Clinical Research Enterprise (CRE)

Standard Operating Procedures

Utilizing DocuSign and Zoom in the Informed Consenting Process

SOP #: 3.11

Version: 2.0

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Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this SOP is to describe the Informed Consent process for remotely consenting patients via video conferencing in HIPAA compliant Zoom or via phone and obtaining signature through Adobe sign.

References

a. FDA 21 CFR Parts 11, 50, and 56

b. FDA Guidelines for Electronic Informed Consent Process
https://www.fda.gov/media/116850/download

c. Adobe Sign Guidance
https://www.uab.edu/it/home/tech-solutions/services/esignature

Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

This SOP is to be followed without deviation.

I. Details

I. Electronic signatures are intended to be the legally binding equivalent of traditional handwritten signatures.

II. Informed Consent Process must be performed in accordance with CRE Informed Consent Process SOP 3.02

II. Procedures

I. Administration of Remote Informed Consent

a. All procedures outlined in CRE SOP 3.02 are applicable to this process as well. The following are additional procedures required in the remote informed consent process for study subjects.

b. Remote consenting must be performed through a HIPAA approved video conferencing system such as UAB HIPAA compliant Zoom or via phone and can be signed using UAB Adobe sign.

c. The participant should enter the secure meeting with the person consenting and the informed consent form should be viewed through a share screen in Zoom. Time should be allowed for any questions to be addressed. If a witness is required, another person may join the video conference or by phone to witness if no staff is available to be personally present.

d. After thorough review and discussion of informed consent form has taken place, this can be routed to the participant and witness (if applicable) through UAB Adobe sign for electronic signature.

e. Signed copy of Informed Consent Form should be sent to participant and filed in the source chart per guidelines in CRE SOP 3.02

III. Related SOPs

I. CRE Informed Consent Process SOP 3.02