The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

ELECTRONIC CONSENT

1.0 PURPOSE

This procedure establishes the process to utilize electronic systems to obtain informed consent and electronic HIPAA Authorizations (when applicable) from subjects or a subject's legally authorized representative.

2.0 OVERVIEW

Electronic consent (e-consent) refers to the use of electronic systems and processes that may employ multiple types of electronic media including text, graphics, audio, video, podcasts, passive and interactive websites, biological recognition devices, and card readers to convey information related to the study and to obtain and document informed consent.

The e-consent process should have the capability to:

- Prove that the actual signer is the intended signer,
- Allow the signer to deny the signature, and
- Contain an assurance that neither the record nor the signature has been altered from the moment of signing; to achieve this, signatures executed to electronic records shall be linked to their respective electronic records to ensure that the document cannot be modified or otherwise tampered with. (Ref. 21 CFR 11.70)

If using a PDF format to collect a signature, verification preferences should be set in advance. This helps ensure that Digital Signatures are valid when a PDF is opened, and verification details appear with the signature. Refer to Adobe Validating Digital Signatures.

The process of e-consenting differs depending on regulation. FDA regulated research requires that software systems be compliant with all requirements under FDA Part 11 regulation (e.g., restricted access, administrative controls, training, identity verification, etc.). (Ref. FDA guidance Part 11, Electronic Records; Electronic Signatures – Scope and Application; 21 CFR Part 11)

FDA regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

The FDA does not certify systems for Part 11 compliance. Sponsors may provide Part 11 compliant electronic consent. For investigator-initiated research, refer to Part 11 options such as RedCAP, DocuSign Part 11 or Adobe Sign Part 11. The investigator is responsible for setting features, demonstrating compliance, providing/documenting training, and administering operational policies and procedures.

3.0 RESPONSIBILITY

The principal investigator is responsible for:

- Determining if electronic Informed Consent (eIC) or electronic delivery of surveys is appropriate for the targeted population;
- Ensuring that prospective participants can use the electronic systems and for providing paper-based consent where appropriate;
- Designing the consent process to include adequate time for the prospective participant/legally authorized representative to review the consent materials before asking for a signature;
- Ensuring that for research involving greater than minimal risk, verifying the identity of the person who will sign the consent form and obtaining the signature of the authorized person on the key research personnel who consented the participant;
- Ensuring that for FDA regulated research, software and transmission methods used for electronic delivery of consent materials and surveys are Part 11 compliant;
- Ensuring IRB approval is received for any proposed informed consent process prior to implementation.

4.0 OVERVIEW

4.1 Participant Considerations:

4.1.1 Participants should be informed of approximately how long the process will take and provided sufficient time to complete to the eIC process.

4.1.2 Electronic materials should be easy to navigate, allowing participants to proceed forward or backward within the system as well as to stop and continue later, if necessary. Hyperlinks may be provided where helpful. The eIC may also incorporate electronic strategies to encourage participants to access all consent materials before documenting their consent.

4.1.3 The eIC may either supplement or replace paper-based informed consent processes to best address a participant's needs throughout the course of participation. Each participant's needs should be taken into consideration, as

some participants may prefer one method over another, have difficulty navigating or using electronic systems, or have physical limitations such as poor eyesight or impaired motor skills. These participants should have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process.

4.2 Location of Consent

4.2.1 The consent process may occur either at the approved research location when both the investigator/designee and participant are at the same location, or remotely.

4.2.2 Self-initiated access of consent forms may take place on personal portable electronic devices using posted QR codes or web-links on study posters, brochures, or websites. Self-initiated accessing of consent forms may occur at the approved research location clinic or remotely.

4.3 Signature Validation

4.3.1 If the entire process takes place at the approved research location, the key research personnel can personally verify the participant's identification, review the eIC content, answer questions about the material, have follow-up discussions, and witness the signing of the eIC.

4.3.2 For FDA-regulated research: If any or all of the consent process takes place remotely and is not personally witnessed by key research personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the participant who will be participating in the research study or is the participant's LAR (ref. 21 CFR 11.100(b)).

4.3.2.1 Examples of verification methods include a state-issued identification or other identifying documents, use of personal questions, biometric methods, or visual methods.

4.3.3 Whether eIC is obtained from the participant at the approved research location or remotely, the eIC process must provide sufficient opportunity for the participant to consider whether or not to participate (ref. 45 CFR 46.116 and 21 CFR 50.20). The informed consent process should include methods to ensure that the eIC process allows participants the opportunity to consider whether or not to participate and to ask questions. This may be accomplished by in-person discussions with key research personnel or through a combination of telephone calls or video conferencing with a remotely located key research personnel.

4.4 Ensuring Participant Understanding

4.4.1 When telephone calls and video conferencing are used during the eIC process, key research personnel should remind participants to conduct the

eIC discussion in a private location to help ensure privacy and confidentiality.

4.4.2 To assist the participant in understanding the material, the eIC may use interactive electronic-based technology, including diagrams, images, graphics, videos, and narration. The eIC should be appropriate for the intended audience, considering the participant's age, language, and comprehension level. The eIC may contain various methods to help a PI assess the participant's understanding of the information presented during the eIC process. For example, the eIC may include optional questions at any time during the eIC discussion that can be used to help educate the participant about the information presented, as well as assess the participant's understanding of the informed consent materials. Such optional questions and other methods may be used to gauge participant comprehension of key study elements and highlight areas where the participant might need further explanation and discussion before signing the informed consent to enter the study.

4.5 Electronic Signatures

4.5.1 FDA and OHRP/HHS regulations permit the use of electronic signatures when written informed consent is required. OHRP/HHS permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted.

4.5.2 FDA regulations require the use of controls to ensure the security and integrity of electronic signatures (ref. 21 CFR 11.300). These controls include:

4.5.2.1 Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

4.5.2.2 Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

4.5.2.3 Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

4.5.2.4 Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

4.5.2.5 Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to

ensure that they function properly and have not been altered in an unauthorized manner.

5.0 DEFINITIONS

Not Applicable

6.0 REFERENCES

6.1 IRB Standard Operating Procedure: SOP 2.02 Informed Consent

6.2 IRB Reference Manual: RM 16 Informed Consent Process

6.3 U.S. Department of Health and Human Services (HHS) 45 CFR 46.116; 45 CFR 46.117

6.4 US Food and Drug Administration (FDA) 21 CFR 50.20; 21 CFR 50.27; 21 CFR Part 11; 21 CFR 11.100(b); 21 CFR 11.300.

6.5 FDA guidance: Part 11, Electronic Records; Electronic Signatures – Scope and Application

6.6 FDA guidance: Use of Electronic Informed Consent: Questions and Answers