ELECTRONIC INFORMED CONSENT CHECKLIST

Institutional Review Board and Human Subjects Office

The purpose of this checklist is to:

- Ensure the electronic informed consent (eConsent) process is compliant with federal regulations
- Assist UI researchers with the use of UI-supported eConsent tools, such as DocuSign (see the DocuSign educational tool)

If you answer 'no' to any of the checklist questions, your eConsent process is noncompliant. Please revise your procedures.
The informed consent process for non-exempt human subjects research must adhere to federal regulations. Further, FDA regulated studies must adhere to FDA-specific criteria. This is especially important when developing an electronic informed consent process.

Informed Consent Regulatory Requirements and Guidance:

- Must contain all required elements of informed consent required by 45 CFR 46.116.
- Must be written in a language understandable to the potential subject or subject's Legally Authorized Representative (LAR)/parent/guardian and conveyed in a manner that minimizes coercion or undue influence.
- eConsent platform should be easy to navigate; subjects can stop or continue the virtual consent at any point.
- Must provide sufficient opportunity for the subject to consider whether to participate (see 45 CFR 46.116) and to ask questions about the study before signing the consent document and throughout the subject's involvement in the research.
- The investigator is responsible for ensuring that legally effective informed consent is obtained before that subject takes part in the study (see 45 CFR 46.116).

Regulatory Requirements for Documentation of Consent (45 CFR 46.117):

- Must employ a method to verify the identity of the subject, parent/legal guardian, and/or the Legally Authorized Representative (LAR)/Parent/Guardian who sign the electronic Informed Consent Document. The electronic signature must
    - Be unique to the subject
    - Be legitimately verified as coming from the subject (or their guardian) participating in the research (i.e., it must be unlikely that any other individual signed the document). Possible verification solutions could include, but are not limited to, use of a:
        - unique log in and password
        - unique code
        - security question
- Must provide a signed copy of the Informed Consent Document to the subject and retain a signed copy in research files (required under both 45 CFR 46.117 and HIPAA regulations).

FDA Regulated Human Subjects Research (21 CFR 50 and 21 CFR 56)

- If the study is conducted or supported by HHS and involves an FDA-regulated product, the study is subject to both 45 CFR part 46 and 21 CFR parts 50 and 56, meaning that both sets of regulations must be followed.
- Where the regulations differ, the regulations that offer the greater protection to human subjects should be followed.
- Research subject to 21 CFR parts 50 and 56 is typically subject to 21 CFR part 11 (FDA regulations regarding electronic records and electronic signatures) which affects the use of eConsent.
- FDA-regulated studies must utilize an electronic informed consent tool that complies with Part 11 regulations (21 CFR 11). The University of Iowa does not currently have a tool meeting these requirements, but a study sponsor may supply one.

Additional regulations regarding eConsent:

- Studies falling under HIPAA (Health Insurance Portability and Accountability Act) or GDPR (General Data Protection Regulations) also have additional levels of security, privacy, and verification requirements.
- The Electronic Signatures in Global and National Commerce Act (E-Sign Act) (Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form.
- There may be other regulations that apply to the use of eConsent for research.

eConsent Tool Checklist

Question	Response	
Does the eConsent document contain all required elements of consent (45 CFR 46.116)?	☐ **Yes**	☐ **No**
Is your study FDA regulated?	☐ **Yes**	☐ **No**
If yes, is your eConsent tool 21 CFR 11 compliant?	☐ **Yes**	☐ **No (STOP- you cannot use eConsent)**
Is the eConsent tool easy to navigate?	☐ **Yes**	☐ **No**
Is the eConsent document in a language understandable to the subject (and/or LAR/parent/guardian)?	☐ **Yes**	☐ **No**
Does the eConsent process allow potential subjects sufficient opportunity to consider participation?	☐ **Yes**	☐ **No**
Does the eConsent process allow potential subjects sufficient opportunity to ask questions?	☐ **Yes**	☐ **No**

Does the eConsent tool incorporate initials or signature for optional agreements?	☐ **Yes**	☐ **No**
Does the eConsent tool allow for verifiable subject signatures?	☐ **Yes**	☐ **No**
Does the eConsent tool allow for verifiable LAR/parent/guardian signatures (as applicable)?	☐ **Yes**	☐ **No**
Does the eConsent tool store a full version of the consent document (including optional agreement responses, signatures, and dates)?	☐ **Yes**	☐ **No**
Does the eConsent tool send a full version of the consent document to the subject and/or LAR/parent/guardian (including optional agreement responses, signatures, and dates)?	☐ **Yes**	☐ **No**
Does the eConsent process ensure that legally effective informed consent is obtained prior to subject participation in study procedures?	☐ **Yes**	☐ **No**
Does the eConsent tool include appropriate audit trails for verifying informed consent?	☐ **Yes**	☐ **No**

Additional sources of information:

- Use of Electronic Informed Consent: Questions and Answers: *Guidance for Institutional Review Boards, Investigators, and Sponsors* https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html
- Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers: *Guidance for Institutional Review Boards, Investigators, and Sponsors* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers