1. PURPOSE

1.1. This guidance establishes recommendations for the informed consent process to take place remotely in non-Exempt Research. This includes via phone, Skype, and/or an e-consent platform.

1.2. The process begins when 1) the principal investigator makes a submission which requests remote consent for many or all subjects -**OR**- 2) the principal investigator determines that it is not possible for a subject or LAR to physically attend an in-person informed consent discussion and submits the HRP-230 FORM: Protocol Exception

1.3. The process ends when the subject is no longer a research subject or potential research subject.

2. BACKGROUND

2.1. The IRB recognizes that remote consent may be applicable for all participants on a certain study OR in isolated, unforeseen situations where it is not possible for the subject or legally authorized representative (LAR) to physically come to AdventHealth for an in-person informed consent discussion (for example, lives outside of area, inclement weather, schedule constraint, study consent time frame, etc.).

2.2. 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 remote and/or verbal consent.

2.3. 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 document /process or that a protocol meets exempt review requirements.

3. GUIDANCE

3.1. The principal investigator has determined that the study design allows the use of remote consent. When applicable, the sponsor has agreed for remote consent to occur.

3.2. The IRB must approve one of the following:

3.2.1. remote consent for many or all subjects in a study as described in the protocol/ submission

3.2.2. remote consent process as described in the HRP-230 FORM Protocol Exception Request

3.3. When the discussion or consent process takes place by a means other than in-person communication (for example over phone/Skype), but still requires written documentation of consent, follow the procedures below to ensure adequate documentation of prospective informed consent for research. Please see AHO SOP 401.116 Informed Consent Process and Written Documentation of Informed Consent. Any deviations from either 401.116 should be explained in the protocol, submitted to the IRB as deviation meeting the promptly reportable requirement or as a protocol exception request.

3.4. E-mail, fax, mail, or provide the consent form by other electronic means to the subject or LAR. (If hard copy will be mailed, two copies will be mailed, so the subject or LAR can keep a copy. A pre-paid, self-addressed envelope should be provided to the subject or LAR to mail back one of the original signed copies.) In rare circumstances where the signed consent form cannot be returned, the IRB may accept and approve an alternative plan. For example, a photograph or digital image of the entire signature page which should include the IRB approval date and document version, if applicable. Another example is to refer to and follow local, state or federal regulations and/or guidance that may allow an alternative plan

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

3.5. The subject or LAR will be instructed to contact the study team after reviewing the ICF or the study team will obtain the patients phone number. A two or three-way call (tele or video) should be arranged with the subject, person obtaining consent, impartial witness (if applicable) and additional participants as requested by the subject, if desired or feasible.

3.6. Identify all who are on the call. Consider including a method to ensure the person being consented is the subject or LAR, e.g., verification of name, relationship to the subject for LARs, state identification or other identifying documents or use of personal questions, biometric methods, or visual methods. 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.

3.7. Confirm with the subject or LAR that all pages are intact and/or visible.

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

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

3.10. If the subject or LAR agrees to study participation, obtain verbal confirmation that they would like to participate in the trial and that the subject or LAR have signed and dated the ICF (in all appropriate sections) that is in their possession. and return a copy to the team by similar means as discussed in section 3.4 above.

3.11. The subject or LAR will be instructed to keep one signed copy of the ICF for his/her own records.

3.12. Once the ICF (signed & dated by the subject or LAR) is received by the research team, the researcher who explained the study should sign the appropriate signature line with the current date (the date they receive the ICF, not the date they consented the subject or LAR). If consent is captured electronically, the protocol should address how this will be handled.

3.13. Ensure all signatures and dates are accurately documented. Any deviations should be noted in a note or memo to file.

3.14. A copy of the fully executed form should be provided to the subject or LAR. The protocol should explain how this will occur.

3.15. 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 and mailed/e-mailed/faxed back/electronically returned. For example only: "*A telephone call was made to [subject or LAR name on xx/xx/xxxx]. An identification of who was present on the phone was conducted….. The consent form was reviewed with [subject or LAR name]. The consenter invited and answered questions from the subject. The consenter also posed questions to the subject or LAR to gauge their understanding of the study. The subject or LAR signed the consent form on [insert date] and was able to scan a copy to the study team on [insert date].*" 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.

3.16. No research-related activities will occur before the consent form is signed. All attempts should be made to receive a copy of the signed form or signature page. Other less restrictive procedures may be allowed per IRB review and/or per other regulatory authority guidances.

4. REFERENCES

4.1. AHO SOP 401.116 Informed Consent Process and Written Documentation of Informed Consent
4.2. FDA Guidance on Use of Electronic Informed Consent
4.3. 21 CFR §50.20, 50.25
4.4. 45 CFR §46.116
4.5. 21 CFR §50.27
4.6. 45 CFR §46.117