Remote Consent & Authorization

1) Submit a modification to the IRB adding a remote consent process to the protocol:
   • If research involves only minimal risk, request a waiver of documentation of consent (waiver of the requirement for a signature on the consent document.)
   • If a HIPAA Authorization (Form B) is needed, request a waiver of the signature requirement on the HIPAA Authorization.

2) Consider the technology you will use to conduct the consent process:
   • UM IT recommends Zoom for Healthcare
     ○ To access this HIPAA-compliant form of ZOOM, contact the TeleHealth team by emailing telehealth@miami.edu.
   • If you cannot use Zoom, arrange a three-way call with the patient, an impartial witness, and if desired and feasible, additional participants requested by the patient, (e.g. next of kin)
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3) Arrange the time and communication method for the consent process for participant, or an existing participant, if the process is for reconsent.
   • Send a copy of the consent document via secure email or U.S. Mail.
   • Arrange for a witness to attend and witness the consent discussion.
   • Let the participant know that a witness will join the consent meeting.
   • Set up a Zoom meeting or 3-way call and send an invitation to the attendees.

4) During meeting:
   • Identify everyone on the call.
   • Review the informed consent with the participant, answer the participant’s questions and ask questions of the participant to confirm comprehension.
   • Ask the participant if s/he consents to participate/continue participation.
   • If the participant agrees, ask him/her to sign and date the consent document.
   • If using 3-way call, ask the participant to confirm s/he signed & dated the document.
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5) Follow the steps in #4 to obtain authorization from the participant.

6) Ask the participant to scan or take a picture of the documents and email the signed/dated documents to the study team. If the person is unable to take a picture, you will document the circumstances.

7) The person conducting the consent process should sign and date a copy of the consent document.

8) The witness should sign & date on the witness line of a copy of the consent document.

9) The person conducting the consent process should document the purpose for the remote consent (COVID-19), and each step of the process. The note should explain why the research team doesn’t have the signed and dated document.
Documentation of Remote Consent

• The originals of the informed consent document signed by the investigator and witness should be placed in the participant’s research record.

• The person obtaining consent should document how s/he confirmed that the patient consented and signed the consent form. The note should include a statement indicating why the informed consent document signed by the participant was not retained, e.g., due to contamination of the document by infectious material.

• If the participant cannot send a picture of the signed document, the person obtaining consent should document why a copy of the signed document is not available. See example on next slide.
Informed consent was obtained on Date at Time. The participant could not come to the site for the consent process due to COVID-19 social distancing requirements. A copy of the consent document was emailed to the prospective participant before the consent discussion.

The consent process was performed by phone/ZOOM. The individuals attending the discussion were: (list the names of the individuals). The consenter explained the research to the participant and answered the participant’s questions. The consenter asked the participant questions to ascertain whether the s/he understood the study, and the participant was able to answer the questions. The participant voluntarily agreed to participate. The research was not able to obtain a copy of the signed original consent document because consent was obtained remotely, and the document may transmit the infection. After signing the consent document, the participant took a picture and sent it to the research team/ OR The participant was unable to send a picture of the document. The consenter should then add similar documentation about the HIPAA authorization.