

## New IDEAS Study Informed Consent Form Checklist

*Instructions: Please utilize this checklist to make sure your patient is correctly consented before uploading their Informed Consent Form into the [New IDEAS Portal](#). Please reach out to [newideas-data@acr.org](mailto:newideas-data@acr.org) if you have any questions. As a reminder, the patient or a legally authorized representative must provide study-specific informed consent prior to study entry and site-specific authorization permitting release of personal health information.*

### Informed Consent Form Document Checklist

- Confirm that the document is the current version of the Advarra IRB approved form – A copy can be found on [CIRBI website](#) under section “IRB Issued Documents.” The date at the center of the footer on the ICF should be 30Jan2023.
  - Confirm that all pages in uploaded document are present, are clear and easy to read.
  - Confirm that all pages have the same date in the center of the footer.
- Confirm that the signature blocks are filled out correctly by both the person obtaining consent and patient and/or the patient’s Legally Authorized Representative.
  - Confirm that the patient has provided their written name and signature.
  - Date line is filled out with the date the patient signed the form, and not predated.
  - Confirm that initials are present for optional components AND corresponding box is checked for each optional component.

### My Patient has a Legally Authorized Representative (LAR)

- Per Advarra IRB’s website, “A LAR “stands in the shoes” of the decisionally impaired person and makes decisions on his or her behalf. Who may act as a LAR varies with the law of the state/province in which the research is being conducted. Therefore, the research staff should be familiar with its own state/provincial law in this area.”
- A LAR should only be used if patient is determined by the physician to be unable to make decisions on their own.
  - If you are unsure about whether the person accompanying the patient is the caregiver or LAR, consult with your site’s principal investigator.
  - Verbal approval from the LAR cannot be used for consent.
  - If a Legally Authorized Representative (LAR) signs patient consent form, the LAR’s initials must be present on optional component lines.

### Addressing an Informed Consent Form Error

- If an error is made on the Informed Consent Form by either person obtaining consent, the patient and/or the LAR, the person who made the error must:
  1. Use a single line to cross out error.
  2. Add correction and initial and date next to where the change was made. See example:
  3. Reupload the corrected

Informed Consent Form into the New IDEAS Portal on the Case Registration Form for review and approval.

Jane Doe  
 \_\_\_\_\_  
 Printed Name of the Person Conducting the  
 Consent Discussion

Jane Doe  
 \_\_\_\_\_  
 Signature of the Person Conducting the  
 Consent Discussion

02/09/2022 JD

02/09/2023  
 \_\_\_\_\_  
 Date