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Consenting during Pandemic

A Spectrum Health IRB Guidance Document

Purpose

This document provides guidance on modifying the consent process to meet the needs of research participants and study staff during a pandemic (specifically COVID-19). This may entail a modification to the consent process to allow for mail, virtual, or phone consenting or other alterations of consent due to the inability to meet participants in person.

Regulatory Guidance

- *FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards* March 2020 (Updated May 14 , 2020)
- 21 CFR 56.109(c) (1) and 45 CFR 46.117(c) (2) – Waiver of Written Documentation of Consent Process
- *IRB Guidance on Electronic Communication with Research Participants* April 21, 2016
- FDA Guidance on *Use of Electronic Informed Consent Q&A (dated December 2016)*

Discussion

Informed consent involves providing a potential subject with adequate information about the research to allow for an informed decision about the subject's voluntary participation in a research study. Informed consent must include a process that facilitates the subjects comprehension of the information and allows adequate opportunity for the subject to ask questions and consider whether or not to participate (45 CFR 46.116 and 21 CFR 50.20).

An IRB may waive the requirement for written documentation of consent for some or all subjects if certain criteria are met.

Minimal Risk Research:
For minimal risk studies seeking a waiver of documentation of consent the study team should provide a writen script of the information that will be provided orally or in writing and all written information to be provided to potential subjects needs to include all required and applicable elements of consent (45

CRF 46.116(b)). Additionally, the research study should not involve any procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature). The IRB may or may not require a written copy of the consent document to be provided to subjects.

For studies that are currently IRB approved and are requesting changes to the consent process a modification needs to be submitted to the IRB for review. IRB modifications and initial applications will need to request a waiver of written documentation of consent and provide a plan outlining how the research team will conduct the consent process (ie, over the phone, teleconference, via mail). Revisions should be made to the protocol to include this process and to the ICF when applicable.

Greater than Minimal Risk Research – Not in Isolation:

FDA regulations generally require that the informed consent of a trial participant be **documented** by the use of a written consent form that has been approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent (21 CFR 50.27(a)).

Study teams may need to obtain informed consent from a potential trial participant or their legally authorized representative when these individuals are unable to travel to the site where the investigator is located due to a pandemic or other travel restrictions. When investigators do not have approval for electronic informed consent (eIC), methods of obtaining informed consent other than a face-to-face consent process may still be acceptable if those methods allow for an adequate exchange of information and documentation, and a method to ensure that the signer of the consent form is the person who plans to enroll as a subject in the clinical investigation or is the legally authorized representative of the subject.

Options for getting the consent form to the subject include the consent form being sent to the subject or the subject's legally authorized representative by facsimile or secure e-mail (see *IRB Guidance on Electronic Communication with Research Participants* April 21, 2016). The consent discussion may then be conducted by telephone or teleconference when the subject or subject's legally authorized representative can read the consent form during the discussion. After the consent discussion, the subject or the subject's legally authorized representative can sign and date the consent form.

Options for returning the consent form to the study team may include facsimile, scanning the consent form and returning it through a secure e-mail account, photographic image of the signed consent form transmitted through electronic means, or posting it to a secure internet address. Alternatively, the subject may bring the signed and dated consent form to his/her next visit to the clinical site, if restrictions on traveling to the site are alleviated, or mail it to the study team.

The enrollment note for each subject must document that informed consent was obtained prior to participation in the trial. In addition, the person signing the consent form must receive a copy of the consent form. Although FDA regulations do not require the subject's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided.

The subject or the subject's legally authorized representative must sign and date the informed consent form before the investigator may conduct any study-related procedures involving the subject. Where it is not feasible for investigators to receive the signed consent form prior to beginning study-related procedures, the investigators should have the subject or legally authorized representative confirm

verbally during the consent interview that the subject or legally authorized representative has signed and dated the form.

The procedures suggested do not apply to the exception from general informed consent requirements under 21 CFR 50.23 or the exception from informed consent requirements for emergency research under 21 CFR 50.24.

For FDA Regulated Research – Patient In Isolation:
For information on how to enroll a subject who is in isolation due to COVID-19 infection control measures, reference *FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards* March 2020 (Updated May 14, 2020)

What about HIPAA authorization?
The HIPAA Privacy Rule requires, that when a covered entity seeks an authorization from a subject (or a subject's personal representative), that the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.

The IRB may approve an alteration of the requirements of written HIPAA Authorization provided the research meets the criteria for waiver or alteration. The most frequent alteration is for verbal HIPAA Authorization when the IRB has also waived the requirement for written consent under 45 CFR 46.117(c)(1)(ii). Any information to be provided orally should include all required and appropriate elements of disclosure (minimum elements required).

HIPAA Authorization for Reimbursement
The HIPAA Authorization for Reimbursement is not technically a research authorization so a waiver or partial waiver cannot be applied. The following are three options that may be utilized if in person consent discussion is not possible/practical:

- Send out the HIPAA Authorization for Reimbursement via standard mail or email and request a signed copy back. The HIPAA Authorization for Reimbursement can be reviewed with the individual via the phone similar to the study's Informed Consent/HIPAA Authorization for Research. If the HIPAA Authorization for Reimbursement contains any of the individual's PHI (ex: name, DOB, MRN), the authorization must be sent to the participant securely. In order to be secure, the study team should confirm the individual's address prior to mailing and if sent via email the individual's email address should be confirmed and then sent securely through Spectrum Health's email system.
- Find a way in which the individual's persmission/authorization can be documented electronically. Other areas of the organization have developed ways to do this during a pandemic such as having the patient/subject email or text their consent/permission.
- Have the patient (or their represntative) enter his/her own information into the payment website(s) directly. If the patient directly enters their information, there is no longer a need for the HIPAA Authorization for Reimbursement. *If opting to have an individual enter their own information into payment website directly, study teams should consult with Research Finance*

about whether any information is required to be collected and provided to them for tax and/or tracking purposes.

Conclusions

- A modification will need to be submitted to the IRB to explain the changes to the consenting process and what methods will be used to obtain consent. The IRB will review the requested changes and will work to provide approval for continuation.
- For studies requiring written documentation of consent, the subject or the subject's legally authorized representative must sign and date the informed consent form before the investigator may conduct any study-related procedures involving the subject.
- For studies requiring written documentation of consent, the person signing the consent form must receive a copy of the consent form.
- A waiver of HIPAA authorization may be granted under certain circumstances provided criteria for approval is met.