Version 1.2, Nov 2021

NEW iDEAS
Imaging Dementia—Evidence For Amyloid Scanning

Guidance on Advarra Submissions for Referring Dementia Physicians and Practice Staff

ACR® American College of Radiology

alzheimer's association®

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Module Overview

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- Create an Advarra Account: **Slide 5**
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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).

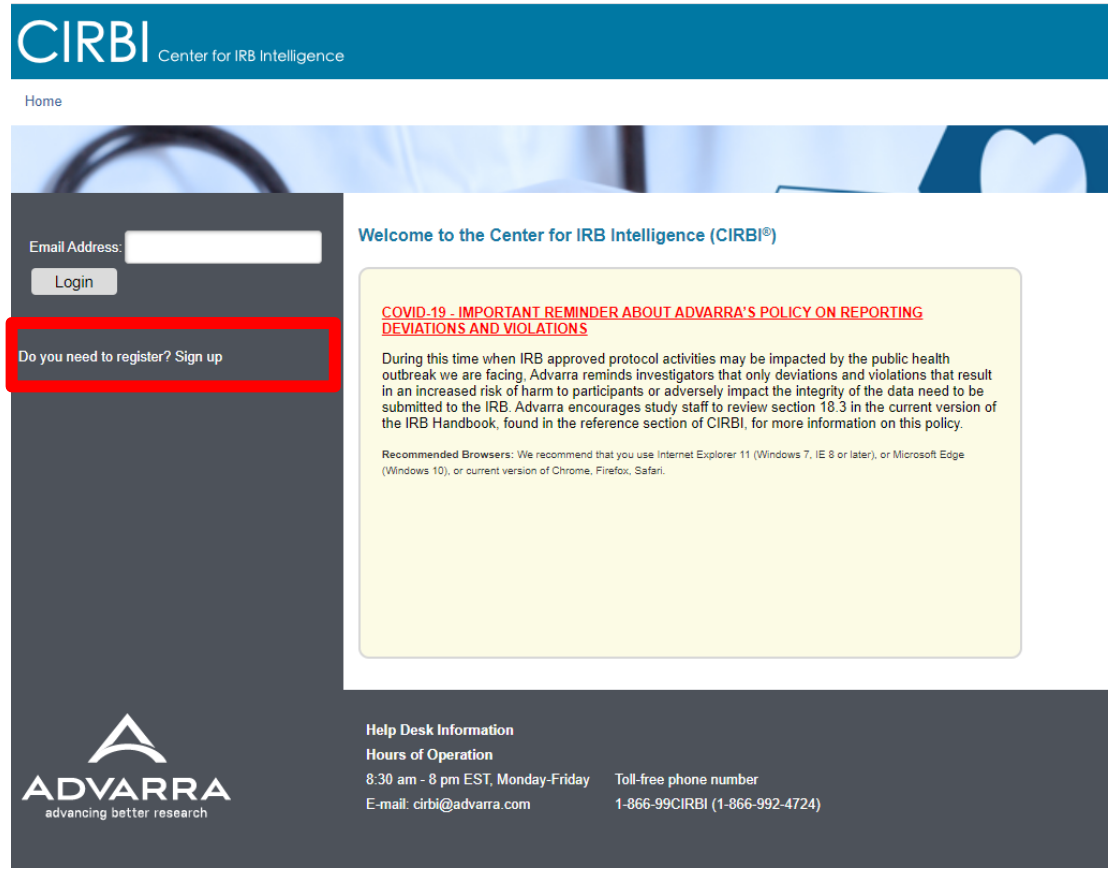
Advarra Overview

- 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

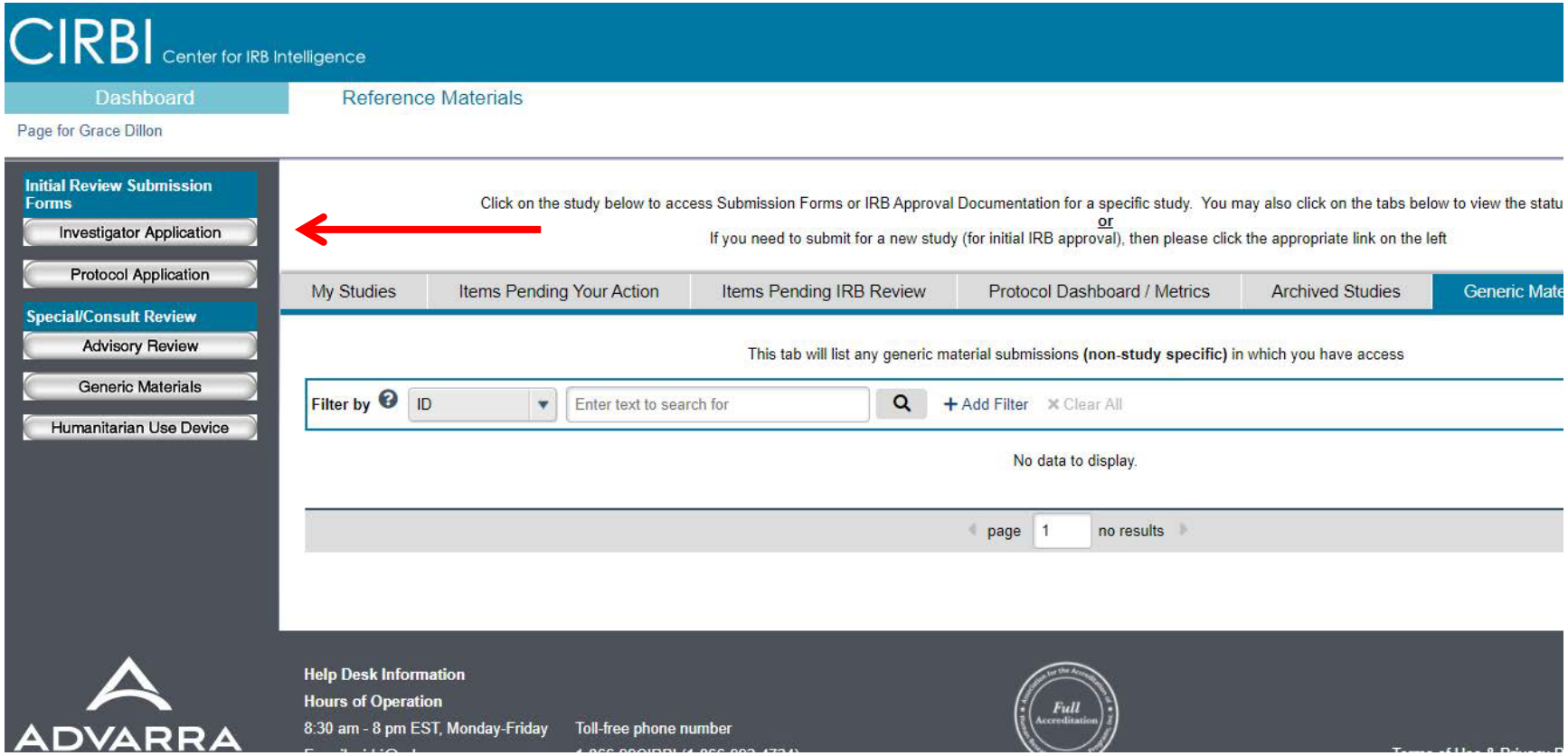
Visit link www.cirbi.net and click “Sign Up” or enter an email address to use an existing account.

New users must sign up and create an account



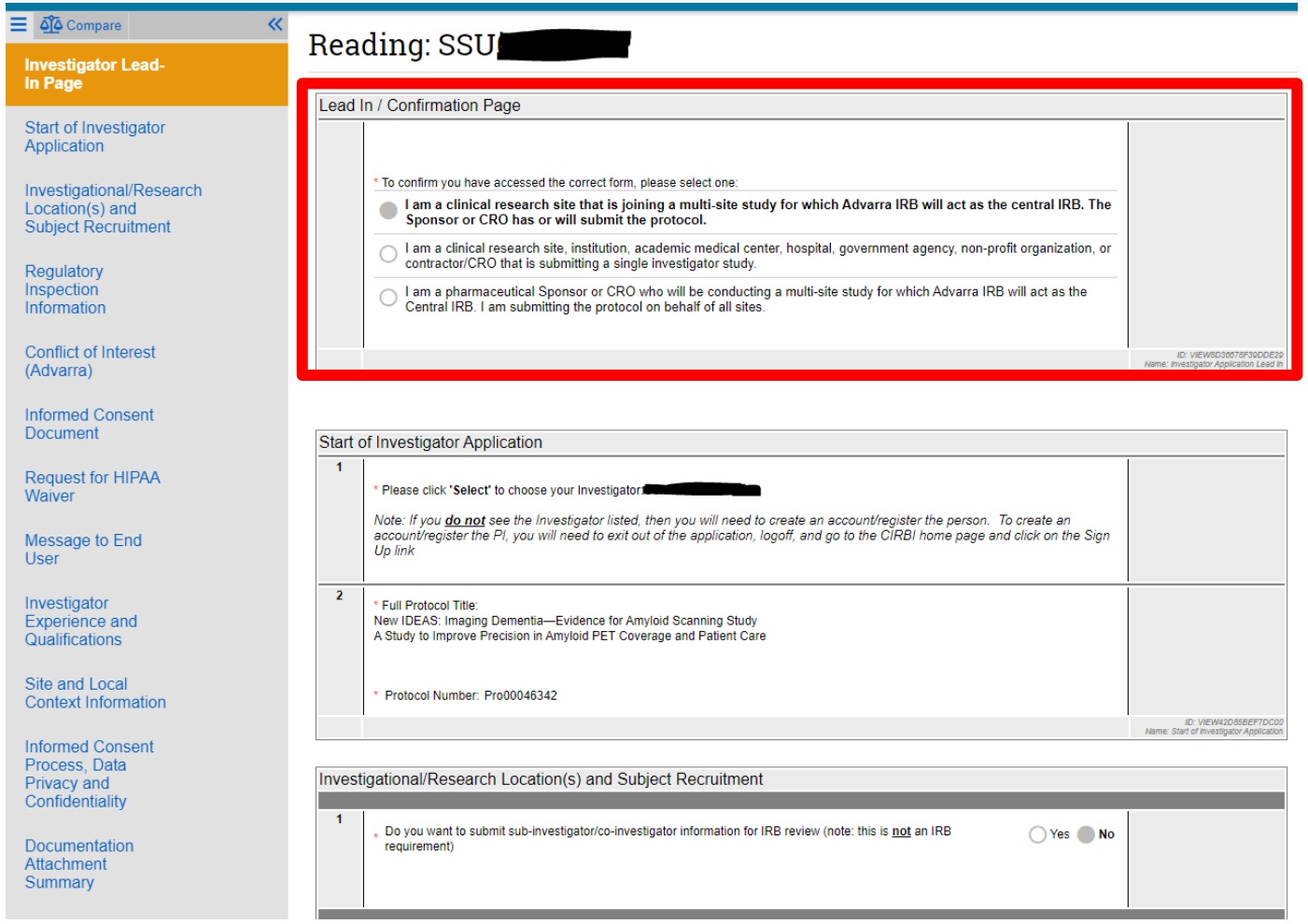
Initial Submission to Advarra

On your Dashboard, select “Investigator Application.”

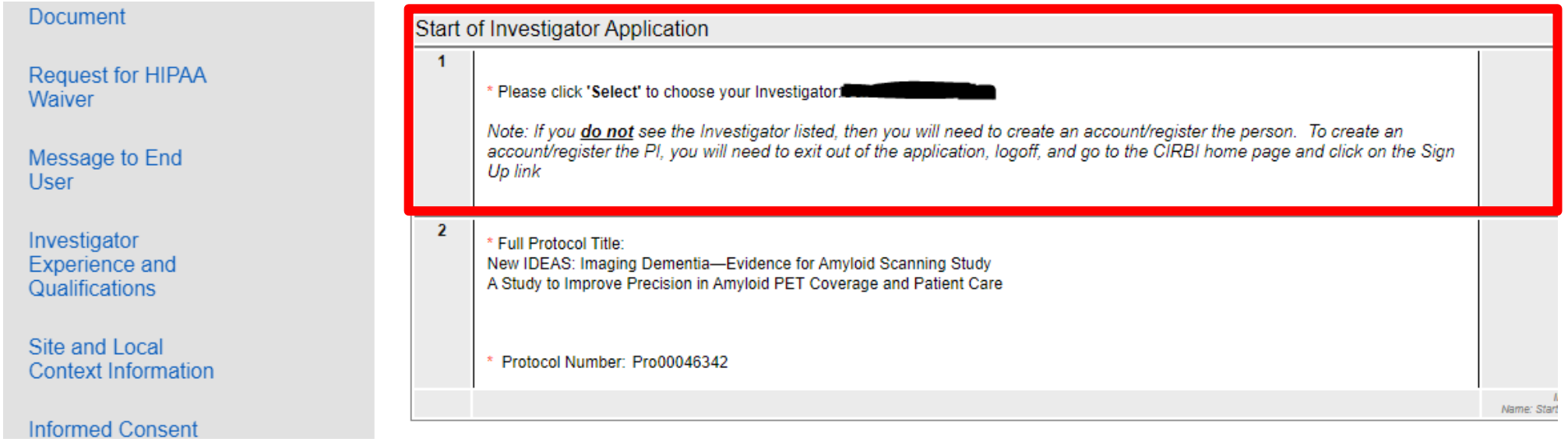


Initial Submission (cont.)

- 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.



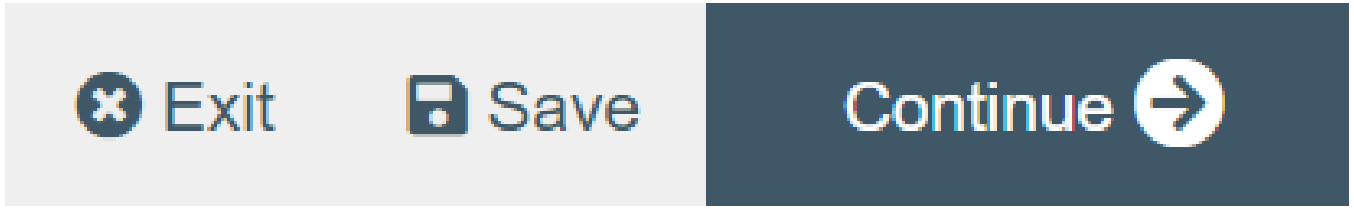
Initial Submission (cont.)



- 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

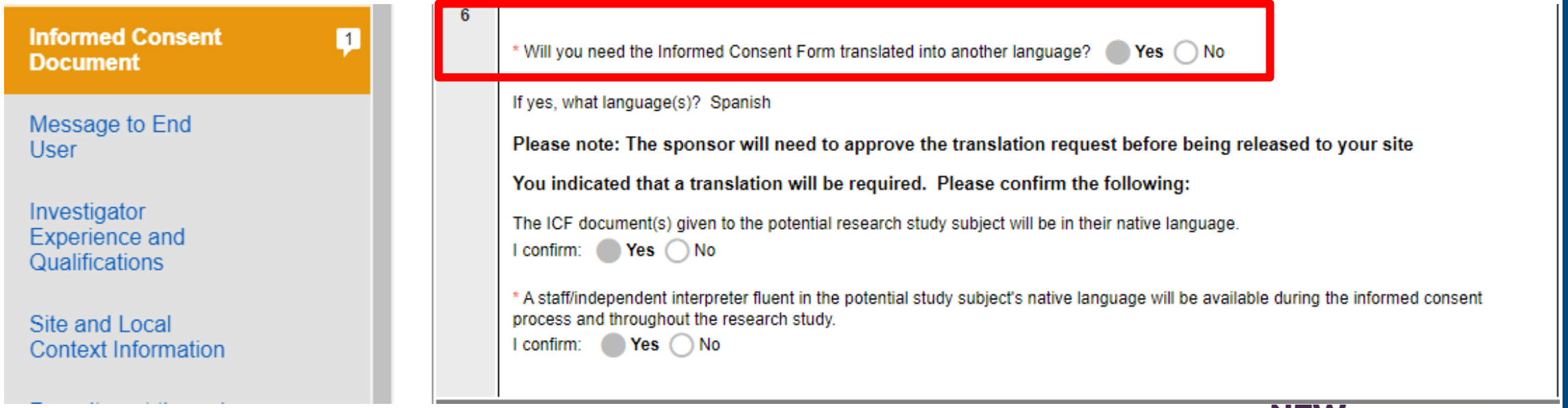
Navigating the CIRBI Form

- 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

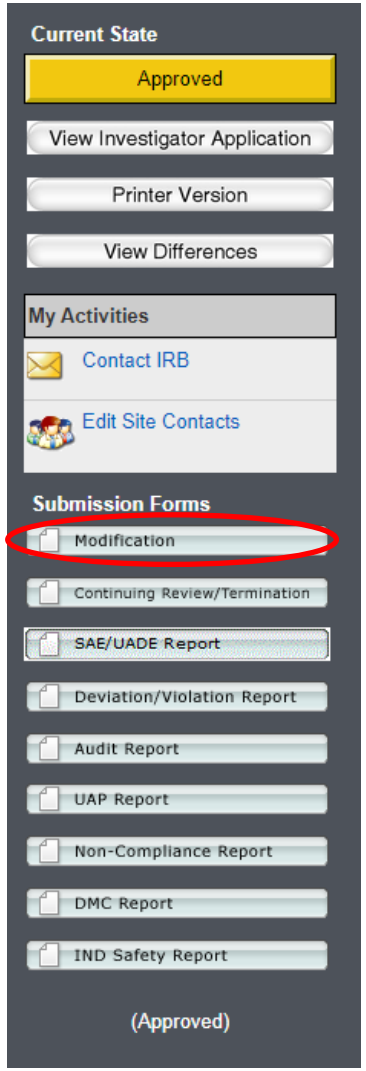


Important Application Information

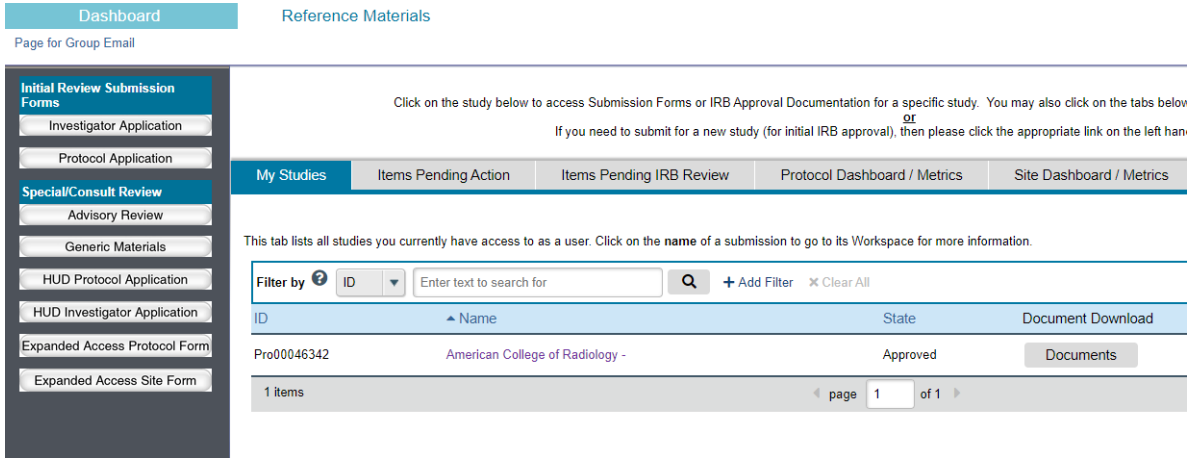
- Protocol Number for New IDEAS: **Pro00046342**
- Translation Services:
  - Select “Yes” to question #6 on Tab “Informed Consent Document.”
    - Ensure that in section “Investigator/Research Location(s) and Subject Recruitment” that question #4 have “non-English Speakers” checked off.



Translation Request

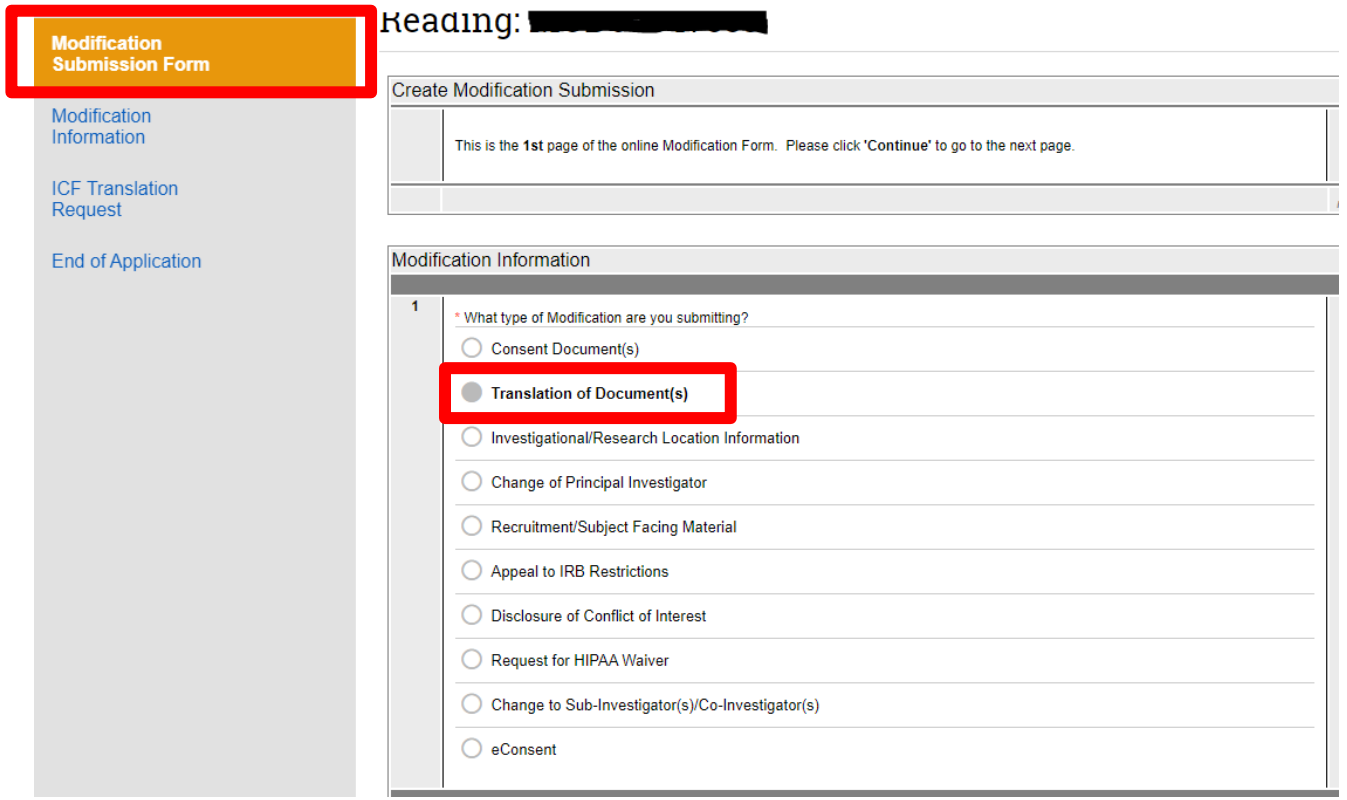


- After receiving Initial Approval, you will need to submit a Modification Form on CIRBI for IRB Translation of the ICF.
- Log into CIRBI (www.cirbi.net).
- Select the New IDEAS Submission protocol on your Dashboard.
- On the left side toolbar under Submission Forms, select “Modification.”



Translation Request (Cont.)

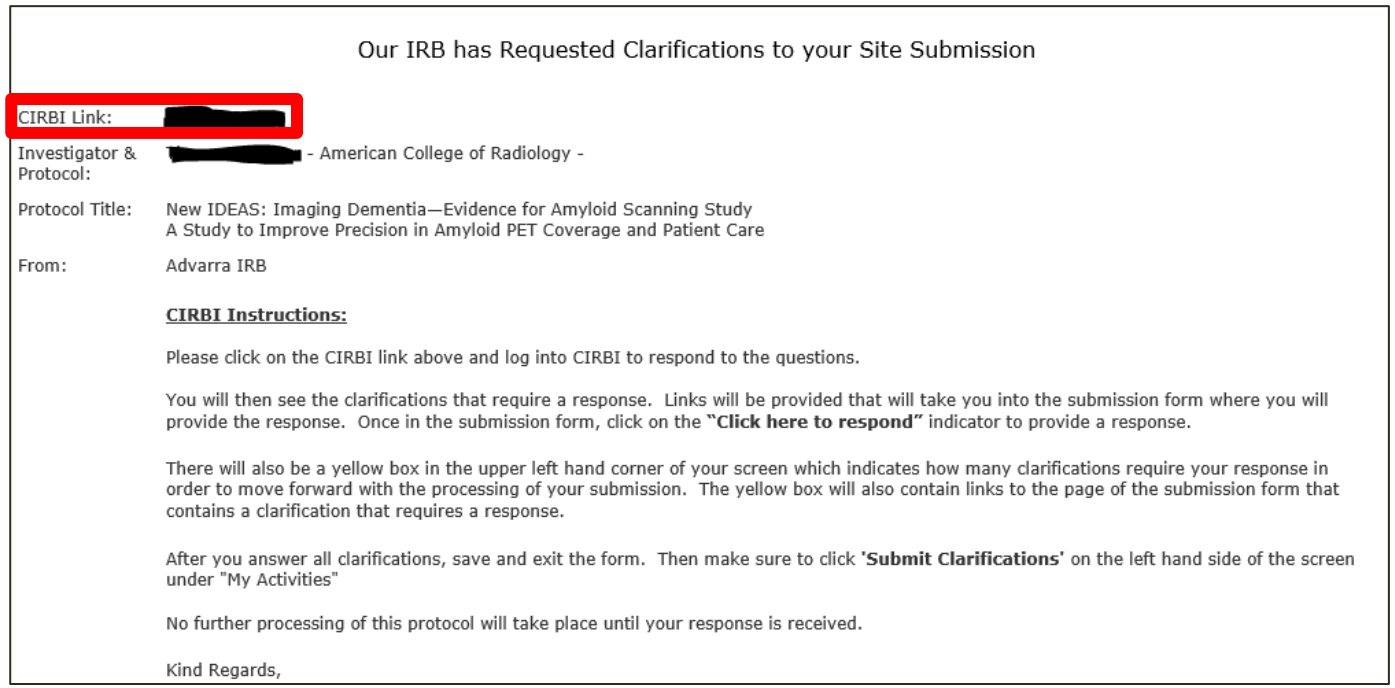
- Select the Modification Submission Form:
  - Question #1:
    - Select “Translation of Document(s)”
  - The language that the ICF needs to be translated into is **Spanish.**



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.

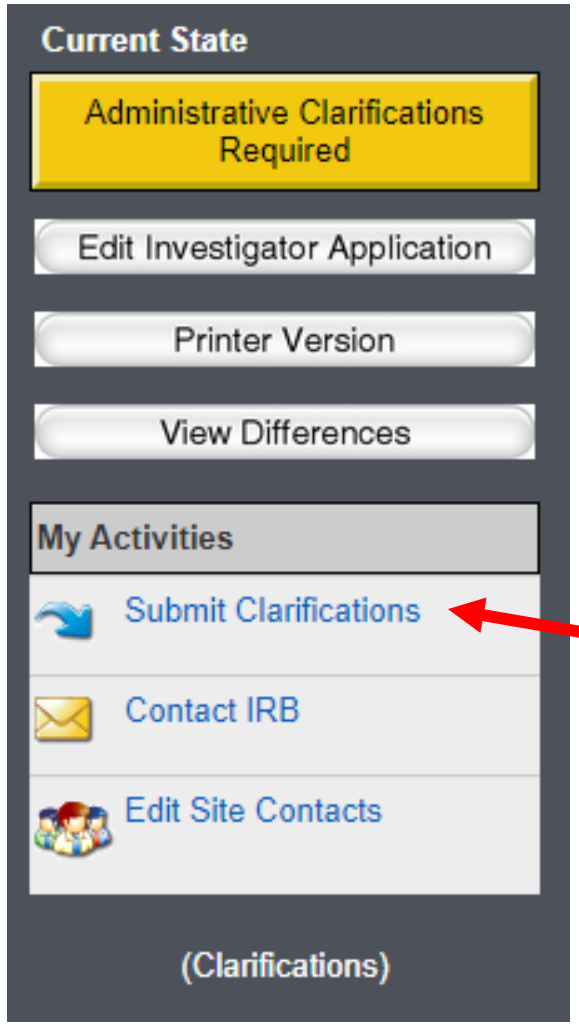
There will also be a yellow box in the upper left hand corner of your screen which indicates how many clarifications require your response in order to move forward with the processing of your submission. The yellow box will also contain links to the page of the submission form that contains a clarification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

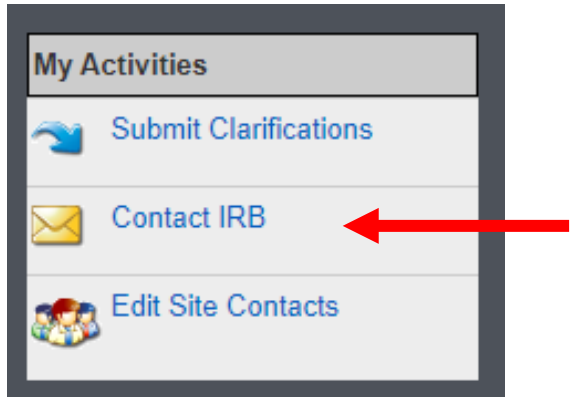
Kind Regards,

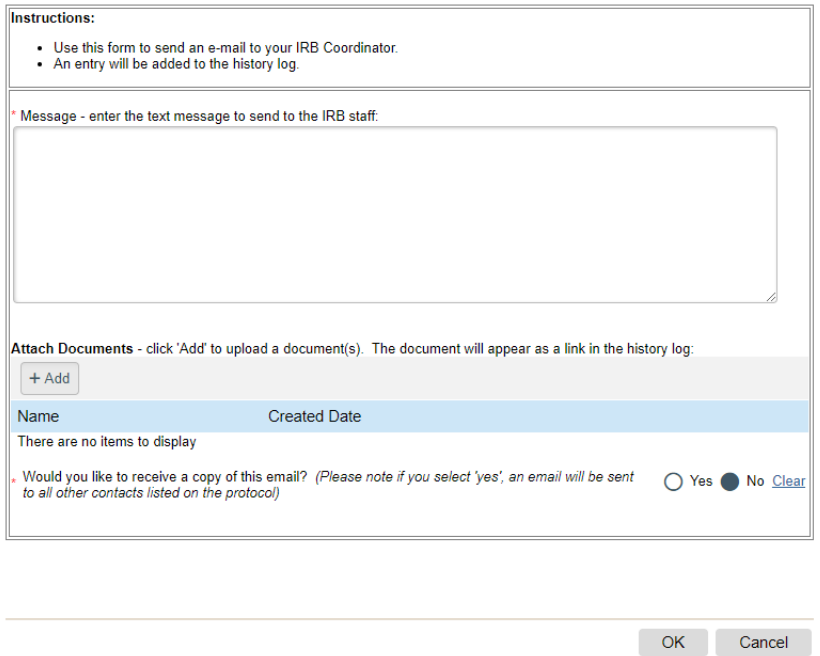
Responding to Questions (Cont.)



- 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



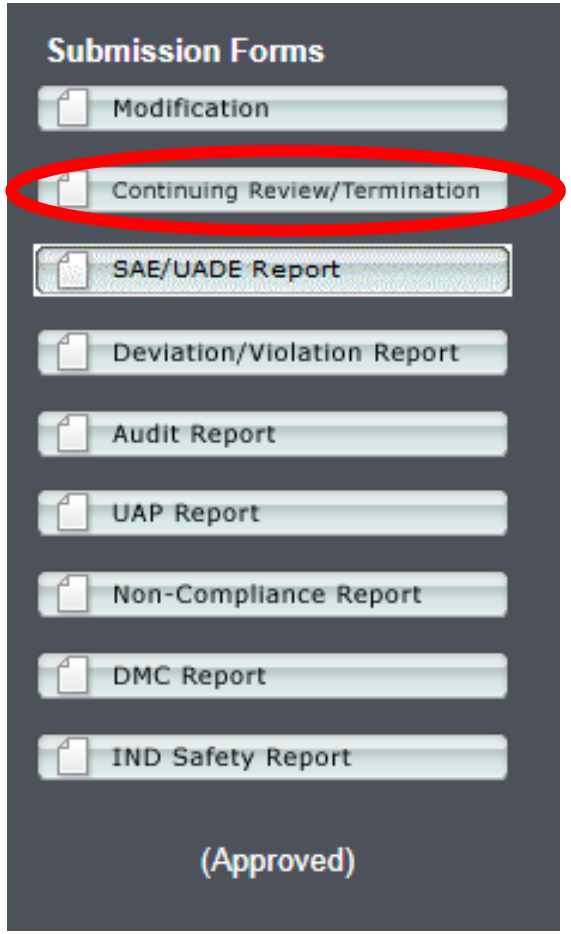


- All communication with Advarra must occur within the CIRBI system. Please follow the directions on how to communicate with Advarra below:
  - Log onto www.cirbi.net
  - Select the “New IDEAS” protocol from your dashboard
  - On the left hand side you will see a toolbar
  - Select “Contact IRB”
  -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

Modification Submission

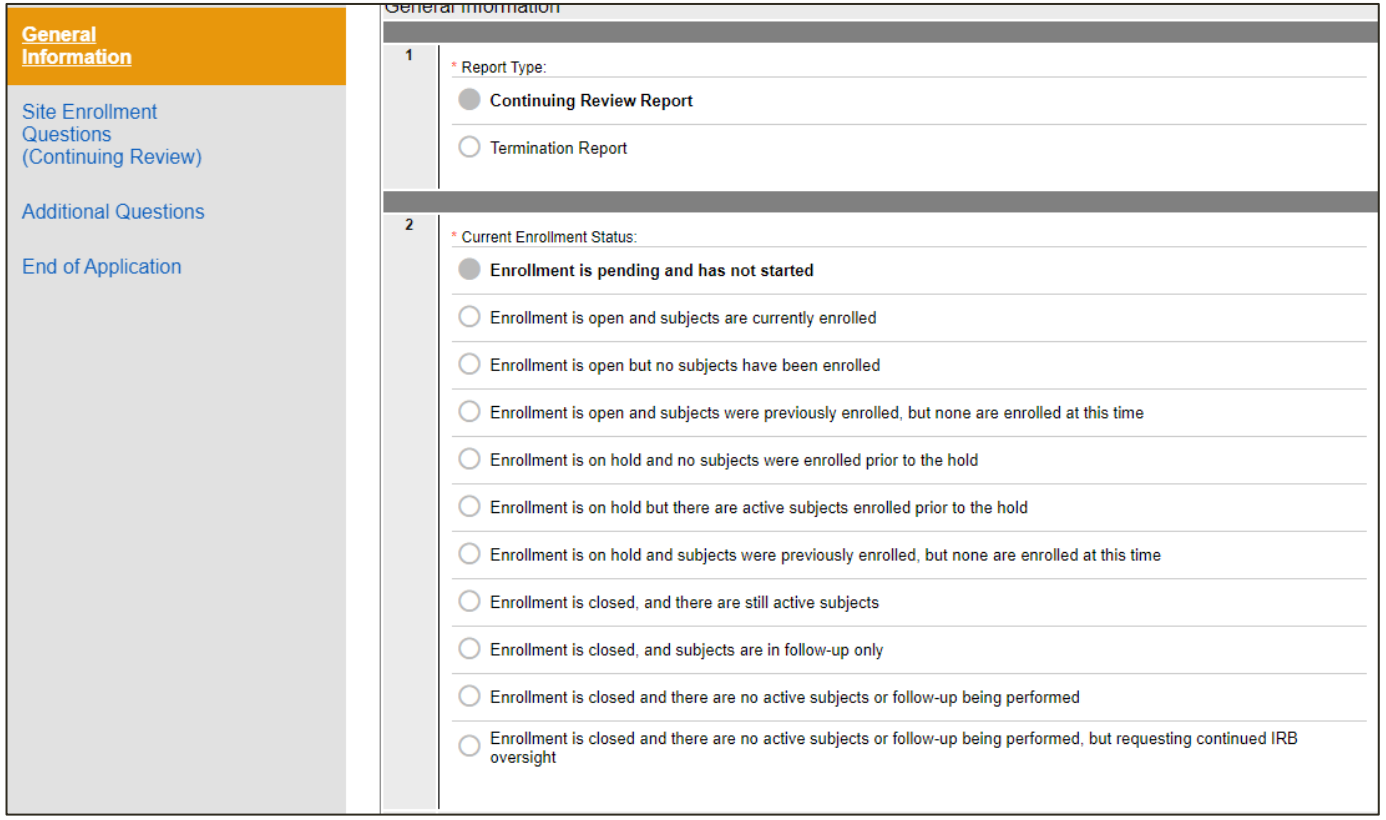
- When you are informed that an Amendment to the protocol or informed consent is needed:
  - You will need to log into CIRBI (www.cirbi.net) and submit a Modification.
- To submit a Modification:
  - Select New IDEAS protocol on your Dashboard.
  - Select “Modification” from the left-hand Toolbar.
-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

Continuing Review Submission



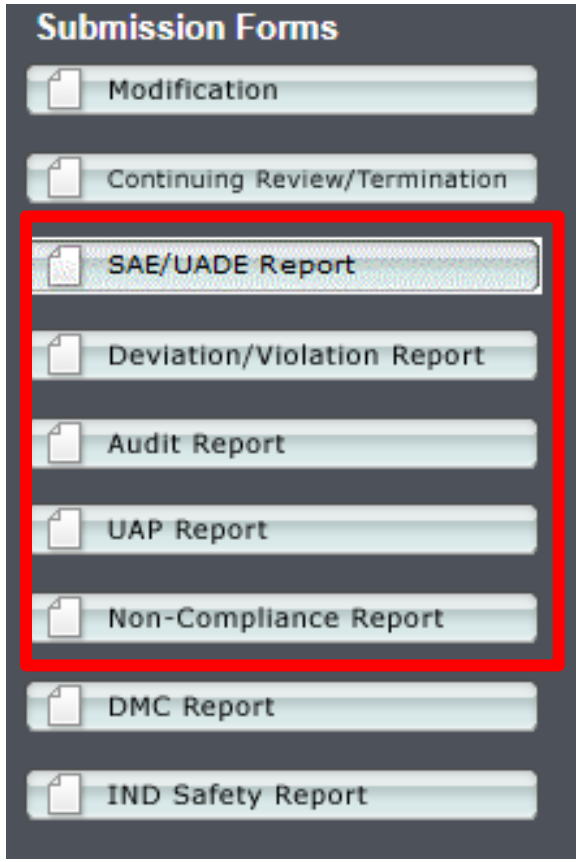
- Login to CIRBI (www.cirbi.net)
- Select “New IDEAS” from your Dashboard.
- Select “Continuing Review/Termination” tab on left-hand toolbar.

Continuing Review Submission (Cont.)



- 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

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