifics about what data may be withdrawn if a subject wishes to discontinue participation)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

consent documents. The study team member obtaining consent will sign a copy at the same time. If needed, the child assent can be obtained over the phone in the same way the parental permission was obtained. The phone consent process must then be documented in the study file.

The subject or parent/LAR will then be required to send back their signed copies of the informed consent documents to the study team and the two signature pages are to be combined. The documents can be sent either by mail, fax, or scanned and emailed. The subject or parent/LAR need not provide the investigator with the original signed consent documents. The subject or parent/LAR must be provided a copy of the fully executed, signed informed consent documents. Once this has been completed, any study procedures (e.g., survey, screening visit, etc.) may be sent to the subjects or parents or scheduled by the study team.

B. Obtaining Electronic Consent

OHRP allows electronic signature of consent documents as long as the IRB has considered applicable issues such as how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject. OHRP does not mandate a specific method of obtaining electronic informed consent (e-consent).

Informed consent may be obtained utilizing an electronic platform in which an IRB approved consent document is presented for the subject/LAR to sign electronically. Prior to obtaining e-consent, the consent form, process and platform of choice must be submitted to the IRB for review and approval. The submission must include the platform to be utilized what information will be accessed, stored, and used by any third party, and their terms and conditions, if applicable.

In addition, the FDA states that the IRB "review any optional questions or methods used to gauge subject comprehension of key study elements. The IRB should also review the usability of the e-consent materials to ensure that they are easy to navigate. If the program uses hyperlinks to convey study-related information, IRBs should review the contents to which subjects are referred in order to determine if the study-related information that has been supplied is accurate and appropriate."

When a subject electronically signs an e-consent form, there must be confidence that the signature can be attributed to the actual person signing the form, and that the person cannot repudiate the signature once invoked. Therefore, prior to utilizing the e-consent platform, understand and document the verification steps to assure the authenticity of the signature and it is not possible to delete the signature. Federal regulations describe variety of methods to obtain a valid electronic signatures such as using computer readable ID-cards, biometrics, digital signatures and user name and password combinations; however, other methods may be utilized.

Obtaining e-consent follows the same principles as in-person informed consent: the e-consent document is to contain all elements of consent, the consent process must allow for time for questions, and signatures given voluntarily. The consent process is to be documented, a copy is to be provided to subjects/LAR, and the consent must be retained securely and inspection ready. If HIPAA Authorization is also obtained with an electronic signature, the signed form must be returned to the subject/LAR.

For FDA regulated studies (i.e. the investigation of a drug, device, or biologic) the platform for the e-consent will require compliance with 21 CFR Part 11. Documentation of the platform's compliance must be included in the IRB submission for review and confirmation.

i. Obtaining consent with an electronic signature

When a potential subject has been identified for the study, the IRB approved informed consent documents are to be made available via display within the electronic platform. The person obtaining consent is to present the consent information in person, or this may be accomplished remotely via a call or with an IRB approved application for face-to-face or verbal communication with the subject or parent/LAR.

If the subject or parent/LAR consents to participate, they will provide their signature on the electronic version of the consent. The study team member obtaining consent is to sign a copy at the same time. If needed, the child assent can be obtained in the same way the parental permission was obtained. The e-consent process must then be documented in the study file.

The subject or parent/LAR must be provided a copy of the fully executed, signed informed consent/assent form either in hard copy or as an electronic file that can be stored on his or her own personal device of choice. Once this has been completed, any study procedures (e.g., survey, screening visit, etc.) may be sent to the subjects or parents or scheduled by the study team.

ii. Waiver of Documentation of e-Consent

The method of utilizing a "Click to Agree" mechanism is not to be considered an electronic signature. An appropriate waiver of documentation of consent must be obtained for this e-consent mechanism.

When the IRB approves a waiver of documentation of e-consent, the subject or parent/LAR must be presented with an information sheet prior to giving consent/permission. The information sheet is to be reviewed and approved by the IRB and the IRB template utilized. This information sheet must be presented in the electronic platform prior to obtaining consent to participate.

Similar to "paper" in-person consent documentation waiver, a consent process to present the information to the subject/LAR must still occur. It is recommend to also include an option for the subject/LAR retain a copy of the information sheet.