The Christ Hospital IRB **Number:** 2.16
Submitted By: Erica Jones, CIP **Effective Date:** 09/14/22
Reviewed By: Steve Roberts, MD
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STANDARD OPERATING PROCEDURE

REMOTE CONSENT

1.0 PURPOSE

This procedure establishes the process to obtain informed consent remotely from subjects or a subject's legally authorized representative (LAR).

1.1 The process begins when an individual identifies a subject as a potential candidate for a research study.

1.2 The process ends when a subject or the subject's legally authorized representative provides legally effective informed consent or declines to do so.

2.0 POLICY

2.1 Remote Consent may only be used where the IRB has granted permission. Face to face communication between investigators and study candidates with ample time to discuss issues and answers questions is always the preferred scenario, but at times this is neither necessary nor feasible. A straightforward survey study may be readily explained in a consent, without need for much education or interaction. Consenting for a greater than minimal risk interventional study, even if done remotely, must allow for education, questioning and dialogue.

2.2 Remote Consent may be permitted for the following situations:

- **2.2.1** No research activities require in person contact with the subject
- **2.2.2** The Legally Authorized Representative (LAR) cannot travel to the site to meet a time sensitive inclusion criterion
- **2.2.3** Hospital visitor restrictions
- **2.2.4** Need to limit in-person contact
- **2.2.5** Compelling logistical issues
- **2.2.6** Other situations at the discretion of the IRB

2.3 Remote SOP 2.02 Informed Consent: Elements, Process and Documentation outlines the required elements and establishes the process to obtain and document written informed consent of a subject or a subject's legally authorized representative.

2.4 The IRB must review and approve all electronic media that the subject will receive or view during the consent process

2.5 When consenting remotely using an IRB approved process, the obtained consent is valid. It does not have to be repeated using a paper process.

2.6 If consent is obtained remotely and the subject must subsequently take part in an in-person visit as part of the study, then a focused review of the consent form must occur on the day of the visit, allowing for questions and answers before the in-person research activities occur. This conversation should be documented in the research record. For FDA regulated research, a paper consent form must be completed at this time using the date and time of this focused review.

2.7 If a LAR provided consent remotely, this focused review should occur at the first opportunity that the LAR presents in-person and the research staff is present. This focused review may occur after intervention has begun or is completed.

2.8 If after a focused review a subject or LAR withdraws consent, this should be reported as a subject withdrawal.

3.0 RESPONSIBILITY

3.1 The principal investigator is responsible to ensure these procedures are carried out.

4.0 PROCEDURE

4.1 OBTAINING REMOTE CONSENT

4.1.1 Send copy of current approved version of the consent / authorization form to the prospective research subject or LAR for review. The mechanism should be acceptable to the subject and can be provided by one of multiple mechanisms including online access, (e.g. a form in REDCap or other secure software), iOPEN or other approved E-consent module, fax, postal mail, Email or smart phone. Screen sharing can be used during the consent process but does not constitute sending a copy of the consent form to the prospective subject or LAR

4.1.2 The ability for the subject to be able to have questions answered prior to agreeing to consent is an absolute requirement. This can be done by phone or video, chat function or emails. The details of the chosen method(s) as well as the qualifications and the availability of those answering the questions should be included in the request to the IRB. The method of communication must be HIPAA compliant (e.g. VSEF or HIPAA compliant ZOOM).

4.1.3 As with in-person consenting, remote consent is only valid if the subject has the cognitive and legal capacity to give consent. This determination will generally require research team-subject interactions to assure subject comprehension.

4.1.4 In most cases, arrange for a conversation between the subject and the authorized members of the research team to allow for full discussion of the

combined consent /authorization form following the process in SOP 2.02. This conversation can be done by phone or video communication.

4.2 DOCUMENTING REMOTE CONSENT

4.2.1 The method(s) of documentation of consent must be IRB-approved and comply with appropriate OHRP and FDA regulations and guidance as applicable. (ref. 45 CFR 46.117; 21 CFR 50.27)

4.2.2 The subject or LAR may print, sign and return the completed consent form; options for the return of consent documentation via electronic means are scanning the document, taking a picture, or sending the form attached to an email or text message. Regular postal mail may be used. The informed consent process is not valid and study enrollment cannot proceed unless the form is received by the study team and appropriately filled out by the subject/LAR along with the consent document. Alternately, documentation of consent can be obtained using REDCap e-consent framework or a scripted name or legal mark using a secure signature capture platform (e.g. DocuSign, Adobe Sign, Apple Pen).

4.2.3 For FDA-regulated clinical investigations, the electronic system used for obtaining the electronic signature must meet the relevant requirements contained in 21 CFR part 11. The identity of the subject/LAR who will be electronically signing an electronic informed consent for FDA-regulated clinical investigations must be verified per regulation 21 CFR part 11. FDA regulations do not specify any particular method for verifying the identity of an individual and accepts many different methods. During the first in-person visit, a paper consent must be completed using the date and time of the focused review described in 2.6.

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

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

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