

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 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	