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**Imaging Dementia—Evidence
For Amyloid Scanning**

***Guidance on Advarra Submissions
for Referring Dementia Physicians
and Practice Staff***



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Module Overview

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Helpful Tips for Submitting to Advarra

Section “Informed Consent Documents”

Tip #1:

- If the only changes to the ICF are the first page address for site and the compensation section, you do not need to submit to Advarra. They will update this information automatically when you receive approval.
- Make sure that the address, phone number, and compensation language of the Consent matches what it put in the Advarra Form.

Tip #2:

- Make sure question #3 compensation language matches the language in your site-specific protocol.
- Please note this is for consents that the site has added their site-specific language. If your site does not add language, please indicate “n/a”.

Tip #3:

- Make sure if you choose to have the ICF translated, that you go back to section “Investigational/Research Location(s) and Subject Recruitment” question #4 and indicate that non-English speakers will be enrolled.

Section “Investigational/Research Location(s) and Subject Recruitment”

Tip #4:

- Please ensure that you do NOT provide the PET scan location.
 - This is considered a part of standard of care and not research

Section “Investigator Experience and Qualifications” and “Documentation Attachment Summary”

Tip #5:

- Please ensure that the PI has GCP and Human Protection Trainings from an accredited program (i.e. CITI).

Advarra Overview

- Referring physician sites must use Advarra IRB as the IRB of record overseeing their research activity.
- Costs of review are covered by the study
 - i.e. ACR is invoiced directly by Advarra
- If you have a local IRB, an agreement will have to be put in place between the site and Advarra.
 - For more information visit: <https://www.ideas-study.org/Getting-Started/Institutional-Review-Board>



Create an Advarra Account

Visit link www.cirbi.net and click “Sign Up” or enter an email address to use an existing account.

CIRBI Center for IRB Intelligence

Home

Email Address:

Login

Do you need to register? Sign up

Welcome to the Center for IRB Intelligence (CIRBI®)

COVID-19 - IMPORTANT REMINDER ABOUT ADVARRA'S POLICY ON REPORTING DEVIATIONS AND VIOLATIONS

During this time when IRB approved protocol activities may be impacted by the public health outbreak we are facing, Advarra reminds investigators that only deviations and violations that result in an increased risk of harm to participants or adversely impact the integrity of the data need to be submitted to the IRB. Advarra encourages study staff to review section 18.3 in the current version of the IRB Handbook, found in the reference section of CIRBI, for more information on this policy.

Recommended Browsers: We recommend that you use Internet Explorer 11 (Windows 7, IE 8 or later), or Microsoft Edge (Windows 10), or current version of Chrome, Firefox, Safari.

ADVARRA
advancing better research

Help Desk Information
Hours of Operation
8:30 am - 8 pm EST, Monday-Friday
E-mail: cirbi@advarra.com

Toll-free phone number
1-866-99CIRBI (1-866-992-4724)

New users must sign up and create an account

Initial Submission to Advarra

On your Dashboard, select “Investigator Application.”

The screenshot shows the CIRBI (Center for IRB Intelligence) dashboard for a user named Grace Dillon. The dashboard has a blue header with the CIRBI logo and navigation tabs for 'Dashboard' and 'Reference Materials'. A sidebar on the left contains several buttons under the heading 'Initial Review Submission Forms', with 'Investigator Application' highlighted by a red arrow. The main content area includes a navigation bar with tabs for 'My Studies', 'Items Pending Your Action', 'Items Pending IRB Review', 'Protocol Dashboard / Metrics', 'Archived Studies', and 'Generic Materials'. Below this, there is a search filter section with a dropdown menu set to 'ID' and a search input field. The main content area currently displays 'No data to display.' and a pagination bar showing 'page 1 no results'. The footer contains the Advarra logo, help desk information, and a full accreditation seal.

Initial Submission (cont.)

- The application will open to an online form.
- In the “Investigator Lead In Page” section:
 - **Select option #1:** “I am a clinical research site that is joining a multi-site study for which Advarra IRB will act as the central IRB. The Sponsor or CRO has or will submit the Protocol.”
- Select “Continue” on bottom right-hand corner to populate the correct form.

The screenshot displays the IDEAS application interface. On the left is a navigation menu with the following items: Investigator Lead-In Page (highlighted), Start of Investigator Application, Investigational/Research Location(s) and Subject Recruitment, Regulatory Inspection Information, Conflict of Interest (Advarra), Informed Consent Document, Request for HIPAA Waiver, Message to End User, Investigator Experience and Qualifications, Site and Local Context Information, Informed Consent Process, Data Privacy and Confidentiality, and Documentation Attachment Summary. The main content area is titled 'Reading: SSU [redacted]'. It contains three sections: 1. 'Lead In / Confirmation Page' (highlighted with a red border) with three radio button options for selecting the role of the user. 2. 'Start of Investigator Application' with two numbered steps: step 1 asks to click 'Select' to choose an investigator, and step 2 displays protocol details including the title 'New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning Study A Study to Improve Precision in Amyloid PET Coverage and Patient Care' and protocol number 'Pro0046342'. 3. 'Investigational/Research Location(s) and Subject Recruitment' with a single question: 'Do you want to submit sub-investigator/co-investigator information for IRB review (note: this is not an IRB requirement)'. The 'No' radio button is selected.

Initial Submission (cont.)

Document	Start of Investigator Application	
Request for HIPAA Waiver	1	<p>* Please click 'Select' to choose your Investigator: [REDACTED]</p> <p><i>Note: If you do not see the Investigator listed, then you will need to create an account/register the person. To create an account/register the PI, you will need to exit out of the application, logoff, and go to the CIRBI home page and click on the Sign Up link</i></p>
Message to End User	2	<p>* Full Protocol Title: New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning Study A Study to Improve Precision in Amyloid PET Coverage and Patient Care</p> <p>* Protocol Number: Pro00046342</p>
Investigator Experience and Qualifications		Name: Start
Site and Local Context Information		
Informed Consent		

- In the “Start of Investigator Application” section:
 - Question #1: “Please Select to choose your investigator”
 - A pop-up window will open, where the PI will need to be selected from a drop-down menu.
 - The PI **must** have a CIRBI account to show up in the drop-down selection
 - Please refer to slide 5 on how to create an account

Navigating the CIRBI Form

- On the bottom right-hand corner of the form there will be options to:
- **Continue** saves the form and moves you forward to the next slide.
 - Note: if all the red asterisked (*) questions are not answered, you will not be able to move forward.
- **Save** allows you to save the page in any stage and either exit application or navigate through the form.
- **Exit** takes you out of the form without saving any changes



Important Application Information

- Protocol Number for New IDEAS: **Pro00046342**
- Translation Services:
 - Select “Yes” to question #6 on Tab “Informed Consent Document.”
 - Ensure that in section “Investigator/Research Location(s) and Subject Recruitment” that question #4 have “non-English Speakers” checked off.

Informed Consent Document 1

Message to End User

Investigator Experience and Qualifications

Site and Local Context Information

6

* Will you need the Informed Consent Form translated into another language? Yes No

If yes, what language(s)? Spanish

Please note: The sponsor will need to approve the translation request before being released to your site

You indicated that a translation will be required. Please confirm the following:

The ICF document(s) given to the potential research study subject will be in their native language.
I confirm: Yes No

* A staff/independent interpreter fluent in the potential study subject's native language will be available during the informed consent process and throughout the research study.
I confirm: Yes No

Translation Request

Current State

Approved

View Investigator Application

Printer Version

View Differences

My Activities

Contact IRB

Edit Site Contacts

Submission Forms

Modification

Continuing Review/Termination

SAE/UADE Report

Deviation/Violation Report

Audit Report

UAP Report

Non-Compliance Report

DMC Report

IND Safety Report

(Approved)

- After receiving Initial Approval, you will need to submit a Modification Form on CIRBI for IRB Translation of the ICF.
- Log into CIRBI (www.cirbi.net).
- Select the New IDEAS Submission protocol on your Dashboard.
- On the left side toolbar under Submission Forms, select “Modification.”

Dashboard Reference Materials

Page for Group Email

Click on the study below to access Submission Forms or IRB Approval Documentation for a specific study. You may also click on the tabs below or If you need to submit for a new study (for initial IRB approval), then please click the appropriate link on the left hand

My Studies Items Pending Action Items Pending IRB Review Protocol Dashboard / Metrics Site Dashboard / Metrics

This tab lists all studies you currently have access to as a user. Click on the name of a submission to go to its Workspace for more information.

Filter by ID Enter text to search for + Add Filter x Clear All

ID	Name	State	Document Download
Pro00046342	American College of Radiology -	Approved	Documents

1 items page 1 of 1

Translation Request (Cont.)

- Select the Modification Submission Form:
 - Question #1:
 - Select “Translation of Document(s)”
 - The language that the ICF needs to be translated into is **Spanish**.

Reading: [REDACTED]

Create Modification Submission

This is the 1st page of the online Modification Form. Please click 'Continue' to go to the next page.

Modification Information

1 * What type of Modification are you submitting?

- Consent Document(s)
- Translation of Document(s)
- Investigational/Research Location Information
- Change of Principal Investigator
- Recruitment/Subject Facing Material
- Appeal to IRB Restrictions
- Disclosure of Conflict of Interest
- Request for HIPAA Waiver
- Change to Sub-Investigator(s)/Co-Investigator(s)
- eConsent

Responding to Questions

- You will receive an automated email from Advarra requesting you respond to inquiries.
 - **Do not respond directly to the automated email**
- Click the link and log into CIRBI to respond to questions

Link to CIRBI →

Our IRB has Requested Clarifications to your Site Submission

CIRBI Link: [\[Redacted\]](#)

Investigator & Protocol: [Redacted] - American College of Radiology -

Protocol Title: New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning Study
A Study to Improve Precision in Amyloid PET Coverage and Patient Care

From: Advarra IRB

CIRBI Instructions:

Please click on the CIRBI link above and log into CIRBI to respond to the questions.

You will then see the clarifications that require a response. Links will be provided that will take you into the submission form where you will provide the response. Once in the submission form, click on the “**Click here to respond**” indicator to provide a response.

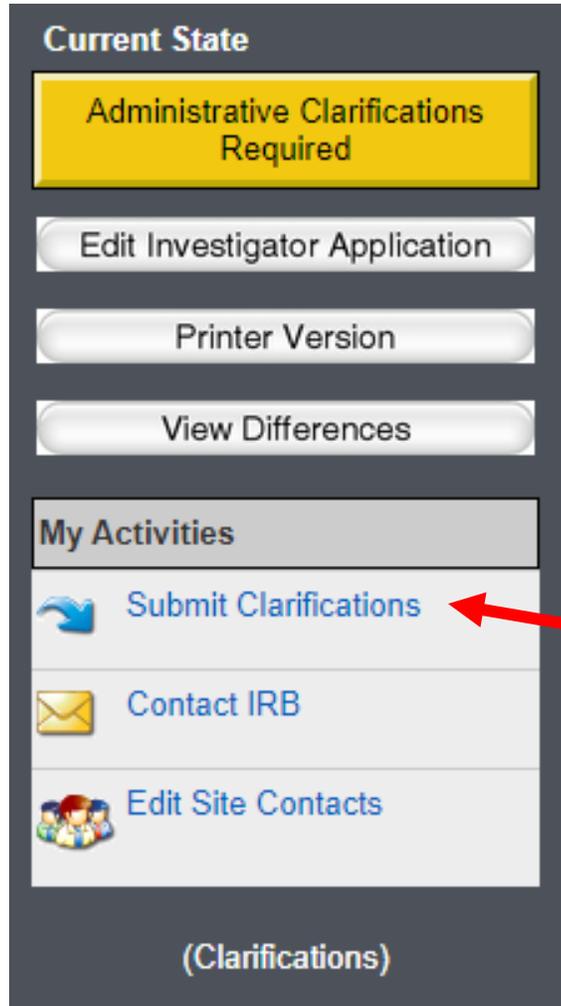
There will also be a yellow box in the upper left hand corner of your screen which indicates how many clarifications require your response in order to move forward with the processing of your submission. The yellow box will also contain links to the page of the submission form that contains a clarification that requires a response.

After you answer all clarifications, save and exit the form. Then make sure to click ‘**Submit Clarifications**’ on the left hand side of the screen under “My Activities”

No further processing of this protocol will take place until your response is received.

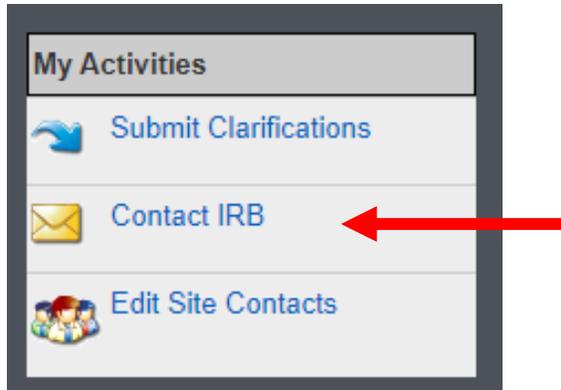
Kind Regards,

Responding to Questions (Cont.)



- Once you are in CIRBI, respond to each inquiry.
- After responding to each inquiry, you **must** submit the clarifications.
 - To Submit:
 - Select “submit clarification” on left hand toolbar and confirm that you wish to submit.

Communicating with Advarra IRB



- All communication with Advarra must occur within the CIRBI system. Please follow the directions on how to communicate with Advarra below:
 - Log onto www.cirbi.net
 - Select the “New IDEAS” protocol from your dashboard
 - On the left hand side you will see a toolbar
 - Select “Contact IRB”
 - This will populate a pop-up screen
 - Type in your question to Advarra
 - Select “submit” to sent communication

Instructions:

- Use this form to send an e-mail to your IRB Coordinator.
- An entry will be added to the history log.

* Message - enter the text message to send to the IRB staff:

Attach Documents - click 'Add' to upload a document(s). The document will appear as a link in the history log:

+ Add

Name	Created Date
There are no items to display	

* Would you like to receive a copy of this email? (Please note if you select 'yes', an email will be sent to all other contacts listed on the protocol) Yes No [Clear](#)

OK Cancel

Modification Submission



- When you are informed that an Amendment to the protocol or informed consent is needed:
 - You will need to log into CIRBI (www.cirbi.net) and submit a Modification.
- To submit a Modification:
 - Select New IDEAS protocol on your Dashboard.
 - Select “Modification” from the left-hand Toolbar.
- Fill out the Submission Form as indicated by the sponsor or site instruction.

Continuing Review Submission



- Login to CIRBI (www.cirbi.net)
- Select “New IDEAS” from your Dashboard.
- Select “Continuing Review/Termination” tab on left-hand toolbar.

Continuing Review Submission (Cont.)

General Information

1 * Report Type:

- Continuing Review Report
- Termination Report

2 * Current Enrollment Status:

- Enrollment is pending and has not started
- Enrollment is open and subjects are currently enrolled
- Enrollment is open but no subjects have been enrolled
- Enrollment is open and subjects were previously enrolled, but none are enrolled at this time
- Enrollment is on hold and no subjects were enrolled prior to the hold
- Enrollment is on hold but there are active subjects enrolled prior to the hold
- Enrollment is on hold and subjects were previously enrolled, but none are enrolled at this time
- Enrollment is closed, and there are still active subjects
- Enrollment is closed, and subjects are in follow-up only
- Enrollment is closed and there are no active subjects or follow-up being performed
- Enrollment is closed and there are no active subjects or follow-up being performed, but requesting continued IRB oversight

General Information

Site Enrollment Questions (Continuing Review)

Additional Questions

End of Application

- You will fill out the form per your site's enrollment status
- Then submit to Advarra

Submitting a Protocol Deviation



- Log onto www.cirbi.net
- Select the “New IDEAS” protocol from your dashboard
- Select the appropriate reportable event from the left-hand toolbar
- This will populate the appropriate form
- Complete the form and select “submit”
- Additional guidance regarding types of protocol deviations
 - <https://www.ideas-study.org/During-Study/Resources>

Please note that you should never put patient PHI or PII to Advarra’s website.
This includes copies of patients unredacted ICF.



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New IDEAS Regulatory

ACR Center for Research and Innovation

newideas-regulatory@acr.org

Phone: 215-574-3177



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