Appendix I

The Office for Humans Research Protection and FDA released a revised version of a guidance on electronic informed consent (eIC) in December 2016. ([http://www.fd.gov/downloads/Drugs/GuidanceComplianceRegulatoryinformation/Guidance s/UCM436811.pdf](http://www.fd.gov/downloads/Drugs/GuidanceComplianceRegulatoryinformation/Guidance%20s/UCM436811.pdf). Or, <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html>.

The guidance is as follows: “For the purposes of this guidance, electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Websites, biological recognition devices, and card readers, to convey the information related to the study and to obtain informed consent”

The Guidance provides recommendations to the procedures that may be followed that includes attentions to detail in regards to: 1) Ensuring protection of the rights, safety and welfare of participants, 2) Facilitating the participant’s comprehension of information presented during the electronic consent process, 3) Ensuring that appropriate documentation of eIC when multiple electronic media are used for consenting and ensuring that the quality and integrity of eIC consenting data is available during inspections.

There are 16 Q and As in the guidance document explaining the process.

**Q1. How should information in the eIC be presented to the subject?**

1. eIC must contain all elements of informed consent form
2. The information must be in a language understandable and at a level to the subject can comprehend or understandable to subject’s LAR

**Q2. How and where may the eIC process be conducted?**

1. The consent process may take place at the study site when both the investigator and subject are at the same location, or it may take place remotely (e.g., at the subject’s home or another convenient venue) where the subject reviews the consent document in the absence of the investigator. The eIC materials may be provided for both on-site and remote access.
2. If any or all of the consent process takes place remotely 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)).

**Q3. How and when should questions from subjects be answered?**

**Q4. What steps may be taken to facilitate the subject’s understanding of the information being presented?**

1. To assist the subject in understanding the material, the eIC may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration. The eIC should be appropriate for the intended audience, taking into consideration the subject’s age, language, and comprehension level.

**Q5. What steps may be taken to convey additional information, including significant new findings, to the subject during the course of the research?**

**Q6. How can electronic signatures be used to document eIC?**

1. The procedure for eIC may include an electronic method to capture the signature of the subject or the subject’s LAR. OHRP and FDA regulations permit the use of electronic signatures when written informed consent is required. OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted (Rowan Policy for electronic signatures)

**Q7. What methods may be used to verify the identity of the subject who will be electronically** signing an eIC for FDA-regulated clinical investigations?

1. The intent is to prevent fraudulent use. Regulations require Rowan to to verifyy the identity of the individual.

**Q8. What special considerations should be given to the use of eIC for pediatric studies?**

1. Parental permission may be obtained and documented using the same eIC procedures as would be used for informed consent.

**Q9. Should subjects receive a copy of their eIC and have easy access to the materials and information presented to them in their eIC?**

**Q10. What steps can be taken to help ensure privacy, security, and confidentiality of the eIC information.**

1. Secured with restricted access. If PHI is used, the system must be encrypted.

**Q11. Can HIPAA authorizations for research, which are frequently combined with informed consent documents, be obtained electronically?**

1. Yes. HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject’s personal representative) is a valid electronic signature under applicable laws and regulations

**Q12. What eIC materials should the investigator submit to the IRB?**

1. The investigator should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process.

**Q13. What are the IRB’s responsibilities in the eIC process?**

1. HHS and FDA regulations require that an IRB review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by the applicable regulations (see 45 CFR 46.109(a) and 21 CFR 56.109(a)). A critical part of this responsibility is for the IRB to ensure there is an adequate informed consent process that protects the rights and welfare of subjects participating in HHS-regulated research and FDA-regulated clinical investigations (see 45 CFR 46.109(b) and 21 CFR 56.109(b) and 56.111(a)(4)). This applies to modifications and amendments to studies.

**Q14. What eIC documentation does FDA require for submission with applications?**

**Q15. What steps can be taken to ensure the system archives the eIC materials appropriately for FDA-regulated clinical investigations?**

**Q16. What materials or documents will FDA require during an inspection?**