REDCap eConsent Frequently Asked Questions (FAQ)

eConsent is available via REDCap. This functionality provides the ability to consent remote participants or participants in clinic via tablet or touchscreen device. Participants will have the capability to sign electronically with a stylus, mouse, or finger. Once the consent form is submitted, participants will receive an email that includes a PDF attachment with a copy of the signed consent form.

Can eConsent be used on all projects?

If your study is sponsored, you must first ask the sponsor if they are agreeable to using eConsent for consenting participants either face-to-face or remotely.

In order to use eConsent, the IRB must first approve the consent for the study. Provide the IRB with details in the protocol related to the consent process, such as: How will consent be collected? Will consent be self-guided or led by a coordinator? How will participants get questions answered before consent? Will a consent assessment be included? How will the participant get a copy of the signed consent? The IRB will approve more than minimal risk studies on a case-by-case basis.

Also, include language in the consent document notifying the participants they will receive a signed copy of their consent via the email address they provide. Email is not a secure means of communication so this should be disclosed as a potential risk for loss of confidentiality, and participants should be aware when they provide consent.

eConsent needs to be set up on a per project basis. This can be setup by anyone with builder access to a specific REDCap project. If your study is subject to FDA oversight, you need to consider 21 CFR Part 11 requirements. See 'Can REDCap be used for studies requiring 21 CFR part 11 compliance**?'** section below for more information.

Can eConsent be used for pediatric studies?

The eConsent is to be used for ADULT informed consent documentation. eConsent is NOT to be used for assenting minors. There is not an electronic assent form available for minors.

Is there an eConsent template available?

Yes, an eConsent template is available. This is a template only and must be updated to meet study needs and match the IRB-approved consent form. This template can be obtained by requesting a new project and selecting the option to use a template. You will choose the **AH Base Project with eConsent** template.

How is eConsent set up in REDCap?

Please review the document "Using REDCap for Participant eConsent – Setup" for detailed instructions on correctly setting up your eConsent REDCap project. It can be downloaded from your project's File Repository when starting a new project with the **AH Base Project with eConsent** template.

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Where can I find instructions for correctly using the REDCap project?

Please review the document "Using REDCap for Participant eConsent – Use" for detailed instructions on correctly setting up your eConsent REDCap project. It can be downloaded from your project's File Repository when starting a new project with the **AH Base Project with eConsent** template.

How do I upload a copy of the signed consent form to the Electronic Medical Record?

You will have to download a PDF of the completed eConsent, print and then scan the eConsent to the EMR. We are working with IAS on an electronic solution; but currently, only a manual process exists.

How do I update the eConsent when there is a change in my Consent language?

Once eConsent is set up for the project, a post-production change can be made to update the consent language. Changes to the consent language should be approved by the IRB before being made in REDCap. This is done via the normal post-production change method. Be aware any eConsent changes will require the REDCap team to review and approve.

When the IRB has approved an amendment to the consent, and the REDCap project changes have not yet been approved, and a participant is consented on the old consent, this is a protocol deviation. You must not collect new participant consent until your changes are approved by REDCap Administrators. Therefore, if you have pending changes in your project, you must wait for those changes to be approved. Plan accordingly and have a contingency plan if REDCap changes have not been approved. REDCap Administrators will reach out to you during review if proposed/submitted changes will cause issues with your eConsent project process or previously collected data.

Can eConsent be added to an existing REDCap project already in production?

No, eConsent can only be used in a project that begins by using the **AH Base Project with eConsent** template, and therefore, can only be used in new projects.

Can REDCap be used for studies requiring 21 CFR part 11 compliance?

REDCap is not automatically 21 CFR Part 11 compliant, but OCTR and the REDCap Administrators can be contacted for assistance to meet compliance. Compliance must be met on a per project level. 21 CFR Part 11 also requires studies to validate the identity of the person providing an electronic signature, which includes a biometric method or two distinct identification components such as an identification code and password. This is pre-built into the **AH Base Project with eConsent** template. Please consider if this will be possible for your project's/study's process and consult with OCTR and REDCap Administrators if you have any questions before proceeding with the use of eConsent.

Need help or have questions about your build?

If you have any questions, please email your REDCap Administrators, Kyle Raub - kyle.raub@atriumhealth.org or Varsha Evans - varsha.evans@atriumhealth.org.

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