Remote Consent (HRPP 5.3)

Description:

This policy describes UNMC's requirements for use of remote informed consent process.

The IRB MAY approve the use of a remote consent process for clinical and non-clinical research.

Policy Summary:

- The IRB may authorize use of remote consent for new subjects or re-consent of current subjects
- If the IRB has not previously approved use of remote consent, they may authorize use of remote consent **for a single subject** if:
    - Face-to-face contact places an unreasonable burden on the subject, or
    - In-person interaction would prohibit enrollment in research with direct benefit, or
    - New information must be delivered promptly and cannot wait for an in-person visit

Process for Utilizing Remote Consent:

Enrollment of New Subjects:

- **Pre-Consent Requirements:**
    - Subjects must receive the following prior to the remote consent process:
        - *Informed consent form (ICF)*
        - *"Rights of Research Subjects"*
        - *"What Do I Need to Know?"*
    - These may be sent:
        - In paper form by mail or fax
        - In PDF form electronically
        - Through RSS or another desktop, mobile, or web-based application remotely

- **Consent Discussion:**
  - Conducted per HRPP Policy 5.1
  - **Greater than minimal risk research:**
    - **If the interventions take place on-site:** must get written in-person consent at the first opportunity
    - **If the interventions take place off-site:** informed consent process must utilize a video component, unless waived by the IRB
- **If the subject agrees to participate:**
  - **Paper/PDF form of ICF: s**ubject prints, signs, and returns via mail, fax, or scan/email
  - **App-based form of ICF** *(RSS, etc.):* Signed digitally using RSS E-signature
  - **If the subject is unable to return the ICF:**
    - They may supply a photo of the signed ICF OR a dated attestation by a witness who participated in the call and by the investigator that confirmed the subject agreed to participate and signed the ICF
  - **The investigator must verify the identity of the person signing the form/providing electronic signature.** Verification can include:
    - *Direct/video observation of the signing*
    - *Using information from official identification (e.g. birth certificate, passport, driver's license)*
    - *Security questions/digital signature (21 CFR Part 11 compliant)*
    - *Written witness attestation*
  - No greater-than-minimal risk interventions may begin before the signed ICF is received by the investigator
  - **Paper/PDF form of ICF:** Investigator must sign and date ICF upon receipt with explanatory note on lapse in time between signatures *(e.g. "received by mail 10/30/18; consent obtained 10/27/18")*
  - Subject must receive signed copy (unless the subject can print it on their own)
- **Waiver of Documentation:**
  - If granted:
    - Verbal consent is sufficient
    - No signature needed from subject or investigator

- **The process of remote consent must be documented in the medical or individual subject study record, if applicable, or in a separate consent log.**
    - This must include:
        - Date and time of remote consent
        - Names of all personnel involved in obtaining and documenting consent

Re-Consent (New Information or Protocol Changes):

- Remote consent allowed for updates impacting subject's continued participation
- Same procedures as listed above apply
- **If new information requires immediate verbal updates to the subject** *(e.g. serious adverse event, significant change in protocol):*
    - Subject can be notified by phone prior to supplying the revised ICF; the phone conversation should be witnessed by a member of the Organization NOT associated with the research
    - Written follow-up re-consent required promptly as per listed above

Decisionally Impaired Subjects (When LAR is Unavailable in Person)

- Remote consent permissible if enrolling decisionally-impaired subjects whose LAR is unavailable in person
- Same procedure as listed above
- The phone conversation between the investigator and LAR should be witnessed by a member of the Organization NOT associated with the research
- Assent of the impaired subject must be obtained per HRPP Policy 4.6