Emory Guidance for the use of Electronic Informed Consent

**Background**
The purpose of this document is to explain the current options Emory researchers have for obtaining electronic signature for informed consent forms (eICF), including those containing HIPAA authorization language.

*NOTE:* This guidance is not applicable for cases where the IRB can waive written signature (aka “documentation”) of consent (e.g. online survey studies), or for studies done at the VA or CHOA.

**Using electronic informed consent (eICF) for research studies**

**Reminder:** Electronic documentation of consent is not currently permitted by CHOA or the AVAMC (though they do allow online consent with waiver of signature when regulatory criteria are met).

As of 3/2/2017, the approved software/apps to implement eICF at Emory are Redcap and eSign. The IRB is working with LITS to offer more options for investigators. This guidance will be updated every time more options are available.

- The protocol and/or smartform should state how the eICF will be presented. The study team should **not** send the consent form to subjects via email unless the email is encrypted. A link to an online consent form may be sent via email to the subject or LAR. Or, the eICF may be presented to the subject or LAR in person, via touch-screen-enabled device.
- The signature area could be the same as the normal ICF/HIPAA template, or could be crafted to allow for the person obtaining consent to sign at a later time, if needed. Here is an example of the latter:

<table>
<thead>
<tr>
<th>Name of Person Conducting IC discussion</th>
<th>Date when IC discussion took place</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Signature of Person Conducting IC discussion</th>
<th>Date when IC was signed by person obtaining consent</th>
</tr>
</thead>
</table>

- It is important that any eICF captures the signature of the subject in a way that it can be electronically audited.
- The protocol and/or smartform must include a plan for verifying the identity of the subjects that will be electronically signing the Informed Consent, for FDA-regulated investigations.
  - FDA regulations do not specify any particular method for verifying the identity of an individual and accepts many different methods. For example, verifying someone’s identity can be done by using information from some form of official identification, such as a birth certificate.
certificate, government-issued passport, or a driver’s license. In addition, use of security questions to confirm an individual’s identity can also be considered.

- The protocol and/or smartform should include a plan for providing copies of the consent to participants. HHS and FDA regulations require that the person signing the informed consent be given a copy of the informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)), unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c).
  - Although FDA regulations do not require that the subject’s copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eICF was signed be provided to the subject.

- The copy provided to the subject can be paper or electronic (i.e. be provided on an electronic storage device, not via email unless encrypted).
  - If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion (if paper version is provided, it should contain the necessary content from any hyperlinks).

- 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.

- To avoid investing software development time prior to IRB approval of the consent language, the study team may first submit an MS Word version of the informed consent language that will be signed electronically by subjects, prior to submitting the final electronic version that the subject will see.
  - The study team should then submit, via amendment, a final electronic eICF to the IRB to show that the final electronic version contains the same information as the mock-up approved by the Emory IRB, including document approval and version date. The study team cannot enroll anyone with the electronic method until this amendment is approved.

- If not using previously LITS reviewed software or apps:
  - Study team should submit a ticket requesting a data security review of the platform using this link: [https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2](https://emory.service-now.com/sp?id=kb_article&sys_id=e5c2cd88f5cdf1c055c77bd8604896c2)
    - The form has the information to provide under “more information”
  - Next, email Derek Spransy at dsprans@emory.edu (LITS) and Maria Davila at maria.davila@emory.edu to make them aware that a ticket was put in place. Please reference the name of the app or software to be reviewed.
  - Be advised that this process may take time, as LITS has limited resources to review all requests. It is estimated that this process may three months or more.