

Program for the Protection of Human Subjects Consent at a Distance (aka remote consent) Policy – 9/10/2020

POLICY:

1. Remote Consent may only be used where the Program for the Protection of Human Subjects (PPHS) has granted permission. Face to face communication between investigators and study candidates with ample time to discuss issues and answers questions is always the preferred scenario, but at times this is neither necessary nor feasible. A straightforward survey study may be readily explained in a consent, without need for much education or interaction. Consenting for a greater than minimal risk interventional study, even if done remotely, must allow for education, questioning and dialogue.
2. Remote Consent may be permitted for the following situations:
 - a. No research activities require in person contact with the subject
 - b. The Legally Authorized Representative (LAR) cannot travel to the site to meet a time sensitive inclusion criteria
 - c. Hospital visitor restrictions
 - d. Need to limit in-person contact
 - e. Compelling logistical issues
 - f. Other situations at the discretion of the PPHS
3. SOP 090 establishes the process to obtain informed consent from subjects, the LAR of adults unable to consent, or the parents or guardians.
4. SOP 091 establishes the process to document the informed consent process in writing.
5. This policy describes the modification to the process to obtaining informed consent (SOP 090) and documenting the informed consent process (SOP 091) when these processes are performed remotely.
6. The IRB must review and approve all electronic media that the subject will receive or view during the consent process.
7. When consenting at a distance using an IRB approved process, the obtained consent is valid. It does not have to be repeated using a paper process.
8. If consent is obtained at a distance and the subject must subsequently take part in an in-person visit as part of the study, then a focused review of the consent form must occur on the day of the visit, allowing for questions and answers before the in-person research activities occur. This conversation should be documented in the research record.
9. If a LAR provided consent remotely, this focused review should occur at the first opportunity that the LAR presents in-person and the research staff is present. This focused review may occur after intervention has begun or is completed.
10. If after a focused review a subject or LAR withdraws consent, this should be reported as a subject withdrawal.

PROCEDURE FOR OBTAINING REMOTE CONSENT:

1. Send copy of current approved version of the consent / authorization form to the prospective research subject or LAR for review. The mechanism should be acceptable to the subject and can be provided by one of multiple mechanisms including online access, (e.g. a form in REDCap or other secure software), iOPEN or other approved E-consent module, fax, postal mail, Email or smart phone. Screen sharing can be used during the consent process but does not constitute sending a copy of the consent form to the prospective subject or LAR.
2. The ability for the subject to be able to have questions answered prior to agreeing to consent is an absolute requirement. This can be done by phone or video, chat function or emails. The details of the chosen method(s) as well as the qualifications and the availability of those answering the questions should be included in the request to the PPHS. The method of communication must be HIPAA compliant (e.g. VSEF or HIPAA compliant ZOOM).
3. As with in-person consenting, remote consent is only valid if the subject has the cognitive and legal capacity to give consent. This determination will generally require research team-subject interactions, though in some cases with less risky projects, stand-alone consenting platforms (e.g. iOPEN) may have sufficient assessment (e.g., quizzes and feedback) built-in to the consent process to assure subject comprehension.
4. In most cases, arrange for a conversation between the subject and the authorized members of the research team to allow for full discussion of the combined consent /authorization form following the process in SOP 090. This conversation can be done by phone or video communication.
5. For those studies where communication will not be in real-time, for example using iOPEN or other eConsent platform, details need to be provided to the PPHS and the request has to be explicitly approved by the PPHS

PROCEDURE FOR DOCUMENTING REMOTE CONSENT

1. The method(s) of documentation of consent must be IRB-approved and comply with appropriate NYS Electronic Signatures and Record Act (ESR) and OHP and FDA regulations and guidance as applicable.
2. Subject or LAR may print, sign and return the completed consent form; options for the return of consent documentation via electronic means are scanning the document, taking a picture, or sending the form attached to an email or text message. Regular postal mail may be used. The informed consent process is not valid and study enrollment cannot proceed unless the form is received by the study team and appropriately filled out by the subject/LAR along with the consent document.

Alternately, documentation of consent can be obtained using REDCap e-consent framework or a scripted name or legal mark using a secure signature capture platform

(e.g. DocuSign, Adobe Sign, Apple Pen). iOPEN and other ISMMS developed systems can be used with PPHS approval.

3. For FDA-regulated clinical investigations, the electronic system used for obtaining the electronic signature must meet the relevant requirements contained in 21 CFR part 11. The identity of the subject/LAR who will be electronically signing an electronic informed consent for FDA-regulated clinical investigations must be verified per regulation 21 CFR part 11. FDA regulations do not specify any particular method for verifying the identity of an individual and accepts many different methods.

DOCUMENTATION OF PHONE CONSENT (for minimal risk, non FDA regulated studies)

1. This is only permitted for studies that are both minimal risk and non-FDA regulated.
2. If there is an impartial witness on the phone or video at the time of the initial verbal consent, there is no need to have the consent documentation returned and data collection can begin.
3. An impartial witness should listen to the conversation between the person obtaining consent and proxy or surrogate, verify the identity of the health care proxy or surrogate and the fact that consent was obtained.
4. A note documenting the consent and the witness should be placed in the research record. The note should be countersigned by the impartial witness to the conversation and contain the date, time and content of the conversation and the identity of the impartial witness.
5. An impartial witness may be a staff member who is not on the study team and does not report to the PI. The impartial witness may not be a person involved in the design, conduct, or reporting of the research study. The impartial witness and the interpreter may be the same person if the interpreter is present on the phone or video, unless the interpreter is authorized to obtain consent.
6. If there is no impartial witness to the phone consent/authorization, documentation of consent and return of the document is required as described in the previous section. Data collection may begin once verbal consent is obtained. However, if the signed consent document is not returned, the research team must destroy the collected data, as their use in this research context is not permitted.

References

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html>

<https://its.ny.gov/electronic-signatures-and-records-act-esra>