5.3 Use of a Remote Consent Process

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for use of remote informed consent process. For the purpose of this policy remote consent includes telephone, video-conferencing, or use of desktop, mobile or web-based applications or similar technologies.

2.0 Policy

It is the policy of the Organization that

- 2.1. Remote consent may be used in both clinical and non-clinical research, provided such communication satisfies requirements of HHS regulations at 45 CFR 46.116 and 45 CFR 46.117 and FDA regulations at 21 CFR 50.20 and 21 CFR 50.27, and satisfies the additional requirements in the policy.
  - 2.1.1. The convened IRB or a qualified expedited reviewer (if the research or change in protocol qualifies for expedited review) may authorize use of remote consent or documentation for new subjects, or re-consent for current subjects.
  - 2.1.2. If the convened IRB or a qualified expedited reviewer has not previously authorized the use of remote consent, the IRB Executive Chair or designee may authorize use of remote consent or documentation for a single subject if:
    - 2.1.2.1. Direct face-to-face contact with the research staff would place an unreasonable burden on the subject (for example, because of distance), OR
    - 2.1.2.2. Requirement for direct face-to-face contact would prohibit enrollment of a potential subject in research with the prospect of direct benefit, OR
    - 2.1.2.3. Provision of new information to the subject would be inappropriately delayed by requiring direct face-to-face contact with the research staff.

3.0 Process for Utilizing Remote Consent

- 3.1. Enrollment of new subjects
  - 3.1.1. The informed consent form (as well as all protocol related ancillary materials) and a copy of "The Rights of Research Subjects" and "What Do I Need to Know?" must be provided to the subject for review prior to the remote consent process. These items can be provided to the subject in paper form by mail or fax, in PDF or equivalent form electronically, or through RSS or another desktop, mobile or web-based application remotely.
  - 3.1.2. The process of consent will be conducted as per the requirements of HRPP policy 5.1 (Obtaining Informed Consent from Research Subjects), HHS regulations (45 CFR 46.116(a)) and FDA regulations (21 CFR 50.20).
    - 3.1.2.1. For research posing greater than minimal risk, if remote consent is utilized and the research interventions take place on the premises of the Organization, the investigator must also obtain in-person written informed consent at the first opportunity (ideally prior to any intervention involving greater than minimal risk).
    - 3.1.2.2. For research posing greater than minimal risk, if remote consent is utilized and the research interventions do not take place on the premises of the Organization, the consent process must utilize a video component, except when specifically authorized by the IRB or by the Executive Chair or designee.

    - 3.1.3. If the subject agrees to participate in the research:
        - 3.1.3.1. If the ICF is supplied in paper form the subject is instructed to sign and date the ICF and return the signed document to the investigator by mail, fax or a scanned copy via email.
        - 3.1.3.2. If the ICF is supplied in PDF or equivalent form the subject is instructed to print, sign and date the ICF and return the signed document to the investigator by mail, fax or a scanned copy via email.
        - 3.1.3.3. If the ICF is supplied remotely through RSS or another desktop, mobile or web-based application, the subject is instructed to sign through that application.
        - 3.1.3.4. If the signed ICF (noted in sections 3.1.3.1.or 3.1.3.2 above) cannot be collected by the investigator, the subject may supply a photograph of the ICF, OR a dated attestation by a witness who participated in the call and by the investigator that the subject confirmed that he/she agreed to participate in the study and signed the informed consent.
        - 3.1.3.5. In all cases, the investigator must verify the identity of the person signing the form or providing the electronic signature. Verification of identity and signature can be accomplished by direct (or video) observation of the process of signing, or by using information from some form of official identification, such as a birth certificate, a government-issued passport, or a driver's license, or via security questions, or via a digital signature (per FDA regulations at 21 CFR part 11, and OHRP guidance), or by the written attestation of a witness to the signature.
        - 3.1.3.6. No research interventions constituting greater than minimal risk can be conducted until a signed copy of the ICF has been received by the investigator electronically, or by email, fax or mail except when specifically authorized by the IRB or by the Executive Chair or designee.
        - 3.1.3.7. When the ICF has been signed by the subject in paper format it must also be signed and dated by the investigator upon receipt of the document with a note added on the form which explains the lapse in time between signatures (for example, "received in the mail 10/30/2018; remote consent obtained 10/27/2018").
        - 3.1.3.8. A copy of the ICF signed by the investigator must be provided to the subject (unless the subject has the ability to print the signed ICF through the desktop, mobile or web-based application.
    - 3.1.4. If the research satisfies the requirement for waiver of documentation of informed consent under 45 CFR 46.117(c) the ICF does not need to be signed and returned by the subject to the investigator and research interventions may begin as soon as verbal consent is obtained. In addition, ICF does not need to be signed and dated by the investigator.
    - 3.1.5. The process of remote consent must be documented in the medical or individual study subject record, if applicable, or in a separate consent log. The documentation must include:
        - 3.1.5.1. The date and time of remote consent.
        - 3.1.5.2. Identification of all personnel involved in obtaining and documenting informed consent.
- 3.2. Re-consent to disclose new information or protocol changes
    - 3.2.1. Remote Consent may be utilized for the purpose of disclosing new information which may relate to the subject's willingness to continue participation in the research, or protocol changes that may affect the subject directly.
    - 3.2.2. Procedure will be as per sections 3.1 above.
    - 3.2.3. If new information requires immediate verbal transmission to the subject (for example, a serious adverse event, or significant change in protocol which is required immediately) the subject may be notified by phone prior to supplying the revised ICF. The phone conversation between the investigator and the subject should be witnessed by a member of the Organization not associated with the research. Written re-consent as per section 3.1 should follow promptly.
- 3.3. Enrollment of decisionally impaired subjects whose LAR is unavailable in person
    - 3.3.1. Remote Consent may be utilized for the purpose of enrolling decisionally impaired subjects whose LAR is unavailable in person.
    - 3.3.2. Procedure will be as per section 3.1 above.
    - 3.3.3. The phone conversation between the investigator and the LAR should be witnessed by a member of the Organization not associated with the research.
    - 3.3.4. Assent of the decisionally impaired person must be obtained as required in HRPP policy 4.6 (Research Involving Subjects with Impaired Decision-Making Capacity).

DOCUMENT HISTORY:

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Revised: 6/11/2020 - previously titled policy: Use of a Telephone Consent Process

Revised: 1/19/2021 - clarify authority of convened IRB, expedited reviewer and IRB Executive Chair in authorizing use of remote consent (sections 2.1.1 and 2.1.2)

Revised 2/9/2024 - Revised to allow use of remote consent for all research (regardless of level of

risk); revised to delete difference in requirements for clinical vs non-clinical research; added requirement that for research posing greater than minimal risk, the investigator must also obtain in-person written informed consent at the first opportunity if the research interventions take place on the premises of the Organization (section 3.1.2.1), or must utilize video remote consent if the research interventions do not take place on the premises of the Organization (section 3.1.2.2); clarified research interventions may begin immediately when remote consent is obtained electronically (sections 3.1.3.6 and 3.1.3.7); deleted requirement to document the rationale for use of remote consent. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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