

Use of Electronic Informed Consent in Clinical Investigations Summary of Federal Guidance

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf>

- In general, electronic consent as part of the process may use an interactive interface which may facilitate subject's ability to retain and comprehend information.
- Standard rules apply for presenting language that is understandable and presenting in a format that is easy to navigate forward or backward. May not be appropriate for subjects who have poor eye sight, unfamiliarity with e systems, impaired motor skills, etc.
- Process description should include enhancements (*interactive, multimedia, quizzes*) and standard process issues such as who, what, when, location (at site or remote). Remote requires additional system methods to ensure person signing is subject and responses can't be altered.
- Subject questions – may be in person or electronic communication (messaging, phone call, videoconferencing, live chat) as long as data is secure and privacy protected.
- Describes steps to facilitate subject understanding – diagrams, images, graphics, video technology and narration.
- Provision of significant new findings during the study – re-consent process must provide opportunity to ask questions.
- DHHS permits electronic signatures if legally valid within jurisdiction. IRBs should consider applicable issues such as how the electronic signature is created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the subject upon request.
- HIPAA Authorization may be signed electronically, provided legally valid, secure, & no risk to the integrity of PHI.
- FDA permits provided compliant with FDA Part 11. The [21 CFR11.100\(c\)](#) regulation requires specific system controls, identity verification, and certification that the electronic signatures in the system are intended to be the legally binding equivalent of traditional handwritten signatures. FDA does not mandate a specific method of identity verification or E-signature (*digital, signature pad, voice or fingerprint & date*).
- Pediatric considerations – provision for assent.
- Confidentiality – system security.
- Subject copies – FDA recommends signed/dated; include transcript of audiovisual presentations; in format that can be retained (*paper or E-copy is fine but warn subject about confidentiality limitations of E-copy since may be housed indefinitely on subject's personal computer*).
- System must be secure with restricted access and methods to ensure confidentiality regarding the subject's identity, study participation, and personal information after informed consent has been obtained. If covered entity, must be HIPAA Compliant. OK to use combined HIPAA/Consent Documents – Authorizations may be signed electronically with valid E-signature and subject must be given a copy of signed authorization.
- IRB Considerations – FDA recommends PI communicate with IRB early on, prior to finalization, to make sure IRB agrees with format. Then IRB should see final format and all materials that subject would see. IRB should be aware of institutional security policies.
- System archiving – audit trail with all versions available.
- FDA Submission – IDE requires consent; IND regulation doesn't specify that consent be included; however, CDER or CBER may request consent documents.
- FDA Inspection expectations – FDA will expect access to all site-specific versions of ICF, all material submitted to IRB, all amendments to ICF either electronic or paper form.