

Guidance for Electronic and Remote Informed Consent New IDEAS Study

Practices engaging in remote consent activities must comply with Advarra’s regulations for remote consent in the New IDEAS study. Prior to engaging in remote informed consent with patients, please review the [Advarra IRB Handbook](#) and the following information. If you have any question, please contact the New IDEAS Operations Team at newideas@acr.org and Advarra IRB at cirbi@advarra.com.

IRB Approval Required for Electronic Signature Use:

Advarra considers any electronic or digital signature to fall under the eConsenting category. Advarra **requires** that any site using electronic signatures, or any digital signature format must submit a modification to the IRB for eConsenting (see page 3, “Guidance on How to Submit a Modification for eConsenting to Advarra IRB”). This includes the following methods for capturing consent:

- Use of DocuSign, Adobe or Cosign or any other electronic signature service.
- The use of a stylus, mouse, or subject’s finger to electronically capture the name or mark of the subject (i.e., handwritten signatures executed to electronic records).
- The use of at least two distinct identification components (such as an identification code and password issued by the study staff for a specific individual study subject).

Please review [Advarra IRB’s Handbook](#) to clarify if your site falls into eConsenting category.

Advarra’s Guidance for Obtaining Electronic Signatures:

Electronic signatures need to meet 21 CFR Part 11 Compliance. It is important the site staff have a discussion with the patient (and document this) and not simply send them the form. Examples of software with date/time stamp functionality include but not limited to: DocuSign, Adobe, and Cosign.

Within the electronic signature system, the signature manifestations must be associated to the record being signed. The signature manifestation include:

- The printed name of the signer
- The date and time that the signature was applied.
- The meaning of the signature. This is fulfilled by the signature line identifying who is signing (i.e. patient, LAR, witness, etc.)

John Doe		
Participant’s Printed Name	 <p>Informed Consent Form must contain digital time stamp of date and time signature was applied</p>	
		
Participant’s Signature		4/28/2021 Date

Additional guidance from Advarra can be found on the following page: [Guidance on Remote Electronic Signatures](#) and in the [Advarra IRB Handbook](#).

Guidance on Handwritten Signatures Captured in Digital Format:

It is acceptable for sites to capture a patient’s handwritten signature through a digital format (i.e., signature pad). However, the following requirements, per federal guidance, must be met:

- The signer’s identity needs to be verified
- Signatures must be done in person; not over email/video call
- The signature must be done in such a way that cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

Advarra’s Guidance for Obtaining Signatures Remotely:

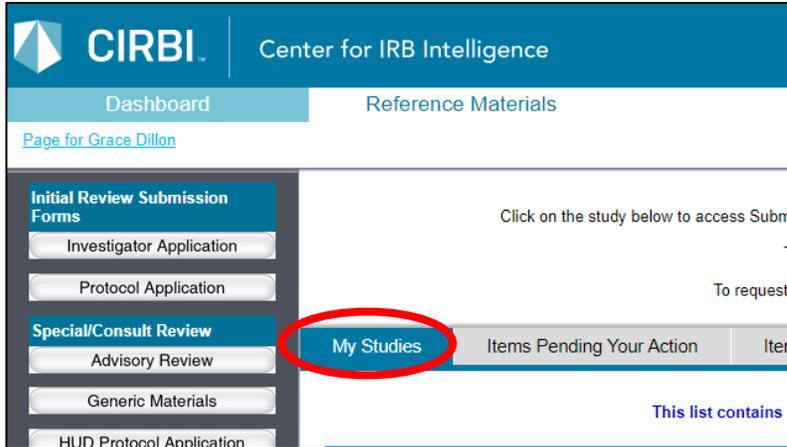
It is acceptable for the site to fax/email the consent form to the patient and have them fax/email it back. When a copy of the fully executed ICF will be returned to the study team, informed consent may be obtained by telephone/videocall. When obtaining consent by telephone/ videocall, researchers must:

- Document how the ICF was transmitted to the participant (e.g., email, fax, mail, etc.).
- Document how the participant’s signature was obtained. For example:
 - Electronic signature
 - Scanned and emailed, faxed, or mailed back to the study team.
 - Photograph of signature/signature page sent back to the study team.

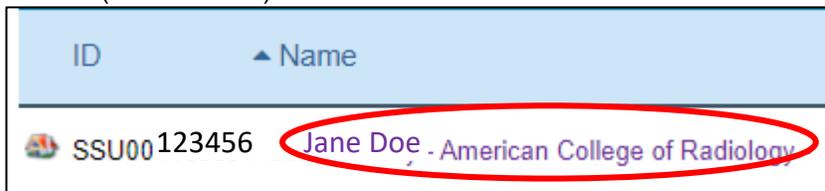
Guidance on How to Submit a Modification for eConsenting to Advarra IRB

If your site intends to use electronic signatures of any kind, whether remote or in-person, please follow the below guidance on how to submit a modification to the IRB:

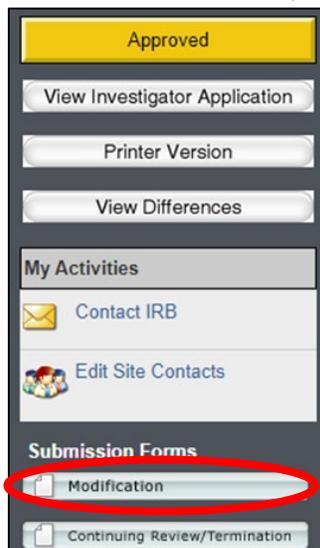
1. Login to www.cirbi.net.
2. Select the “My Studies” tab from the center blue ribbon (circled in red below).



3. Select your site’s page by clicking on the name of your Principal Investigator shown after an SSU number (shown below).



4. On the left-hand toolbar, select the “Modification” tab to open the Modification form.



5. Select “continue” in the bottom right corner to populate the form.
6. For question 1: select “eConsent” as the type of modification (shown below).

Modification Information

1	<p>* What type of Modification are you submitting?</p> <p><input type="radio"/> Protocol Document(s) only</p> <p><input type="radio"/> Consent Document(s)</p> <p><input type="radio"/> Product Information only</p> <p><input type="radio"/> Protocol Document(s) and Product Information</p> <p><input type="radio"/> Translation of Document(s)</p> <p><input type="radio"/> Recruitment/Subject Facing Material</p> <p><input type="radio"/> Appeal to IRB Restrictions</p> <p><input checked="" type="radio"/> eConsent </p>
----------	---

7. Complete the following questions as appropriate to your site’s situation.

Please confirm that the planned eConsent process meets regulatory requirements for obtaining documented informed consent by answering YES to all that apply (If NO to any, an explanation must be provided):

- * The electronic informed consent form (ICF)(s) will be a complete and exact copy of the current, IRB approved study consent document(s) and will be updated to match IRB-approved revisions. Yes No
- * Consent/authorization signatures will comply with applicable law, and the consent process will include a method to confirm the identity of the signer(s). Yes No
- * Web-linked materials, graphics, videos, etc. (if applicable) will only include materials approved by the IRB (reviewed with initial protocol, or eConsent or Recruitment/Subject-facing material MOD). Yes No
- * The stored electronic ICF(s) identify the subject, study staff (if applicable), and date (and time, if applicable) that the consent(s) were signed; and signed electronic ICFs are stored with appropriate access, with all consent versions easily retrievable. Yes No
- * The electronic consent process/ electronic ICF will present subjects with the entire contents of the IRB-approved consent. There is/will be no function available to allow a subject to navigate directly to the signature field(s) or skip any section of the IRB approved consent contents. Yes No
- * The subject will receive a copy of the consent. Yes No
- * Parent/Guardian credentials are/will be used to set up, verify, and document assent from minors, and assent is captured electronically as a separate field. (Note: can be recorded under Parent/Guardian’s eConsent credentials) [if not applicable, indicate N/A]. N/A

Please upload any attachments:

Name	Created Date
eConsent.docx(0.01)	... 1/25/2022 1:57 PM

8. On the “eConsent” Tab of the form, at the bottom of page under the “Please upload any attachments:”, please attach the type of document you use to consent.
 - o For example, if you use a PDF that you have a patient sign with a stylus, attach the PDF.
9. At the end of the form, select “submit application” (circled in red below).

End of Application

* Please select one of the options below and then click 'Continue'. If you select 'Submit Application', t

Submit Application

Save Application, but DO NOT submit

10. Click “save” on the bottom left-hand corner.
11. You will receive a confirmation email from Advarra IRB.

Advarra IRB may reach out to you via email with clarifying questions before you receive approval. You must receive approval from Advarra IRB prior to eConsenting patients.