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1. Purpose

- 1.1. To outline the procedure for obtaining electronic signatures in informed consent documents.

2. Scope and Responsibility

- 2.1. This SOP applies to all individuals participating in the conduct of clinical research at UTHealth. Study personnel who are involved with the informed consent process are required to follow this SOP.

3. Definitions

- 3.1. **eConsent:** Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

4. Policy

- 4.1. The Principal Investigator (PI) is responsible that legally effective informed consent is obtained before a subject takes part in the study.
- 4.2. All consent forms (electronic and paper) and other informational materials, including any videos and Web-based presentations, which the subject will receive and view during e-consenting should be IRB approved.
- 4.3. The informed consent process for each study should be IRB approved, specifying in detail any aspect of the process that will be conducted remotely.
- 4.4. DocuSign and REDCap eConsent are the UTHealth approved platforms for eConsent. Within these platforms, Part 11 compliant modules should be used for studies being done under an FDA IND or IDE.

5. Procedures

- 5.1. **Identifying Potential Participants:** The process of identifying and contacting potential participants to invite them to participate in the research study should be IRB approved.

- 5.1.1. If potential participants are being identified from medical records, an IRB approval for waiver of consent and HIPAA authorization for screening should be on file.
- 5.1.2. Specify how initial contact with potential participants will be made e.g. by letter, phone or email.

- 5.2. **Informed Consent Process:**

- 5.2.1. Clarify in the IRB application, the most likely scenarios for consent process and electronic signature, such as:
 - a. Remote consent discussion and electronic signature
 - b. In person consent discussion and electronic signature
- 5.2.2. If conducting a remote consent, research staff may send the consent document by email or regular mail and schedule a time to talk with the potential participant.

- 5.3. **Remote Consent Discussion and Wet Signature**

- 5.3.1. Send the consent document to the potential participant by regular mail or e-mail.

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- 5.3.2. Remote informed consent discussion may happen over phone, UTHealth TeleHealth platforms, Microsoft or Zoom using UTHealth Houston login credentials.
- 5.3.3. Review the consent document with the potential participant as per standard consent process allowing time for questions and clarifications.
- 5.3.4. After the consent discussion, if the potential participant is interested in participating in the study, ask them to sign and date the consent form and return the signed page by:
 - a. Scanning the signed page returning it through a secure e-mail account.
 - b. Taking a photograph of the entire signed page and sending it via secure e-mail or text.
 - c. Uploading to a secure internet address.
 - d. Sending the signed page by mail.
 - e. Bringing signed and dated consent form at next visit.

5.4. Remote Consent Discussion and Electronic Signature:

- 5.4.1. If the consent process is occurring remotely, the discussion may happen over phone, UTHealth TeleHealth platform, UTHealth WebEx, UTHealth Zoom or UTHealth Google Meet.
- 5.4.2. If the potential participant is interested hearing more about the research study, send the consent form. The consent form may be sent by email or via the eConsent platform.
- 5.4.3. Review the consent document with the potential participant as per standard consent process allowing time for questions and clarifications.
- 5.4.4. If they are interested in participating in the research study, ensure they have received the notification from the eConsent system and offer to help with the electronic signature.
- 5.4.5. When the signed document is received, the person obtaining consent should also sign the eConsent and send a copy of the consent with both the signature (participant or LAR and person obtaining consent) back to the participant.

5.5. In Person Consent Discussion and Electronic Signature

- 5.5.1. Review the consent document with the potential participant as per standard consent process allowing time for questions and clarifications.
- 5.5.2. If the potential participant is interested in signing the consent form, open the electronic consent application in a computer or tablet and assist the participant in applying their electronic signature.
- 5.5.3. If there are any options in the consent form, make sure the participant checks the boxes to indicate their choice.
- 5.5.4. After participant signature, the person obtaining consent should apply their electronic signature.
- 5.5.5. Give the participant an electronic or paper copy of the signed document according to their preference.

5.6. Consent Documentation

- 5.6.1. Document the consent process by writing a note explaining how the consent discussion and signature occurred in the participants research file.
- 5.6.2. Send email of the signed consent to – for uploading to MHH EHR system

5.7. Legally Authorized Representative

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- 5.7.1. If potential participants is unable to give consent themselves, ensure that the IRB has approved consent from legally authorized representative for the research study. Before discussing the research study with the LAR, verify the identity of the LAR.
- 5.7.2. Check medical records to confirm documentation of the LAR
- 5.7.3. If medical records do not have LAR information, methods for confirm LAR identify include of verification of a state-issued identification such as driver's license, use of personal questions or visual methods
- 5.7.4. If the participant or LAR do not speak or read English, they should be presented a consent document and consent discussion in a language they are comfortable.

5.8. Reconsent

- 5.8.1. During the course of a research study, if the informed consent changes in such a way that the IRB requires re-consent of a participant, participants may be re-consented using electronic or paper informed consent methods independently in combination throughout the course of the study.

6. References

- 6.1. Use of Electronic Informed Consent - [FDA and OHRP Guidance](#)

7. Appendices

- 7.1. REDCap Instructions for eConsent.
- 7.2. DocuSign Instructions for eConsent.

If you find errors in this document, contact clinicaltrials@uth.tmc.edu

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