WRIGHT STATE UNIVERSITY

Remote Consent Guidance
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Using Electronic Systems and Remote Procedures to Obtain Informed Consent

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) regulations permit the use of electronic and paper informed consent methods independently or in combination. Federal and local requirements also allow for methods other than an "in-person" discussion as part of the informed consent process.

The purpose of this guidance is to provide investigators with information about how to design informed consent processes that do not involve in person discussion (a.k.a., remote consent) and/or physically signed consent forms. It also describes the Wright State University Institutional Review Board (IRB) submission requirements and review processes when such research will be conducted under the auspices of Wright State University (Wright State) or when the IRB serves as the IRB of Record for an external entity.

Electronic Informed Consent Requirements

Electronic informed consent (eConsent) refers to the use of electronic processes and systems (i.e., information presented vis computers, tablets, websites, or smartphones) to:

- Convey study information and/or
- Document informed consent from a subject or Legally Authorized Representative (LAR).

Use of eConsent is permitted when investigators meet the same regulatory and institutional requirements of an in-person paper-based informed consent process unless the IRB approves a waiver of documentation of consent and/or authorization. See following sections for more information that should be addressed and included (as applicable) in the Consent Process sub-section of your IRB application:

General Requirements

- An eConsent must contain all elements of informed consent required by 45 CFR 46.116 (HHS) and as found in the *Informed Consent Policy* and IRB consent form template(s).
- An eConsent process/form can be used to either supplement or completely replace paper-based informed consent. If eConsent is used for initial consent, modifications (that require re-consent) are not required to also utilize eConsent.
- An eConsent process can be used to obtain parental permission and child assent.
- The electronic format utilized should be easy to navigate for the targeted study population. Strategies that enhance comprehension of information are permitted, including but not limited to:
    - Narration of text
    - Hyperlinks to additional information
    - Images, such as pictures and charts

    - Videos
- All relevant information about study procedures should be included in the eConsent process and subjects must be given sufficient time to consider whether to participate. This includes the chance to stop and continue eConsent process later.
- The eConsent process between a subject and the study team member (a.k.a. investigator) obtaining consent can take place either remotely or in person, prior to having the subject sign the consent.
    - If done in person, the study team member(s) obtaining consent will verify the subject's identification, review the eConsent content, address questions, and witness signing of the eConsent.
    - If done remotely, there must be a method for subjects to have discussions with the study team (e.g., messaging, telephone calls, video conference, chat) prior to documenting consent. If discussions are not in real time, subjects should be informed of how they will receive responses to questions. Subjects should be reminded to use a private location to help ensure privacy and confidentiality. Additionally, the electronic system must include a method to ensure that the participant or LAR electronically signed the form, and not another person.
- Electronic methods to capture the signature of the subject or LAR are permitted. OHRP permits electronic signatures if such signatures are legally valid withing the jurisdiction where the research is to be conducted. The following represent requirements in state of Ohio:
    - Ohio Revised Code 1306.01(H) defines electronic signature as an "electronic sound, symbol or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record."
    - Ohio Revised Code 1306.07 requires that the individual signing must be capable of retaining the record in electronic or print form.
    - Ohio Revised Code1306.04 and 1306.16 requires that it be possible for individuals to opt out of signing electronically for a particular transaction.
- The subject/LAR electronically signing the eConsent must be given a copy.
    - The copy can be paper or electronic (email, text, photograph or another electronic format)
    - If hyperlinks are included in the eConsent, the links must be maintained through completion of the study.
    - If a paper copy of the eConsent is provided, a paper version of the study-specific hyperlinked information should be included.
- The principal investigator (PI) and/or study team member obtaining consent must ensure that a valid signature has been obtained prior to the subject participating in any study activities.

Additional Requirements for FDA-Regulated Research

- An eConsent must contain all elements of informed consent required by 21 CFR 50.25 (FDA) and as found in the *Informed Consent Policy* and IRB consent form template(s).
- FDA considers electronic signatures to be valid and generally equivalent to paper-based signatures. Signature requirements can be found at 21 CFR 11.10.
- The FDA does not mandate types of electronic signatures. Methods permitted by FDA include but are not limited to:
    - Digital signatures
    - Computer-readable ID cards
    - Biometrics designed to ensure that they cannot be used by anyone other than the subject.
    - Username and password combinations
- The electronic system used for eConsent must capture and record the date that the subject/LAR provides consent.
- Subjects should be provided with a copy of the eConsent. However, FDA regulations do not require a "signed" copy but recommend that the copy include date of signature.
- Prior to initiating research activities with subject, the identity of individual must be verified as required by 21 CFR 11.100(b). Methods permitted by FDA include but are not limited to:
    - Use of birth certificate
    - Government-issued passport
    - Driver's license
    - Use of security questions
- Study teams should obtain a statement from the vendor of the electronic system that describes how the signature is created and that the system meets the requirements of FDA regulations at 21 CFR 11.
    - The electronic system must have restricted access and be secure. Additionally, the system should ensure confidentiality regarding subjects' personal and private information.
    - Approved options at Wright State that do not require a formal statement, include DocuSign Part 11, Adobe Sign Part 11 and/or REDCap.
- If an FDA-regulated study is subject to an FDA site inspection, the FDA must be granted access to all site-specific versions of the eConsent (initial version and all amended versions) and all eConsent signed by subjects.

Additional HIPAA Requirements

- If the research will use or disclose protected health information (PHI), the eConsent used for the informed consent process must comply with the HIPAA Privacy, Security, and Breach Notification Rules (45 CFR 160 and 164). The electronic system should include either:
    - Encryption of subject's information, or

    - Documentation of measures equivalent to encryption with justification for why encryption is not possible.
- HIPAA authorization to use or disclose PHI is permitted to be obtained electronically, if the electronic signature is valid under applicable laws and regulations (See Ohio requirements under General Requirements).
- Subjects/LARs must be provided a copy of the signed eConsent/authorization.
- Study teams should obtain a statement from the vendor of the electronic system used for eConsent that indicates compliance with the HIPAA Privacy, Security, and Breach Notification Rules and include it with their IRB application.
- HIPAA compliant platforms include Qualtrics and REDCap.

General Requirements for Remotely Obtaining Informed Consent

Remote consent means an informed consent process that does not involve in-person discussions. For certain studies that do not use a valid eConsent process as described above, investigators may still need to conduct the informed consent process remotely or with limited contact with subjects (e.g., COVID-19 patients). In these cases, the study team must submit the following information in the Consent Process sub-section of the IRB application that includes the following:

- Description of the method to be used to provide consent form to subject or LAR, including but not limited to:
    - Mailing a paper consent form
    - Faxing or emailing a copy of the paper consent form
- Description of the method to be used to address subject/LAR questions, including but not limited to:
    - Telephone
    - Telehealth or other secure video technology
    - Chat technology
- Description of how the subject/LAR will send back the signed consent form, including but not limited to:
    - A subject/LAR signs the paper consent form, takes a picture of the signature page via a smartphone or camera, and sends the picture of the signature back to the study team.
    - A subject/LAR scans the signed consent form and electronically returns to study team.
    - A subject/LAR faxes the signed consent form to the study team's secure fax number that is only accessible to study team members.
- Description of how the study team members will document that informed consent was obtained from the subject/LAR, including how the study team member will sign as the person obtaining consent.

Summary of IRB Submission Requirements

If a study will involve proposed use of eConsent, the following should be included in the IRB Application:

- Copies of all eConsent/assent in a format that will be used for subjects (or similar if not feasible)
- Copies of any study-specific information linked to in the electronic forms.
- Copies of any videos or images to be uploaded to electronic consent platform in an acceptable file type.
- If the study is FDA-regulated, a copy of the vendor statement that describes how signature is created and the system meets 21 CFR 11 requirements (unless utilizing one of Wright State pre-approved platforms).
- If the study requires HIPAA compliance, a statement from the vendor that system is in compliance with HIPAA Privacy, Security, and Breach Notification Rules (unless utilizing one of Wright State pre-approved platforms)

If a study will involve proposed use of remote consent using paper consent forms, the following should be included in the IRB Application:

- Method used to provide and informed consent form(s) to subject/LAR.
- Method used address questions from subject/LAR prior to signing document.
- Description of how subject/LAR will send back signed informed consent form(s) (e.g., by mail, fax or as electronic image).
- Description of the method the study team will use to document the informed consent process, including how study team member who obtains consent will also sign the consent form(s). Documentation should include date(s), names of individuals present, how process was conducted, discussion points, return mechanism and receipt date.

The Wright State IRB will utilize this information to prospectively review and approve the use of eConsent and/or remote consent and document approval to utilize these alternative methods in the corresponding IRB approval letter.

References

The following resources were utilized to create this guidance:

- 45 CFR 46 (DHHS)
- 21 CFR 11, 50 and 56 (FDA)
- 45 CFR 160 and 164 (HIPAA)
- Informed Consent Procedures Using Electronic System and Remote Use of Paper Documents - University of Michigan
- Ohio Revised Code 1306