FAQs regarding the short from consent process and general questions related to the consent process
Please refer to *HRPP Policy 301, Informed Consent*, for additional information.

Question 1: When is the "short form consent" process used?

Answer: The short form consent process is used for the unplanned enrollment of a non-English speaking subject when the long form version of the consent has not been translated into the language of the subject.

Question 2: Who can be an interpreter for the short-form consent process?

Whenever possible, a professional interpreter, who is in-person, should be used or, alternatively, a professional interpreter can be utilized via a telephone interpretation service. Use of a family member for interpretation is not permitted unless a professional medical interpreter cannot be located. The reasons for using a family member and the attempts made to locate a professional interpreter must be documented in the research record. Family members may not have adequate medical knowledge and are not trained as professional medical interpreters. Additionally, family members may not be impartial or may try to speak for the subject which can limit the subject's decision-making process. (See also Question 14 for more information about when an investigator may server as the interpreter.)

Question 3: How is the consent process conducted when the subject speaks and understands English but is blind or illiterate?

Answer: When the subject speaks and understands English but is illiterate or blind, the English long form should be used to obtain consent from the subject. The short form consent document should not be used. The subject may use assistive technology (such as screen readers for sight-impaired individuals) to read the consent, or the consent form should be read to the subject. There must be a witness to the entire oral presentation of the consent. The witness then signs the witness line on the English long form consent. Subjects who are unable to sign their name can make their mark on the signature line. (e.g. They may make an "X," or provide a fingerprint.) The consent note in Clinical Records Information System (CRIS) or the research record should document the process and include a statement that there was a witness to the entire consent process and any special circumstances regarding documentation of consent.

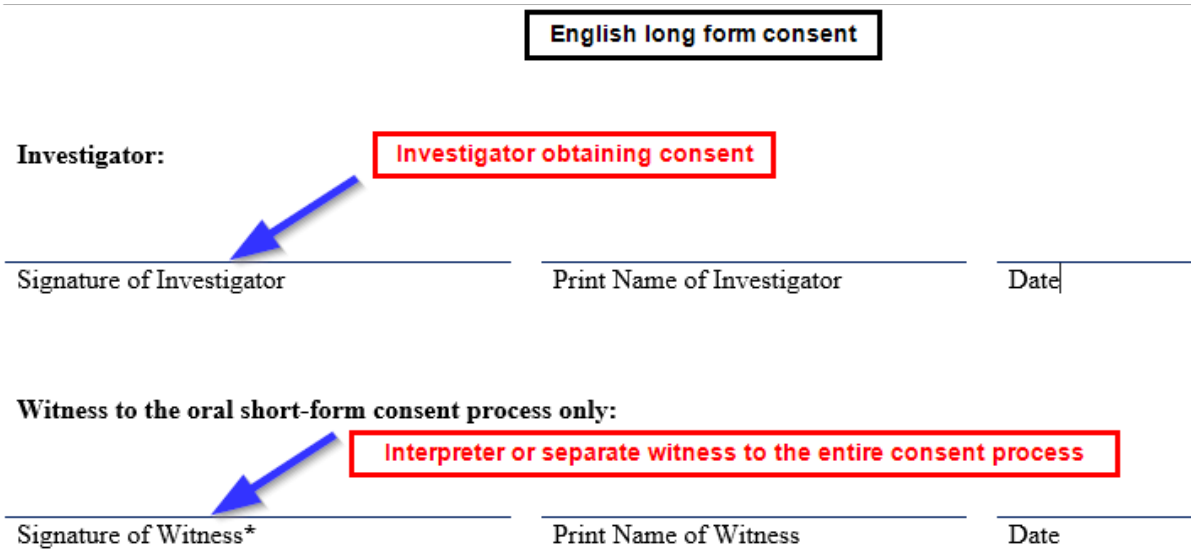
Question 4: How is the consent process conducted for non-English speaking subjects for whom no written language exists?

Answer: When conducting the consent process with a subject for whom no written language exists, the process is similar to that used with a blind or illiterate subject. There should be an oral presentation of the English long-form consent by the interpreter. There must be a witness (who can be the interpreter if they are willing to act as the witness) at the location of the investigator, who is present during the entire oral presentation. The subject must sign or make their mark on the consent, and the investigator and witness both sign the consent. The administrative block for interpreters must be completed, and there must be a note in CRIS or the research record documenting the consent process used in this circumstance.

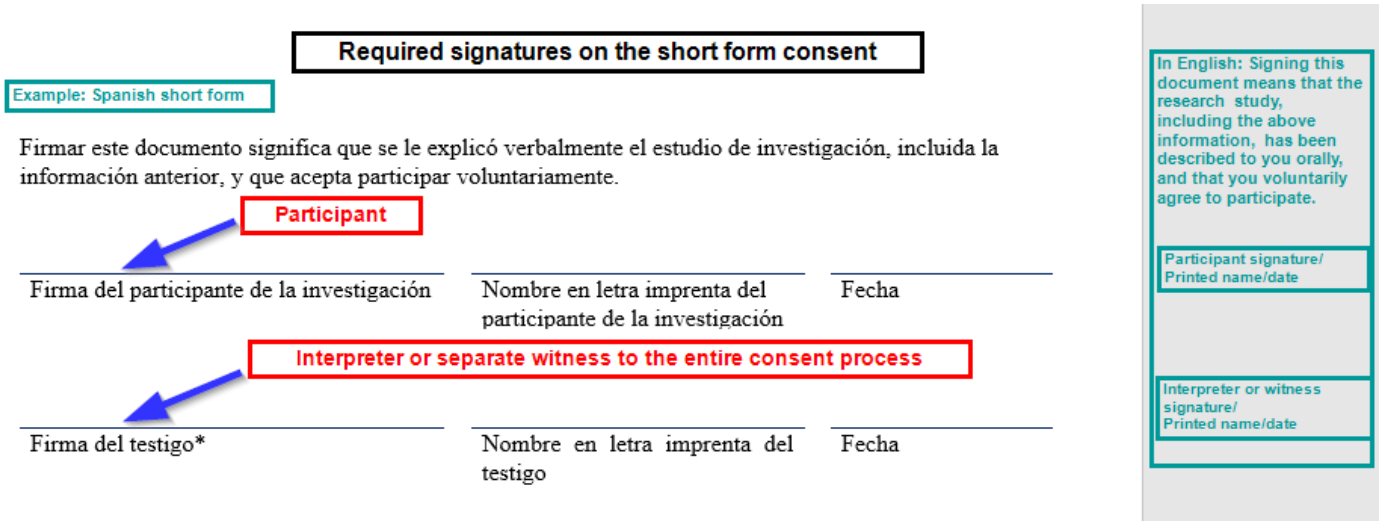
Question 5: When a short form consent document in the language that can be read by the subject is

used, and the written IRB-approved summary of what is to be said to the subject is the English long consent form, who signs the English long form and who signs the short form?

Answer: For the **English long form consent**: the investigator obtaining consent and the witness sign the English long form consent document. The interpreter may also act as the witness.



For the **short form consent that is in the language that can be read by the subject:** The subject and the witness sign the short form consent document.



Confirm that the witness has signed **both** the short form in the language of the subject and the English long form used as the summary of what is to be said to the subject.

Question 6: When a Clinical Center (CC) interpreter facilitates the informed consent process, is the interpreter **required** to also serve as the witness?

Answer: NIH staff members who are federal employees and whose job description involves interpretation services should sign the short and long form consent as the witness when facilitating the short form consent process. Contract staff or volunteers providing interpreter services may sign as witnesses but cannot legally be required to do so. If the interpreter declines to act as the witness, a separate individual must witness the entire short form consent process and sign as the witness. In all cases, the identity of the interpreter will be noted as indicated in Question 8 below.

Before starting the consent process, confirm with the interpreter if they are willing to witness the consent. If the interpreter will not serve as the witness, a separate adult witness must be identified, and the witness must be fluent in both English and the language of the subject. The witness must be present for the entire oral presentation.

In the vary rare instance that the interpreter is unable or unwilling to act as the witness, and a witness who is fluent in both English and the language of the subject cannot be located, then the witness should verify with the interpreter that the subject understands the information presented, that all questions have been satisfactorily addressed, and that the subject agrees to participate. The witness, or investigator, obtaining informed consent should document this as a note in the record documenting the short form consent procedure.

Question 7: What should you do if the short form consent process is conducted in person, but the interpreter is on the phone?

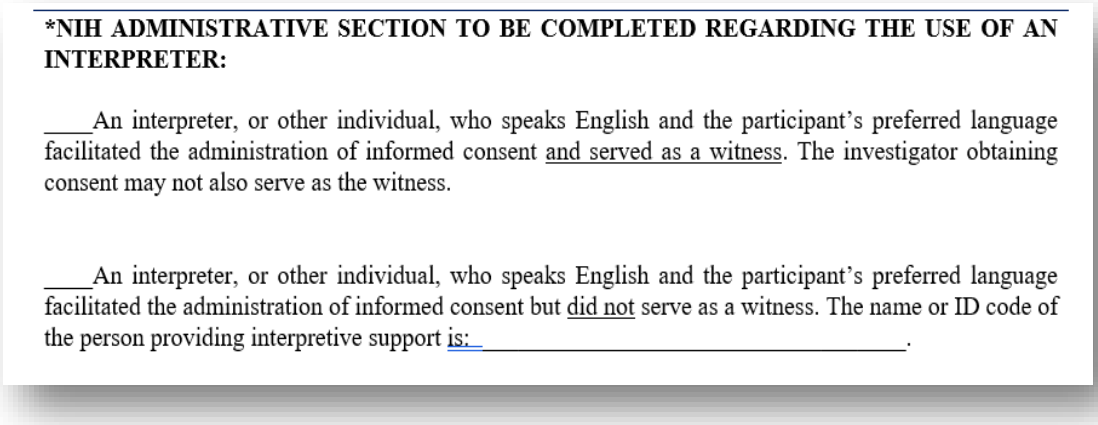
Answer: A telephone service interpreter **cannot** act as a witness since they are not physically present to observe the consent process. Another individual must observe the entire consent process at the site of the investigator and sign as the witness. Information regarding the interpreter should be included in the administrative section of the long form consent document as described in Question 8.

Question 8: How do you document the use of an interpreter on the long and short form consents?

Answer: Both the English long form and the translated short form includes a section titled **NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER** which must be completed when the short form consent process is used. (Note: On the translated short form, this section will be in the subjects preferred language.) This section allows NIH staff to attest that an individual speaking both English and the subject's preferred language facilitated the consent process and also indicates whether the individual acting as the interpreter also served as the witness to the short form consent process.

If the individual providing interpretation services did not serve as a witness, the interpreter's name (for on-site interpreters), or ID number (for telephone-based interpreters), should be entered in the designated 2nd field shown below.

English long form administrative block



***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

Examples of scenarios

- *An NIH staff member who is a federal employee and whose job description involves interpretation services acted as interpreter and signed as witness:* The first option is checked and the interpreter signs as the witness.
- *An NIH contract interpreter is used but states they cannot sign as witness:* The second option is checked, and the interpreter's name or ID code is entered on the provided line. In such cases, there must be a separate individual present to observe the entire consent process and who signs as the witness.
- *A telephone interpretation service (trans-telephonic interpreter service, e.g. "blue phone" service) isused and the consent is obtained in person (person obtaining consent and the subject are co-located):* Since the interpreter is not physically present and cannot serve as witness, the second option is selected, and the name or ID of the interpreter is entered. In such cases there must be a separate individual present with the investigator to observe the entire consent process and who signs as the witness.

Question 9: What is required when the short form consent process is used to obtain consent by phone from a subject who is not in the same location as the investigator? This includes consent processes using an interpreter who is either on the phone (remote from the investigator) or who is present with the investigator.

Answer: The difference from the earlier examples relates to the location of the individual who will serve as the witness, and timing of the investigator and witness signatures.

- The subject should be provided with both the short form consent and the long-form English consent prior to the phone discussion.
- The investigator who is obtaining consent is in the same place as the witness (this may/may not be the interpreter).
- The investigator, interpreter, and witness (if the interpreter will not/cannot serve as the witness) must all be involved for the duration of the consent process conducted via phone.
- After completion of the consent process, the following should be completed in real time:

    - The subject signs and dates the short form consent and returns it to the investigator.
    - At the time of the consent process, the investigator and the witness sign and date the long form English consent that was used as the basis of translation.
    - The administrative section on the last page of the long form English consent is completed.
    - The investigator documents the process in a consent note in the subject's medical chart or research record (in real time after the consent discussion).
- Upon receipt of the signed and dated short form consent from the subject, the investigator completes the administrative section of the short form, and the same witness signs and dates the short form consent using the current date. (It is not backdated to the date that the consent process was conducted by phone.)
- The subject is provided with copies of the signed short and long form consent documents.
- The investigator adds a note to the medical/research record regarding the date the signed short form was received and signed by the witness and indicates when the copies were returned to the subject.

Question 10: What process is used if obtaining consent using the short form consent and the consent process is being conducted remotely with the witness not in the same location as the investigator (e.g., because the witness is teleworking due to COVID and is also on the phone or is witnessing via a telehealth platform)?

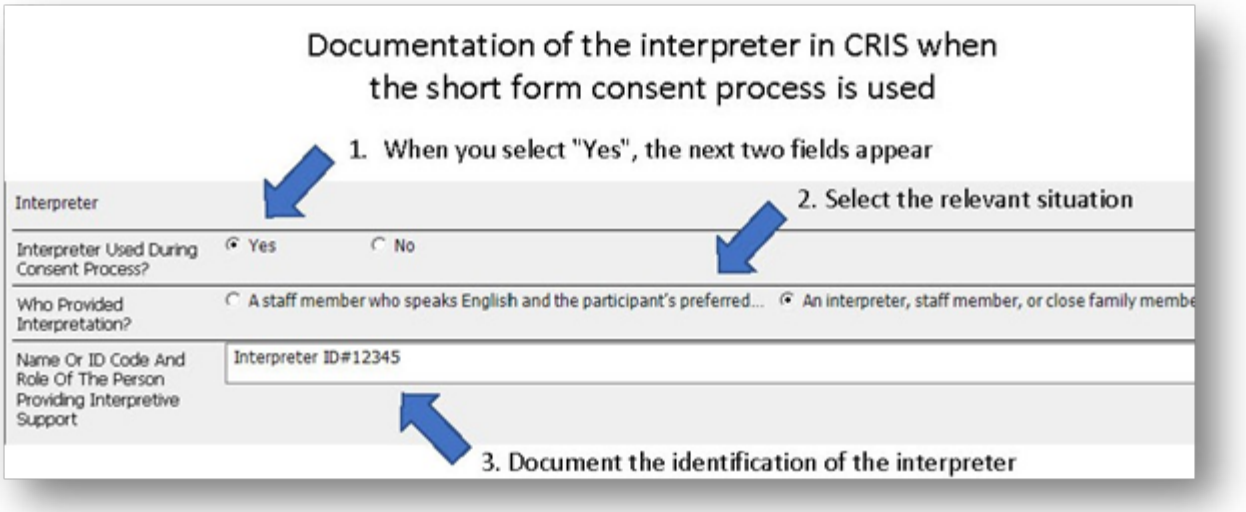
Answer: The short form consent process requires that the witness attest, by signature, to the validity of the consent process and the subject's agreement to participate. If the witness is unable to sign the required documents, it is not acceptable for the PI to make a notation in the research record on behalf of the witness.

In such scenarios, the acceptable options for obtaining informed consent are to either: 1) translate the full consent into the language of the subject, or 2) if it is urgent to enroll the subject, the short and long form consents could be provided electronically to the witness, who will then sign and return the documents electronically. Note, that such signatures must be "wet" signatures using a pen, mouse or stylus and not electronic signatures.

If these options are not feasible, then it may not be possible to enroll the subject.

Question 11: What documentation should be entered in CRIS when an interpreter is used for the **short form** consent process?

Answer: The CRIS documentation of the Informed Consent Progress Note has been updated to include the required fields related to use of interpreters and witnessing the consent process. Whenever an interpreter facilitates the informed consent process, the PI or investigator who is obtaining consent should complete the check box fields in the progress note and include the name or ID number of the interpreter in the designated field.



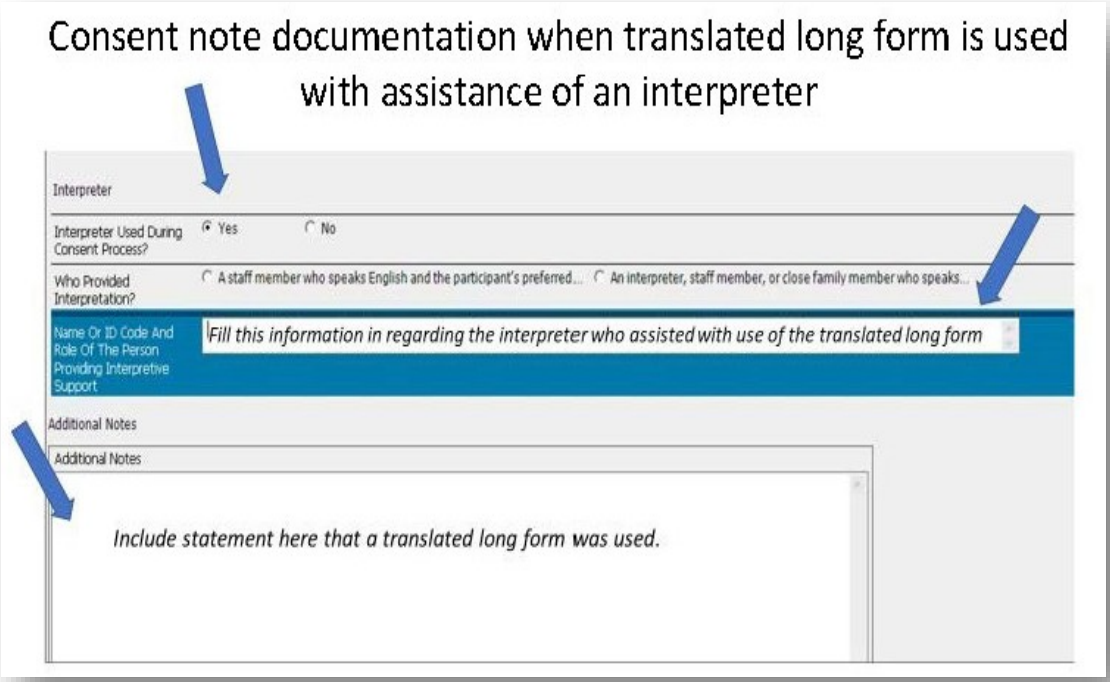
Question 12: Who signs the IRB-approved fully translated (non-English) **long form consent** document?

Answer: If investigators anticipate enrolling subjects who speak a specific language other than English, the English long form consent should be fully translated into that language and submitted to the IRB for approval. In this case, an interpreter is also used to facilitate the discussion and answer the subject's questions, and the investigator obtaining consent and the subject both sign the fully translated long form consent (as they would if the long form was in English).

In this case, since an interpreter is used, a witness is not required to sign the long form consent, and the second box in the administrative section should be checked to indicate that the interpreter facilitated the consent process but did not serve as the witness.

Question 13: When an interpreter is used during the consent process using **a translated long form**, how is this documented in the consent note in CRIS?

Answer: Check "yes" to the question, "*Interpreter used during the consent process?"* Fill in the name or ID code of the person providing interpretive support. Under additional notes, include a statement that a translated consent long form was used. See below.



Question 14: Can a bilingual investigator approved by the IRB to obtain consent do so using the translated long consent form or the short form process?

Answer: If the investigator is truly fluent in English and the language of the subject, consent may be obtained using the IRB approved translated long form if it exists, and no witness is needed. When the short form process is used because the long form has not been translated into the subject's language, the bilingual investigator conducts the consent process in the language of the subject and explains all applicable elements of consent using the English long form as the summary of what is said to the subject. The investigator obtaining consent cannot act as the witness, so the second option in the administrative block noted in question 8 above is checked, and the investigator's name is noted on the provided line. In such cases, there must be a separate individual present to observe the entire consent process who signs as the witness.

Question 15 : What happens when there is no short form in the language of the proposed subject?

Answer: If the long form has not been translated into the language of the proposed subject, the subject should not be enrolled until a short form in their language is available. If you need a short form that is in a language which is not available on the IRB website, then you must obtain a translation of the appropriate English short form version. A resource for obtaining a translation is the NIH Library. Once you receive the translation, submit the translated short form and the certificate of accuracy to the IRB via iRIS using an amendment form.

Question 16: How are embedded questions on the English long form consent handled when the short

form consent process used?

Answer: The interpreter should ask the subject the embedded question and convey their response to the investigator obtaining consent. The investigator indicates the subject's response on the long form ICF. Neither the interpreter nor the subject should record the response. This process should also be described in the consent note in CRIS or the research record.

Question 17: How should assent of a potential minor subject who does not read/speak English be conducted when the IRB has only approved use of an English assent form for minor subjects of a specific age?

Answer: Verbal assent should be obtained from the minor, and the process should be documented in the consent note. NIH does not have translated short form assent documents.

When obtaining assent from a non-English speaking older minor, if there is a translated long form and the IRB has approved a process that allows older minors to provide their assent on the long form, then the older minor may read and indicate their assent on the translated long form. Otherwise, verbal assent should be obtained and documented as above.

Question 18: What information about the consent process should be documented in the medical or research record?

Answer: NIH investigators should document the consent process in the subject's record, and describe the method used for communication with the subject and the specific means by which the subject communicated agreement to participate in the study (e.g., their verbal response and signing of the informed consent document). Additional FAQs related to documentation of consent in CRIS are available at this internal link.

Question 19: When obtaining consent from a study subject over the phone using a long form English consent, who needs to sign the consent and what dates are documented?

Answer: The subject should be provided with the consent form in advance of the consent conversation. After the consent process has been conducted and the investigator has responded to the subject's questions, the subject signs the consent form noting the current date. The investigator documents the process in CRIS/medical record (or the research record if there is no medical record) in real time on the day of the consent conversation. When the signed/dated consent form is returned to the investigator who conducted the consent discussion, the investigator signs and dates the consent form with the date s/he received the signed the consent from the subject. The investigator should then record another note in CRIS/research record indicating the updated status and send a copy to medical records (or research record if there is no medical record) and provide a copy of the completed consent form to the subject. The date that the subject signs the consent form is considered their "date on study." If, after the subject has signed the consent form, specimens and/or data are collected locally for research purposes, no analyses of these specimens and/or data may occur until the investigator has verified that the subject has returned a signed and dated informed consent document, unless the IRB has granted a waiver of documentation of consent.

Question 20: If the investigator is planning on obtaining consent remotely, or if they want to add this option to the consent process, how is this handled regarding the protocol? Alternatively, what if this process is anticipated to be needed only temporarily or for a few subjects?

Answer: If the protocol will include use of a remote consent procedure (e.g., by phone or videoconferencing), the process must be described in the protocol, and IRB approval must be obtained. Otherwise, if the plan to use the remote consent process is only temporary and for a few subjects (e.g., due to the pandemic), a single patient planned deviation request form may be submitted rather than a protocol amendment. If the investigator will be conducting such a process via telehealth, use only an approved synchronous video platform that meets required NIH security and privacy standards. For additional information, please refer to Policy 303 Intramural Program Telehealth Requirements which can be found here.

Question 21: Is consent from subjects required prior to prospective review of private medical information for the purpose of screening, recruiting, or determining eligibility of prospective subjects?

Answer: Under the pre-2018 Common Rule regulation (45 CFR 46), unless the research qualified for specific exemptions, prospective consent from the potential subject for recording of their identifiable private information being obtained for recruitment was required, unless waived by the IRB. For protocols subject to the revised (2018) Common Rule **only,** an IRB may approve certain screening or recruitment activities, or activities to determine eligibility, prior to obtaining informed consent. These include:

- Obtaining information through oral or written communication with the prospective subject, OR
- Obtaining identifiable private information of identifiable biospecimens by accessing records or stored identifiable biospecimens.

In this event, the PI does not need to request a waiver of consent, but these activities that will occur prior to obtaining informed consent must be clearly described in the IRB approved protocol. The solicited information should be limited to the minimum necessary for screening, or to determine study eligibility.

Question 22: Is written consent of the subject always required for research that involves only web-based surveys or tasks with minimal-to-no interaction between the investigator and study subjects?

Answer: For minimal risk research being conducted remotely, the IRB may approve a web-based consent form or approve waiver of documentation of consent with no requirement for oral consent. When a research study is subject to the Privacy Act, (i.e., will collect identifiable private information about a subject), the prospective subject must be provided with written Privacy Act notification. If an investigator wishes to conduct an oral consent process and receive a waiver of documentation of consent, they must still at least offer to provide the Privacy Act notification in writing. A description of the plan should be included in the consent section of the protocol. When the subject will not be registered as a patient at Clinical Center, please refer to the section labeled *Privacy Language for Studies Conducted Outside* of t*he Clinical Center* in the Consent Library on the OHSRP website for the Privacy Act information that should be provided to subjects.