The purpose of this policy is to provide guidance on documenting written signature of consent obtained from subjects utilizing methods other than pen and paper. Most frequently, subjects document informed consent by providing their written signature in the provided space at the end of the consent form. This guidance describes other methods that are also sufficient documentation of written informed consent specifically using an electronic signature.

**What is E-Consent?**
Electronic informed consent (e-consent) refers to the use of electronic systems and processes that employ some type of electronic media (including text, graphics, audio, video, podcasts, passive and interactive websites, biological recognition devices, card readers, etc.) to convey consent information and/or to document informed consent. These may be used in place of, or in combination with, paper-based consent methods.

**Requirements**
The following requirements must be described in the IRB application and research protocol.

*Facilitating Comprehension*
Researchers must describe the process that will be used to obtain consent by electronic signature. There must be a process in place to ensure a subject reviews the entire consent document. The consent process itself should be designed to ensure that participants are adequately informed about the research, can easily ask and get answers to questions, and recognize that participation is voluntary. Subjects must be afforded an opportunity to discuss the research with a member of the research team prior to providing their electronic consent. Subjects should be given a description of how and when they will receive answers to their questions, and they must be provided information on how to contact an appropriate individual for pertinent questions about the research and their rights and whom to contact in the event that they sustain a research-related injury. Subjects must be provided with a version of the consent form that they can retain for their records, whether it is a hard copy or an electronic version.

Certain 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 electronic signature process may not be appropriate for these subjects. Therefore, subjects should have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process. Thus it may be possible that the method by which the informed consent signature was obtained may vary from subject to subject in the same study due to particular needs of an individual subject.

Before issuing final approval, the IRB must be able to review a hyperlink or PDF of what the e-consent/e-signature process will look like.

*Verification of Identity*
The process for verifying the participant’s identity must be described. Researchers and the UofL IRB are encouraged to apply a risk-based approach to this issue, i.e., how likely is it that someone other than the subject would provide the consent and how risky would that be to the actual subject and to the integrity
of the study? For example, social behavioral minimal risk research will not typically warrant such verification- and indeed, may qualify for waiving the requirement to obtain documentation of consent. *(For FDA-regulated research, please see below).*

**Documentation of Consent**

Electronic documentation must meet the same requirements as paper documentation – for example, (1) meets all applicable records retention requirements; (2) appropriate protection of the confidentiality and integrity of the records; (3) accessibility by an auditor or monitor; (4) capture and record the date that the subject provides consent; and (5) a copy is provided to the subject. In addition, the electronic documentation system must be legally valid within the jurisdiction where the research will be conducted. The system to be used to obtain electronic signature must be described in the IRB Application and research protocol.

Any website consent information must be maintained until the entire study is completed and closed with the IRB if the website information is part of the consent information provided to the subjects and/or website links are embedded in the consent information. Further, the website consent information (or other electronic means of signature collection) must be maintained for as long as the paper records would have been retained. In other words the retention for the electronic method should be as long as it would have been for the paper/hard copy collection method. *(For FDA-regulated research, please see below).*

Consent obtained by the participants legally authorized representative (LAR) requires the same documentation of relationship as required for a paper consent process.

**Conveying Additional Information and Significant New Findings**

When appropriate, the consent must contain a statement that significant new findings developed during the course of the research that may affect the subject’s willingness to continue participation will be provided to the subject or the subject’s LAR (see 45 CFR 46.116(b)(5) and 21 CFR 50.25(b)(5)). If an update or amendment to a consent is necessary and could affect the subject’s willingness to continue participation in the study, the consent process must provide sufficient opportunity for the subject to consider whether to continue participation (see 45 CFR 46.116 and 21 CFR 50.20). If the consent is updated or amended, the subject should be given sufficient opportunity to ask questions about the amended contents. In such cases, the subject or the subject’s LAR must sign the amended consent before the subject continues in the study (see 45 CFR 46.117(a) and 21 CFR 50.27). OHRP and FDA regulations permit the flexibility of using electronic and paper informed consent methods independently or in combination throughout the course of the study. Thus, amendments to the consent do not need to be electronic and can instead rely on more traditional means, such as paper-based amendments or postal mail, for conveying and transmitting the information to the subject.
FDA-regulated Research
FDA regulations set forth the criteria under which the FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper.

a. The electronic system used must meet the FDA Part 11 requirements for all electronic systems used in research. This is the responsibility of the researcher. The UofL IRB does not provide guidance nor does it review research electronic systems for compliance with Part 11 requirements.

b. Verification of the identity of the individual providing consent must be obtained at the time of the signature, if the e-signature is not personally witnessed by a member of the study team. FDA notes that a child may lack the documentation necessary to verify their identity during the assent process. If so, depending on the study, it may be reasonable for the parent to initially document the child’s assent, which can then be verified when the study team first sees the child.

HIPAA and Protected Health Information (PHI)
Where the HIPAA Privacy Rule applies, the Rule allows a HIPAA authorization for research to be obtained and signed electronically, provided any electronic signature is valid under applicable law. The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a subject (or a subject’s personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.

Research with Child Participants
The electronic consent process can be used to obtain assent from pediatric subjects (when required) and parental permission from their parent(s) or guardian. The general requirements for informed consent apply to this utilization as well. Absent a waiver of the assent requirement, or a determination that assent is not necessary, the IRB must determine that there are adequate provisions for soliciting the assent of a children when, in the IRB’s judgement, the children are capable of providing assent. The language and presentation of the information must be understandable to the child. (For FDA-regulated research, please see above).

Record Retention
All data, including electronically signed consent form documents, must be retained for a minimum of three years past the completion of this research. Additional retention timelines may be required by contractual obligations, University of Louisville departments, HIPAA (e.g. 6 yrs), FDA, or any other applicable regulatory agencies. Review UofL’s Record Retention Policy.

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