Standard Operating Procedure (SOP)

SOP number 851.017	**SOP Name** Remote and Electronic Methods for Conducting Informed Consent in Non-Exempt Research
Location AdventHealth Orlando	**Responsible Department** Research: ORA
SOP Owner/Executive Owner Executive Director of Research Services	**Original Creation Date (If applicable)**
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I. **SCOPE:** This Standard Operating Procedure (SOP) outlines the process that <Research Personnel> delegated the task of conducting the informed consent process must follow when there are plans to utilize remote and/or electronic methods to complete the informed consent process. All applicable federal regulations and institutional policies and procedures will be followed.

II. **PURPOSE:** This SOP describes the process to obtain informed consent from a research participant remotely and/or by utilizing an electronic platform for non-exempt research. Other procedures may be suitable when approved by the Institutional Review Board (IRB) of record and permitted by applicable local, state, and federal regulations.

III. **QUALIFIED PERSONNEL:** <Research Personnel> as delegated by the Principal Investigator (PI) and approved by the IRB of record

IV. **TRAINING:** The investigator is responsible to ensure all <Research Personnel> are trained in accordance with 400.070 POLICY: Investigator obligations in Research.

V. **SUPPLIES & EQUIPMENT:** IRBNet Access, Florence Access

VI. **PROCESS/PROCEDURE:**

Remote consent refers to the process of obtaining consent from a research participant or LAR by phone, AdventHealth telehealth visit, video conference, doxy.me, or other such means where the participant or LAR and person obtaining consent are not together in-person.

Electronic consent refers to obtaining written documentation of consent via an electronic platform. For FDA regulated studies, the platform must be a 21 CFR Part 11 Compliant system. Electronic consent may be obtained remotely or in-person. The participant should have an option, when available per sponsor and/or protocol, to consent via paper instead of electronic format.

Any electronic platform used for remote or electronic consent must be approved by AIT, per CW IS 126 Information Technology (IT) and Services Approval & Procurement Policy.

A. Introduction

1.1. IRB approval of a remote and/or electronic methods of conducting the consent process is required as applicable, including the electronic signature platform to be used when electronic signature for written documentation of consent is obtained.

1.2. The process begins when

1.2.1. the principal investigator makes a submission which requests remote and/or electronic methods for consent for many or all participants **OR**

1.2.2. the principal investigator determines that it is not possible for a participant or LAR to physically attend an in-person informed consent discussion due to unforeseen circumstances and submits the HRP-230 FORM: Protocol Exception to request remote and/or electronic methods for consent.

1.2.2.1. For example: participant or LAR lives outside the area, inclement weather, schedule constraint, study consent time frame, safety of participant or LAR, etc.

1.3. In most all cases, federal regulatory agencies do not regard verbal consent without signature as meeting the requirement for documentation of signed informed consent. In rare circumstances, federal regulatory agencies may allow the use of obtaining consent remotely without obtaining a signature; however, this would require IRB approval.

1.4. The process described below should not be confused with the IRB finding that a protocol meets the criteria for a waiver or alteration of the consent documentation/process or that a protocol meets exempt review requirements.

B. Process:

1.1. The principal investigator has determined that the study design allows the use of remote and/or electronic methods for obtaining consent. When applicable, the sponsor has agreed for remote and/or electronic methods to occur.

1.2. The principal investigator must submit, and the IRB must approve one of the following, as applicable:

1.2.1. remote and/or electronic methods for obtaining consent for many or all participants in a study as described in the protocol

1.2.2. remote and/or electronic methods for obtaining consent as described in the HRP-230 FORM Protocol Exception Request, if AH IRB is the IRB of Record

1.3. When the discussion or consent process takes place remotely, but still requires written documentation of consent, follow the procedures below to ensure adequate documentation of informed consent for research.

1.3.1. E-mail, fax, mail, or provide the consent form by other electronic means to the participant or LAR.

1.3.1.1. If hard copy will be mailed, two copies will be mailed, so the participant or LAR can keep a copy. A pre-paid, self-addressed envelope should be provided to the participant or LAR to return one of the original signed copies.

1.3.1.2. In rare circumstances where the signed consent form cannot be returned, the IRB may accept and approve an alternative plan. For example, returning a photograph or digital image of the entire

signature page which must include the IRB approval date and document version, if applicable.

1.3.1.3. For studies that include sensitive information, take special precautions, as needed, to protect confidentiality (e.g. verify with the participant or LAR that the mailing address, fax, or e-mail is correct, and it is acceptable to send the consent in this way).

1.3.2. The participant or LAR will be instructed to contact the study team after reviewing the ICF or the study team will obtain the patient's phone number. A call (tele or video) must be arranged with the participant or LAR, person obtaining consent, impartial witness (if applicable – for examples of when a witness is needed, see Interpreter Services Guidance) and, if desired or feasible, additional participants as requested by the participant.

1.3.3. Identify all who are on the call.

1.3.3.1. Include a method to ensure the person being consented is the participant or LAR (e.g., verification of name, relationship to the participant for LARs, state identification or other identifying documents or use of personal questions, biometric methods, or visual methods).

1.3.3.2. For FDA regulated studies, FDA Guidance on Use of Electronic Informed Consent requires verification of identity if any or all of the consent process takes place remotely.

1.3.4. Confirm with the participant or LAR that all pages are intact and/or visible.

1.3.5. Review the informed consent and invite a question/answer session to assess the participant or LAR's understanding of the study.

1.3.5.1. When applicable, obtain confirmation from the witness that the participant or LAR's questions have been answered.

1.3.6. If the participant or LAR agrees to study participation, obtain verbal confirmation that they would like to participate in the trial and that the participant or LAR have signed and dated the ICF (in all appropriate sections) that is in their possession.

1.3.7. Instruct the participant or LAR to return a copy to the team by similar means as discussed in section 1.3.1 above.

1.3.8. Instruct the participant or LAR to keep one signed copy of the ICF for his/her own records.

1.3.9. Once the ICF (signed & dated by the participant or LAR) is received by the research team, the researcher who explained the study must sign the appropriate signature line with the current date (the date they receive the ICF, not the date they consented the subject or LAR).

1.3.9.1. If consent is captured electronically, the protocol must address how this will be handled.

1.3.10. Ensure all signatures and dates are accurately documented. Any deviations will be handled in accordance with institutional research policies.

1.3.11. A copy of the fully executed consent form should be provided to the participant or LAR.

1.3.11.1. The protocol should explain how this will occur. For example, a copy may be mailed to the participant or LAR, provided at the next in-person visit, or allow the participant or LAR to download a copy from an electronic source.

1.4. Document as much as possible (in a separate note to file/progress note or electronic file, or with a note under the Principal Investigator's signature line on the ICF) ALL actions that occurred above including the actual dates the consent was mailed/e-mailed/faxed back/electronically returned.

1.4.1. For example only: "A telephone call was made to [participant or LAR name on xx/xx/xxxx]. An identification of who was present on the phone was conducted..... The consent form was reviewed with [participant or LAR name]. The consenter invited and answered questions from the participant. The consenter also posed questions to the participant or LAR to gauge their understanding of the study. The participant or LAR signed the consent form on [insert date] and was able to scan a copy to the study team on [insert date]. Once consent received, it was signed and dated by the consenter and filed in the research records."

1.4.2. Specify in the note the reason for performing the informed consent discussion over the telephone and the participation of the witness, when applicable, to the informed consent discussion.

1.5. When the discussion or consent process takes place in-person, but written documentation of consent will be obtained electronically, follow the procedures outlined in SOP 400.116 Informed Consent Process and Written Documentation of Informed Consent.

1.5.1. A copy of the fully executed consent form should be provided to the participant or LAR.

1.5.1.1. The protocol must explain how this will occur. For example, a copy may be mailed to the participant or LAR, provided at the next in-person visit, or allow the participant or LAR to download a copy from an electronic source.

1.6. No research-related activities may occur before the consent form is signed. All attempts must be made to receive a copy of the signed form or signature page.

VII. DEFINITION(S):

Impartial Witness - A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the entire consent process and reads the consent document and any other written information supplied to the subject as part of the consent process.

VIII. EXCEPTION(S):

IX. REFERENCE(S):

FDA Guidance on Use of Electronic Informed Consent

FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency
21 CFR §50.20, 50.25
45 CFR §46.116
21 CFR §50.27
45 CFR §46.117
CW IS SEC 114 3rd Party Assurance Appendix v2.1
CW IS 126 Information Technology (IT) and Services Approval & Procurement Policy

X. RELATED DOCUMENT(S) / ATTACHMENT(S):

400.070 POLICY Investigator Obligations in Research
SOP 401.116 Informed Consent Process and Written Documentation of Informed Consent