HUMAN RESEARCH PROTECTION

Verbal and electronic informed consent

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Please refer to the IRB webpage for current forms and information:

https://www.hhrinstitute.org/researcher-resources/ohsr/

1) Can I obtain consent verbally?

If the IRB approves a waiver of documentation of consent for a study, consent may be conducted by phone or other institutionally approved synchronous communication applications, such as Zoom. IRB approval for verbal consent is considered on a case-by-case basis and must be appropriate for the study. For example, consent discussions may be conducted verbally for research not greater than minimal risk. When researchers request to obtain informed consent in this manner, they should justify in the protocol submission why a waiver of documentation of informed consent is necessary and describe how the consent process will be operationalized and documented.

The process of conducting and obtaining informed consent verbally must be fully documented in the study record.

2) What if my study requires written documentation of consent?

Hard-copy signatures:

If the IRB requires documentation of informed consent in writing and in-person consent is not possible or practical for the subject or legally authorized representative (LAR), the consent form may be sent to the prospective subject or LAR via USPS or other mail carrier, or electronically (e.g., fax, scan, email or text image attachment). If the consent form is to be sent and returned by mail, include two copies - one for the subject to keep for their records. Once the prospective subject/LAR has received the consent information, a consent discussion between the researcher and prospective subject or legally authorized representative must take place by phone or other institutionally approved synchronous communication application. When subjects/LARs agree to be in the study, they must sign and date the consent form and return it by mail or electronically (e.g., fax, scan, email or text image attachment) to the researcher. When there is a line for signature of the person obtaining informed consent in the consent form, the person verifying informed consent must sign and date the consent form upon receipt of the form from the subject. The process of conducting and obtaining informed consent must be fully documented in the study record.

Electronic signatures:

When part or all of an informed consent process is conducted via an electronic system, the responsibility for obtaining informed consent remains with the investigator and the study personnel to which responsibility has been appropriately delegated. Researchers cannot delegate authority to obtain informed consent to an electronic system, i.e., a verbal consent discussion must take place between the researcher and potential subject or LAR. Electronic signatures must also meet state law requirements.

Minnesota made provision for electronic signatures in its Uniform Electronic Transactions Act (UETA) first adopted in the 2000 legislative session. The Minnesota UETA defines electronic signatures 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."

The definition above is not technology specific and does not mandate the use of a particular hardware or software application. Any tool that can authenticate the signer and the signed document can be considered an acceptable electronic signature, as long as the parties can demonstrate the veracity of the process that created and preserved the records in question.

Electronic informed consent (eIC) may be used to either supplement or replace paper-based informed consent processes to best address the needs of subjects throughout the course of the study. For example, some subjects may prefer one method over another. Other subjects may have difficulty navigating or using electronic systems because of, for example, a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills. In such cases, the eIC process may not be appropriate; therefore, subjects should have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process.

Investigators must provide a detailed eIC plan within the protocol for IRB review. For more guidance on developing an eIC plan see the FDA guidance: Use of Electronic Informed Consent Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors. In some circumstances, it may be appropriate for investigators or study personnel to assist subjects in using the eIC technology. For example, researchers may help the subject understand how to navigate a technology by providing demonstrations.

For FDA regulated research or research data that will be submitted to the FDA in the future as part of a marketing application or other FDA related application, the electronic consent process and platform must meet the requirements of 21 CFR part 11. For example, if any or all of the consent process takes place electronically and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR (see 21 CFR 11.100(b)). Failure to comply with 21 CFR part 11 will result in noncompliance and the FDA may determine that the information collected cannot be used.

Consent and LARs:

If consent from a legally authorized representative (LAR) is allowed for a study, researchers must follow state laws on who is considered a legally authorized representative. The Minnesota laws on surrogate consent in healthcare should be used to determine surrogate consent for research conducted in Minnesota. The following individuals meet this definition in order of priority:

1. Healthcare agent previously appointed by the individual through a healthcare power of attorney
2. Spouse
3. Parents
4. Adult children
5. Adult siblings

3) How do I obtain signatures electronically?

"Digital signatures" may be acceptable forms of written documentation for informed consent. Electronic consent may facilitate record-keeping even when an individual is present and could sign a paper form. Digital signatures may be considered for face-to-face and remote consent, but the technologies and processes used must be described in the protocol.

There are two forms of digital signatures:

(1) Actual signatures on tablets or computers, in which subjects use a stylus or finger to make a representation of their signature

(2) Validated electronic signatures on platforms with password entry (such as those used to sign medical notes or electronically written prescriptions). Validated electronic signatures typically require the researcher to "set up" an identity and password within an electronic system and may not be easily and rapidly activated.

Both forms of digital signature may be used in certain research settings, but because of tracking, privacy, and identity validation issues, this may be more challenging than it initially appears.

When a stylus is used to collect a signature, the usual methods of identity validation should be used, such as comparison to a valid picture identification card with signature. Note: Scanned signatures that are copied and pasted to a document are not acceptable "digital" signatures and for FDA regulated research; for FDA-regulated research, the digital signature platform and process must be 21 CFR part 11 compliant.

When an electronic signature is used, the researcher must specify a method for verifying the identity of an individual. For example, verifying someone's identity may be done using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. In addition, use of security questions to confirm an individual's identity may also be considered.

4) Does HHRI have a recommended tool for obtaining consent electronically that is "Part 11" compliant?

HHRI's Information Technology group is developing an e-Consent module to provide an option for HHRI researchers that doesn't require direct physical interaction with patients to obtain informed consent documentation. This e-Consent platform is being designed using REDCap to provide a computer-based consent form rather than traditional paper documentation. This new process will support a process to obtain consent using a web-based survey which can be accessed on a computer, mobile phone, or tablet. This HHRI REDCap instance is currently being validated to allow for HIPAA and 21 CFR Part 11 compliance.

This new HHRI REDCap e-Consent tool is in the process of being validated and tested and will be piloted using one of the recently initiated COVID-19 protocols. Once e-Consent for that study is fully up and running and IRB-approved, IT will send an announcement and instructions for research use. Researchers interested in being added to the waiting list for access and training on this new tool should send an email to Maddie Mahon in HHRI Administration at mmahon@hhrinstitute.org.

5) Can I store source/study documents electronically?

Generally yes; however, if you plan to store study related documents, including source documents (such as informed consent documentation) electronically, you or your department should develop a standard operating procedure on how documents will be scanned, certified, and stored electronically. Industry and other external sponsors generally have specific requirements for electronic records to comply with 21 CFR Part 11, when applicable. Investigators should seek the written permission from the Sponsor and follow the Sponsor's requirements for electronic storage of source documents prior to creation of electronic source document storage. Documentation of Sponsor permission should be filed with study documents.

Source documents/consent forms should be scanned individually and labeled. The person who certifies the copy as an accurate and complete representation of the original, having all the same attributes and information as the original, should be the same person who actually created the electronic copy from the original. Different software and applications can be used to create certified copies. For FDA regulated research documentation, systems and processes should be FDA compliant (including 21 CFR Part 11). In addition, systems must comply with HHRI and HHS policies and procedures for research data storage.

6) How do I protect the security and confidentiality of research data?

Researchers are expected to plan for the appropriate protection of data that could be identified with individuals or groups through mechanisms appropriate to the medium in which the data are collected, analyzed, stored, or transmitted. You must document this plan in your protocol and explain the provisions for confidentiality.

If appropriate, you may request a waiver or alteration of the consent process or waiver of written documentation of consent to reduce personally identifiable information collected and protect confidentiality.

In order to manage data security risks, HHRI and HHS researchers must ensure that their electronic devices and other resources which store, transmit, or process research information meet the HHRI and HHS information security processes and standards.

7) Does the General Data Protection Regulation (GDPR) affect my research?

The GDPR may apply if you are participating in research that involves the European Union (EU). The GDPR regulates collection, storage, and processing of any personal data collected from individuals present in the EU at the time the information is collected. Research or other sponsored activities involving the collection of such regulated personal data, including clinical trials with subjects in the EU, would thus be affected. The allocation of responsibility for GDPR compliance should be agreed to explicitly with EU collaborators, EU sub-recipients and any third party used for processing of data (including storage and analysis of the data) whether the processor is located in the EU or not. Consent form content, personal data handling, and reporting (in the event of a breach of confidentiality) are all research and trial areas governed by the GDPR.