Alzheimer’s Network Guidance for Electronic and Remote Informed Consent

Practices engaging in remote consent activities must comply with Advarra’s regulations for remote consent in ALZ-NET. 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 ALZ-NET Operations Team at alz-net@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 eConsent 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.)
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/video call, 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).

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

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.
   ○ 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).

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.