METHODS OF REMOTE CONSENT GUIDANCE

The MUSC IRB supports the use of remote consent and remote study procedures, when appropriate. The use of remote methods must be outlined for prospective IRB review and approval to ensure that risks to subjects continue to be minimized and the data integrity of the study can be maintained. This guidance is meant to serve as a resource to guide research teams considering the use of remote procedures for research.

There are multiple methods that can be employed to obtain consent from research participants when the research team is unable to have an in-person meeting. Many use the term "Remote Consenting" to describe the various methods that can be used to obtain consent outside of an in-person meeting. Any method of obtaining informed consent must 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 research study or is the legally authorized representative (LAR) of the subject.

What are the different types of Remote Consent?

A few of the most commonly used methods of Remote consenting include:

1. Waiver of Documentation of Signed Consent
2. Teleconsent
3. Remote consent via paper consent
4. Remote consent using electronic consent (see electronic consent guidance)

Waiver of Documentation of Consent

Federal regulations (**45 CFR 46**; **21 CFR 56**) permit Institutional Reviews Boards to waive the requirement to obtain a signed consent under specific circumstances. To clarify, this waiver applies only to the documentation (e.g., signature) component of the consent process; it does not waive the requirement to obtain consent entirely. In remote consenting scenarios, this is often applied when/if verbal consent will be obtained from a study subject (e.g., via telephone or video conferencing) or when there is no direct with potential subjects (e.g., online surveys). To qualify for the waiver, the study protocol/application must clearly indicate that the waiver is requested and provide adequate justification for how the research meets waiver requirements. The IRB will also likely require that written information about the research be provided to the subject (e.g., via an information sheet). Reference MUSC HRPP 6.2 for additional information.

Electronic consent (e-consent) is a method of obtaining informed consent through the use of an electronic system instead of a paper consent form. Not all e-consent systems contain the ability to document legally effective signatures. (for more information on

electronic consent, please see e-consent guidance)

Remote consent (sometimes referred to as "teleconsent") is a method of obtaining informed consent using a paper or electronic consent form where the study team and participant are not in the same physical location during the consent process.

Remote consent using a paper consent form (or remote paper consent) is a specific type of consent process where a copy of the written informed consent form is provided to the participant via email, fax, mail or during a prior in-person visit. A second blank copy can be provided for the participant, to keep as a reference document. The informed consent process may be conducted over the phone or via video conference (e.g.,Teams). The participant signs and dates a hard copy of the informed consent form during the call and the person obtaining consent signs and dates their hard copy of the informed consent during the call. The participant returns their signed copy of the consent document(s) to the study team via email, fax, mail, or at the participant's first in-person study visit and the blank version is retained by the participant. The consent can be mailed, or an electronic system may be used, including scanning, or photographing the signed consent form and sending it electronically to the investigator. When the signed consent document is received at the research site, the person who obtained consent from the participant combines and staples the signed consent forms. A progress note is entered explaining the remote consent process and the date the consents were combined. A copy of the fully executed consent form is to be provided to the participant.

All remote studies should take into consideration the following when designing a study with remote consent:

- Even when consent is conducted remotely, the participant should experience a consent process as close to what it would be like in-person, as possible.
- The participant should have ample time and opportunity to review the consent form in advance, and then discuss it and ask any questions together with the investigator/authorized research personnel.
- The IRB-approved consent form is used and the IRB-approved Research Protocol/Study Application should include an accurate description of the entire consent process.
- The physical location of the investigator/authorized research personnel and participant can be any place convenient to them (e.g., at home), but must provide

adequate space for privacy and confidentiality.

- The remote environment can be virtual/online or on the phone. Video conferencing is allowable. Regardless of the environment, the participant must be informed in advance if the consent process will be audio and/or video recorded (i.e., at the time of recruitment or screening).

- The study team will document the consent discussion and any questions asked/answered in a progress note. The study team signs and dates their copy of the consent form.

- Items specific to remote consent with a paper consent:
    - The consent form can be provided to the participant via postal mail, email, fax, or another method. If mailed, two copies must be mailed so the participant or LAR is able to retain a copy for reference when their signed consent form is returned to the site and they are waiting to receive the final copy with all necessary signatures back from the site.
    - If the participant agrees to participate, he/she is asked to sign and date one copy of the consent form during the call. The person obtaining consent signs and dates their copy of the informed consent during the call. The participant returns the signed copy of the consent document(s) to the research site and the blank version is retained by the participant. The consent can be mailed or an electronic system may be used, including scanning, or photographing the signed consent form and sending it electronically to the investigator.
    - When the signed consent document(s) are received at the research site, the person who obtained consent from the participant combines and staples the signed consent forms. A progress note is entered explaining the remote consent process and the date the consents were combined.
    - Copies of the signed consent forms (by participant and study team) are then sent to participant. The USPS is the preferred method to send consent forms to and from participants. Use of email for this purpose is only permissible if sent via a secured mechanism. Your unit's IT data security liaison should be consulted to determine appropriate means of sharing documents.
    - The consent is not considered fully executed until the participant turns in the signed version and it is filed with the researchers signed version. Study procedures should not occur until the researcher has the signed consent back from the participant.

REMOTE CONSENT PROCESS and EIRB application

The following suggested language can be incorporated into the IRB study application informed consent section if you wish to incorporate a remote consent option into the consent process for your study. You will not need to make any changes to your consent document(s).

NOTE: No study related procedures may occur until a signed copy of the consent is in the possession of the study team (this can be a faxed, emailed or mailed copy) unless the IRB has approved a waiver of documentation of consent to allow select activities to occur before written consent is finalized.

"Revisions to the informed consent process are being permanently adopted for this research. Remote consent will be used as opposed to in person consenting where possible to reduce unnecessary in person encounters specifically for a consent procedure. In the event remote consent is utilized, participants will be provided with a copy of the Informed Consent prior to the remote consent meeting either via email, fax, mail or previously provided during an in person visit.

The identity of the participant signing the informed consent, whether the subject in the research study or the subject's legally authorized representative, will be verified through some form of official identification or other method [describe].

Participants will be given adequate time to consider the research study and ask questions prior to signing the consent form during the call. The study team member obtaining consent must verify the participant physically signed the consent document either by viewing via video conference, obtaining a photo of the signed consent document, or obtaining verbal confirmation from the participant that he/she signed the consent form or agreed to participate electronically. The participant or LAR will sign and date the informed consent document. The person obtaining consent will sign and date their copy of the informed consent form during the call. The participant will then mail, email or fax the document to the person obtaining consent. Once the original is received by the person obtaining consent, the copies will be attached to make a single document. A progress note is entered explaining the remote consent process and the date the consents were combined.

The consent is not considered fully executed until the participant turns in the signed version and it is filed with the researchers signed version. Study procedures will not occur until the researcher has the signed consent back from the participant.