Version 1.0, December 2023

NEW IDEAS
Imaging Dementia—Evidence For Amyloid Scanning

Informed Consent Form Training

New IDEAS Data Management Guide for Dementia Practice Staff

ACR® AMERICAN COLLEGE OF RADIOLOGY

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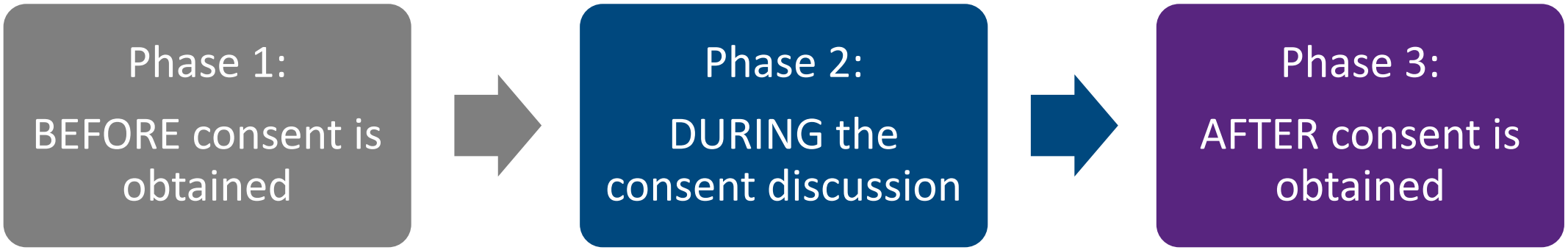
The Informed Consent Discussion: A Three Phase Process



Patients must be consented before they are registered in the New IDEAS Portal.

Before Consent is Obtained

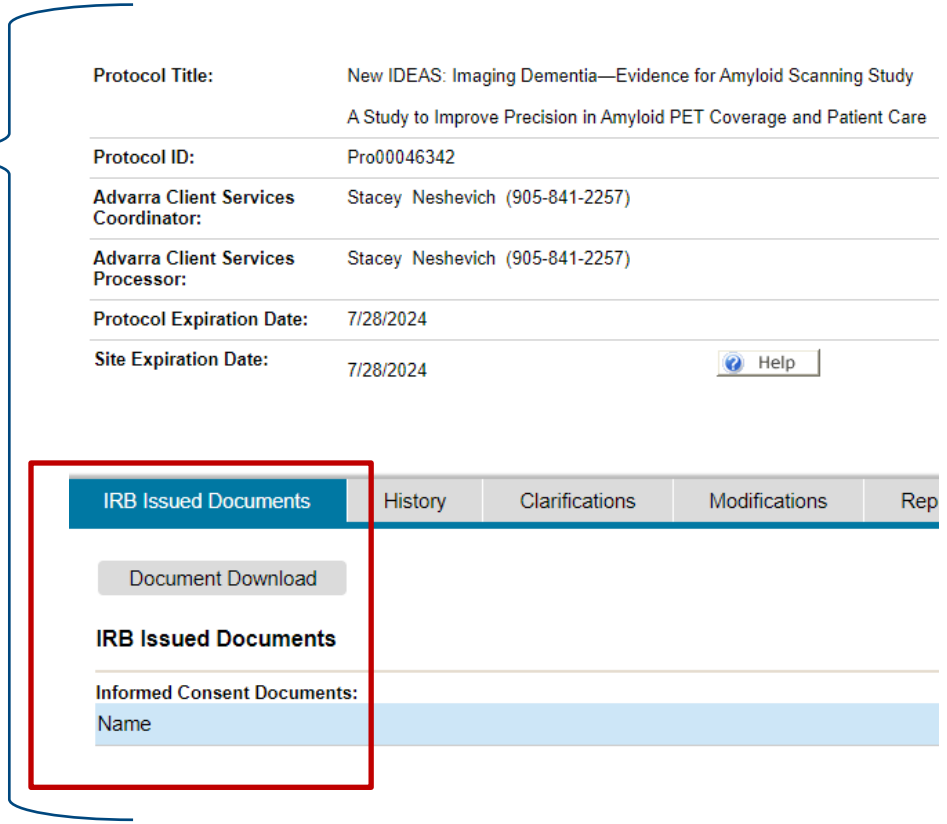
- All consenting staff members **must**:
  - Be registered in the New IDEAS Portal.
  - Have completed Human Subjects Protections (HSP) Training within the last 3 years.
  - Have a copy of the HSP Training certificate in the New IDEAS Portal.
- Staff with expired HSP Training are **NOT** authorized to consent patients until an updated training certificate is provided.
- Complete the Human Subjects Protections Training Course free of charge.

Before Consent is Obtained (continued)

Print out a copy of the most recently approved Informed Consent Form from the site's Advarra CIRBI Portal

Confirm all pages were printed and have the same version date in the middle footer.

Determine if the patient has a Legally Authorized Representative (LAR).



During the Consent Discussion

If the patient has a LAR, the *LAR* will sign AND initial the *LAR's initials* on behalf of the patient.

3 Optional Components Sections:

- Patient/LAR must check the box that applies to them.
- Patient/LAR must add initials to the line as appropriate.

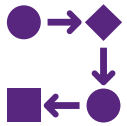
Main Study Consent Section:

- In the appropriate sections:
  - Patient/LAR provides their **written name.**
  - Patient/LAR provides **signature.**
  - Patient/LAR provides **date.** *Do not predate.*
  - Person obtaining consent provides **name, signature AND date.** *Do not predate.*

After Consent is Obtained

Before the patient/LAR leaves the appointment, **confirm all dates, signatures and initials are on the form.**

Upload a copy of the ICF with all pages in numerical order to the New IDEAS Portal on the Case Registration Form.



The New IDEAS Data Management Team will review the ICF. **You will be notified via email if there are any errors***

Store the original copy of the ICF in a safe place for future reference.

*ICFs marked as "Not Approved" will show the following notice:

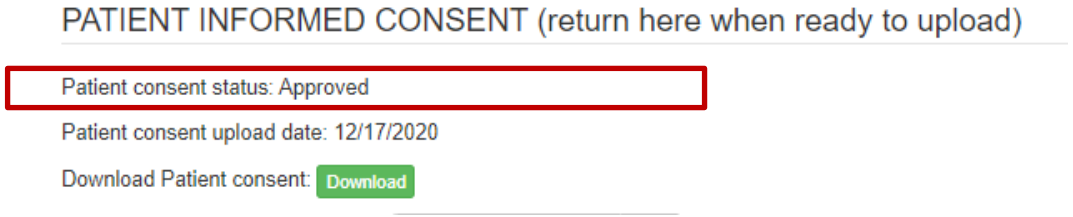
> This patient has an unapproved Informed Consent Form (ICF). Please contact newideas-data@acr.org for more information about why the ICF was marked as unapproved and for next steps. To update the patient's ICF, navigate to the patient's Case Registration form. Scroll down to section Patient Informed Consent and upload the updated ICF.

NEW iDEAS

How to **Re-Upload** an ICF Document

1. Log in to the New IDEAS Portal
2. Select *Data Collection*
3. Select *Case Registration*
4. Clear Filters
5. Search by Case ID or Patient Name
6. Click on Case ID of interest
7. Click on *Case Registration Tab*
8. Scroll down page to Informed Consent Form section
9. Select *Upload Document*
10. Save form and send an email to newideas-data@acr.org to confirm receipt.

Every patient in your New IDEAS Portal must show Patient Consent Status as “Approved”



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New IDEAS Data Management Team

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