Electronic Consent (eConsent)

Introduction

The goal of the informed consent process is for prospective participants to make a voluntary, informed decision about clinical trial participation. The use of eConsent digitizes the informed consent form (ICF), which allows for, but does not require, interactive enhancements, such as videos, hyperlinks to additional information about elements of the study, and quizzes or other self-assessments of understanding, intended to increase participant understanding and decrease participant and site burden. It also allows for the consent process itself to be virtual or remote.

Considerations for IRBs and ECs

- Description of trial risk:
    - Trial risk does not impact the IRB/EC review of the informed consent *process*, which should enable participant understanding. The informed consent process may be problematic regardless of the trial risk.
    - Trial risk does impact the nature of protocol review and consent, including trials using eConsent. For example, tele-visit or in-person assistance may not be required during the eConsent process for minimal-risk studies.

- Method for verification of participant (or Legally Authorized Representative [LAR]) identity:
    - Comply with standards to verify individuals; these can vary by country, state, and institution. This process should not place an undue burden on the participant.
    - If the investigator has no previous contact with or knowledge of the participant, more in-depth verification may be required.

- eConsent content:
    - The language of the eConsent should be reviewed similarly to traditional consent.
    - The IRB should pay particular attention to visual images, videos, and other information associated with the eConsent to ensure that:
        - The information is fair and balanced and, as for all trials, not biased in favor of one arm of the trial, the intervention, or participation itself.
            - Embedded hyperlinks should be reviewed to ensure that the information is fair and balanced, and non-promotional.
        - The information in the eConsent is consistent with the rest of the informed consent and study.
        - The information is accessible and/or alternative formats for the same or similar information is available.
        - Translations of the eConsent, if available, are consistent.

- Images are inclusive and considerate of the intended study population and community.
- IRB/EC review of the consent language may be performed while the platform is designed and developed. After the platform is developed, an expedited review can be completed. A working link can be provided for evaluation of the actual eConsent experience which potential trial participants would see.
- Appropriate features of eConsent should include:
  - Ability to move forward and backward within the document.
  - Ability to stop and resume at a later timeA method to verify identity as the participant or legally authorized representative (LAR).
  - Translation to the preferred language of the participant.
  - Modifications to the eConsent document and process for people with disabilities.
  - Any included hyperlinks work.
  - Possible inclusion of questions to assess ongoing understanding (optional).
- Short form eConsents are generally not acceptable.
- Necessary terms are defined in plain language for all consent forms. There may be additional terms to be defined in a DCT.
- A method for obtaining a validated participant signature must be provided.

- Assistance that will be offered to potential participants:
  - If eConsent is fully remote:
    - Participants need
      - Access to technical assistance, if necessary.
      - A method to receive help for questions regarding the trial or content of eConsent
      - A printed or electronic copy of the signed eConsent.
  - If eConsent involves a remote or tele-visit or is done in person:
    - The responsible person(s) for assisting in the eConsent process should be identified.
    - Any tele-visit conducted as part of the consent process should be documented.

- Measures implemented to assure platform security:
  - Documentation of platform security should be provided. Third-party vendors have often undergone review and have the necessary documents to show compliance with security regulations.
  - If this is not the case, an IRB may require institutional validation of security or accept PI assurance that platform security is compliant.

- Storage of eConsent records:
  - Investigators and sponsors should have or have access to:

        - An audit trail to identify the participant, study staff, and the date/time of eSignature and PDF creation of an IRB-approved informed consent document.
        - Access to the system that is restricted to appropriate personnel
        - Appropriate archiving capability with restricted access and with all versions easily retrieved.
    - Other questions to consider
        - Where will eConsent records be stored?
        - Will any vendors or 3rd parties have access to the records?

- Implementation of eSignature:
    - The acceptability of eSignatures varies by country. The signature process should comply with national and local laws and regulations.
    - When eSignatures are acceptable, the use of a Qualified eSignature, which entails providing a participant with a unique code that must be entered along with their eSignature, is considered best practice. However, this process is often burdensome, and the need for it must be considered in the context of a specific trial.

- Pediatric participants:
    - The Parent/Guardian/LAR's credentials should be used to create, verify, and document consent and assent in the eConsent system.
    - Assent should be captured electronically as a separate field in the eConsent system.