Electronic Informed Consent Forms - eIC

Background:

The research community is showing increasing interest in using electronic media to supplement or replace paper-based informed consent processes. An eIC may be used to provide information usually contained within the written informed consent document, evaluate the subject’s comprehension of the information presented, and document the consent of the subject or the subject’s legally authorized representative (LAR). Electronic processes to obtain informed consent may use an interactive interface, which may facilitate the subject’s ability to retain and comprehend the information. Furthermore, these electronic processes may allow for rapid notification to the subjects of any amendments pertaining to the informed consent that may affect their willingness to continue to participate. Electronic processes may also promote timely entry of any eIC data into a study database and allow for timely collection of the subject’s informed consent data from remote locations.

1. Q: What eIC materials should the investigator submit to the IRB?

Unless using the REDCap eConsent system (discussed at the end of this Investigator Guideline), the investigator should discuss plans for using eIC with the IRB before finalizing development of the eIC to ensure that the IRB agrees that such a format may be used to obtain informed consent for the applicable research. Examples include the use of electronic tablets or on-line web application for consents. The investigator must 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. The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy.

The IRB must also review any optional questions or methods used to gauge subject comprehension of key study elements, as well as the usability of the eIC materials to ensure that they are easy to navigate. Since eICs may not be able to display the IRB stamp, a method for the IRB to ensure the final consent document is consistent with the language the IRB has approved, must be provided.

2. Q: Will the IRB always allow the use of an eConsent?

No. The IRB must ensure that the consent process is appropriate for the risk level of the proposed research. In some cases the IRB may decide that informed consent must be obtained face-to-face, which may preclude the use of an eIC.

3. Q: Should a place for the person obtaining consent be placed on the eConsent form?

Generally yes. If you feel it is not practical to include that signature, please provide your justification to the IRB as part of your submission.

4. Q: How should information in the eIC be presented to the subject?
Any eIC should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful. The eIC may also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.

Electronic informed consent may be used to either supplement or replace paper-based informed consent processes in order to best address the subject’s needs 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 for these subjects. **Therefore, subjects must have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process.**

5. **Q: How and where may the eIC process be conducted?**

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.

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.

6. **Q: How and when should questions from subjects be answered?**

The investigator should have methods in place to ensure that the eIC process allows subjects the opportunity to consider whether or not to participate and to ask questions. This may be accomplished by in-person discussions with study personnel or through a combination of electronic messaging, telephone calls, video conferencing, or a live chat with a remotely located investigator or study personnel.

7. **Q: How can electronic signatures be used to document eIC?**

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.

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

When approving an eIC assent process, an IRB should consider whether the capability of a child to assent may be affected by the method used to obtain and/or document child assent. For example, if
assent would otherwise be required, the method used to obtain eIC assent should not impede the child’s capability to provide assent. The language and presentation of information must be understandable to the child. In addition, when the IRB determines that assent is required, it must also determine whether and how assent will be documented.

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

Yes. HHS and FDA regulations require that the person signing the informed consent (i.e., the subject or the subject’s LAR or the parents or guardians of subjects who are children) be given a copy of the written informed consent form. The copy provided to the subject can be paper or electronic and may be provided on an electronic storage device or via email.

10. Q: What materials or documents will FDA require during an inspection?

During inspections of clinical investigation sites, FDA regulations require that FDA be granted access to records and reports made by the investigator, including site-specific versions of the eIC, the materials submitted to IRBs for review and approval, all amendments to the site-specific eICs, and all subject-specific signed eICs. These should be available at the site either in electronic or paper form. FDA reserves the right to review the content of the eIC program or informed consent document and the corresponding informed consent of the subject or the subject’s LAR and the signature of a witness, where applicable, along with the date that the eIC was signed. Any updates to the documentation should also be available for review.

11. Q: What do I need to do if I want to use REDCap to provide an eConsent (eIC) alternative?

The UF IRB has approved the REDCap version of the eIC process, and confirmed that it meets all local and federal consenting requirements. If you wish to use REDCap as your eIC option, please comply with the following steps:

1. Please read this Investigator guideline to ensure you are familiar with the regulations on eIC’s
2. Submit your protocol to the UF IRB as usual through the myIRB. Provide the IRB with only the paper version of your consent form(s). At this point do not include anything regarding the eIC.
3. Once your protocol and paper consent forms are approved, a stamped version of your consent form will be available in myIRB under your newly approved study.
4. Go to the following link https://www.ctsi.ufl.edu/files/2018/01/eConsenting-using-REDCap-Instructions-updated.pdf to construct your eIC per the REDCap staff’s instruction manual.
5. Once your eConsent is completed, you must submit a revision to your protocol to add the eIC process and upload the REDCap version of your consent form on the smart form page where the paper consent is located. Please name the new eConsent to include eConsent in the name title.
6. Once the IRB approves your revision, you will need to provide your IRB approval letter for your eConsent process to the REDCap staff, who will ensure what you have constructed is in order, and then move your eConsent into production mode. Once this process is completed, and you will be able to start consenting subjects via the eIC.

12. Q: What if I need to revise my informed consent form, and I’m using the REDCap eConsent system?

This will require two separate revisions to your protocol. You should first submit your revised informed consent on your paper consent form. Once approved, you will need to submit a second revision to upload the REDCap consent containing the newly stamped consent form you have placed in the REDCap eConsent system.