# ALZ-NET IRB Start Up Guidance

# Module Overview

# IRB Overview

- ALL sites must use Advarra IRB as the IRB of record overseeing their research activity.
- Each site is responsible for submitting to Advarra IRB and obtaining IRB approval prior to participating in the ALZ-NET study.
  - **The Advarra IRB protocol number for ALZ-NET is Pro00064645**
    - See instructions on how to submit to the Advarra IRB.
- IRB 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: slide 4

# Agreements with Advarra IRB

Each site must rely on Advarra IRB as the IRB of Record for this multisite protocol.

Sites with a local IRB

- Choose from the options below for your sites appropriate agreement:
  - **External Reliance Agreement** - This non-exclusive agreement outlines the roles and responsibilities of both organizations and provides all deferral and organizational numbers for any trial the institutional site wishes to submit.
  - **SMART IRB Ceding Letter** - Any SMART IRB member institutional site can use this document to indicate that your institution will cede to Advarra using Smart IRB. Because Advarra is also a member, the site can use this agreement for the deferral and org numbers.
    - Check to see if your institution is participating in the SMART IRB agreement by searching the SMART IRB website.
    - Two options for ceding to Advarra using Smart IRB.
  - **Institutional Authorization Agreement** - Provides the deferral and org numbers for a specific study.
  - **Advarra Statement of IRB Oversight Waiver** - Can also be used to cede oversight to Advarra (for a non-federally funded study)
- To submit the agreement, please send to institutions@advarra.com

Sites without a local IRB

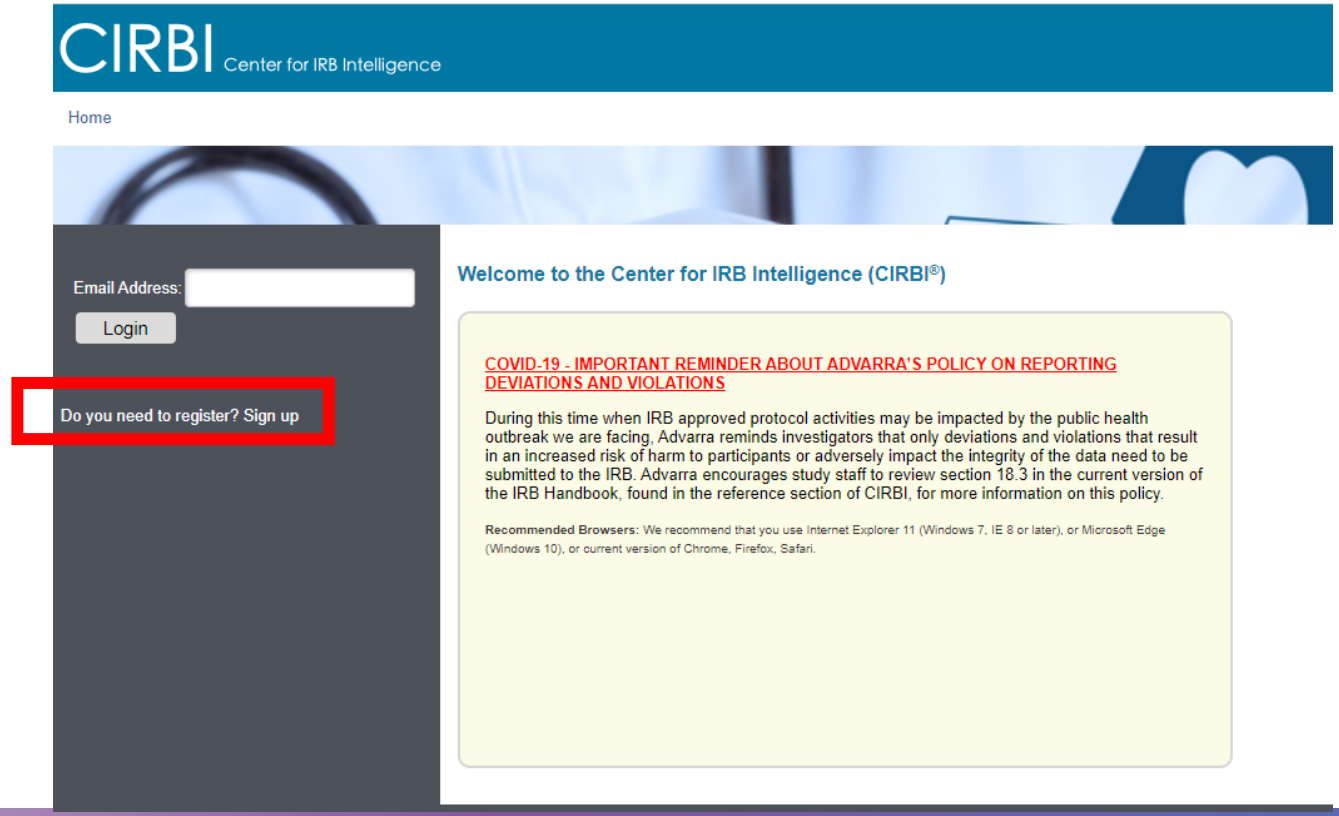
- If your site does not have a local IRB, you can submit directly to Advarra IRB without an agreement between Advarra and your site.

# Creating a CIRBI Account

- CIRBI is Advarra IRB's platform for submissions and review by the IRB
- 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

Site coordinator and PI will need to have an account



# Creating a CIRBI Account (Cont.)

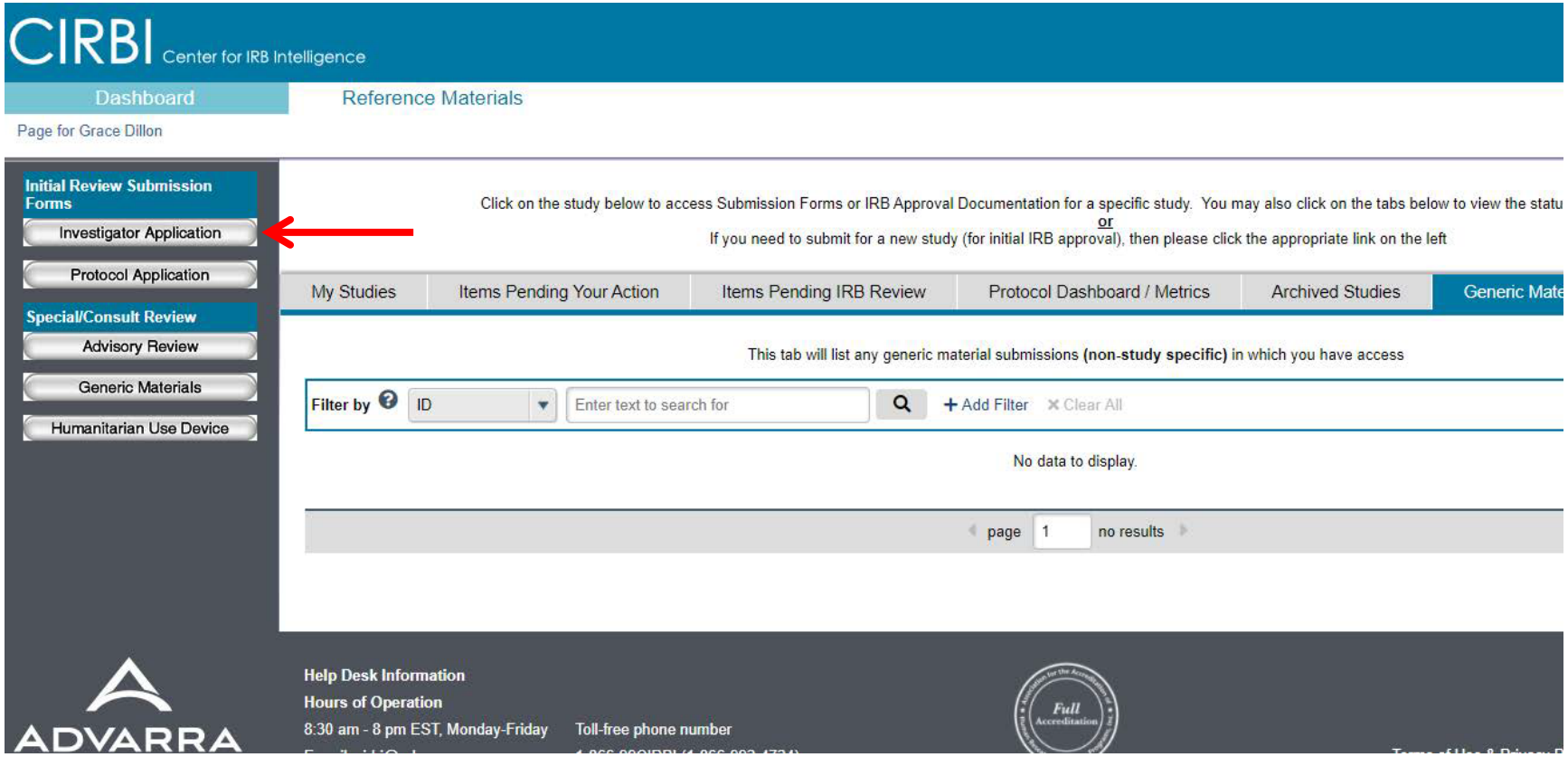
- Fill out the registration form including the following information:
  - a. First Name
  - b. Middle Name (if applicable)
  - c. Last Name
  - d. Credentials/Degrees
  - e. E-mail Address
  - f. Organization/Company Name
  - g. Role/Type
  - h. Address 1
  - i. Address 2
  - j. City
  - k. State/Province
  - l. Zip/Postal Code
  - m. Country
  - n. Phone Number
  - o. Do you need access to an existing study (Yes/No) i. If you need access to an existing study, you can indicate which study/PI/site
- Click "**Register**" at the bottom of the form

**Please note the following**:

- Each person registering must have a unique email address (no duplicates)
- The email address that you provide will be used to create your Username which, along with your password, is case-sensitive. Also, you need to register only **once**. You can request updates to your account at any time.
- The Principal Investigator **must** be registered
- Any study personnel who will need access to download documents and/or complete submission forms **must** be registered

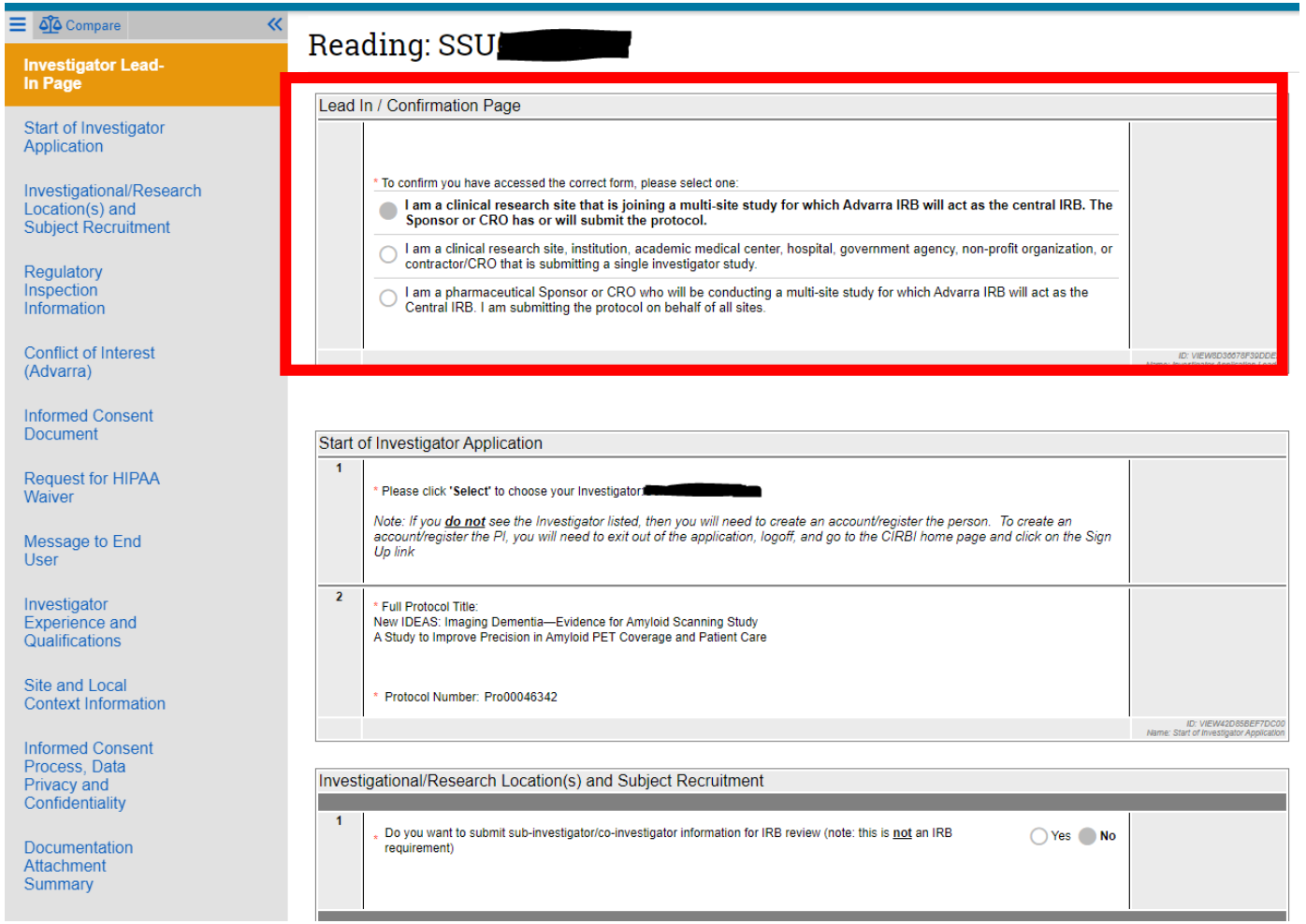
# Initial Submission to Advarra

On your Dashboard, select “Investigator Application.”

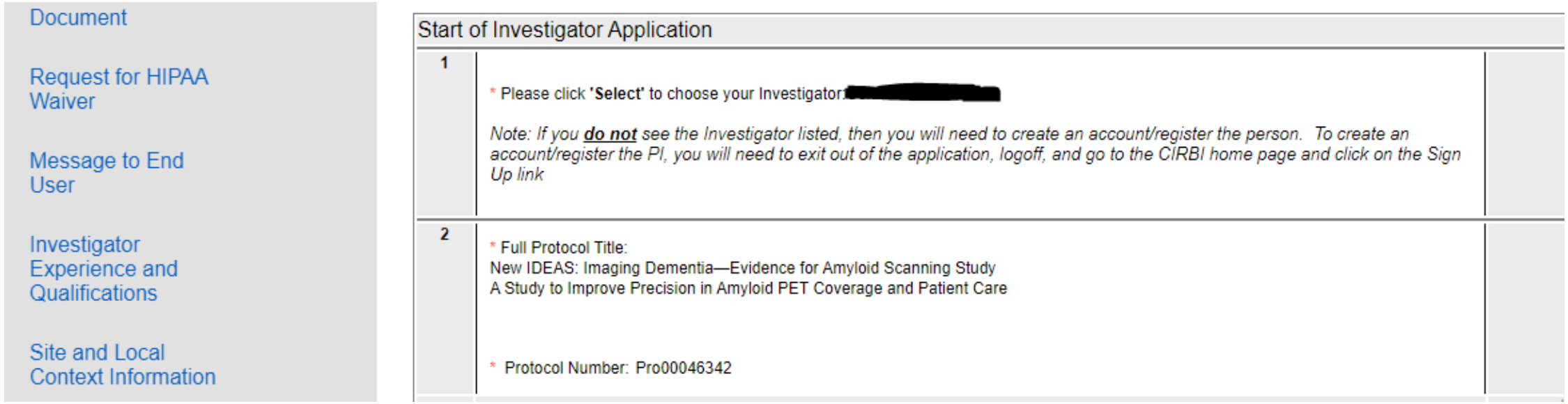


# Initial Submission (cont.)

- 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 5-6 on how to create an account

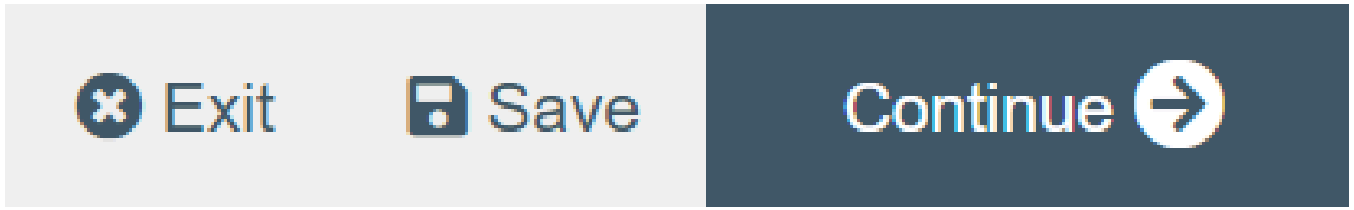
# Initial Submission (cont.)

## Documents Needed for Submission

- A copy of the PI's CV
- Informed Consent
  - Only if you have made edits to the master ICF
- HIPAA Form
  - Advarra IRB does not require review of this document, however the sponsor requires that it be reviewed and approved by the IRB.
- IRB Waiver of Oversite
  - Only if your site has a local IRB

# Navigating the CIRBI Form

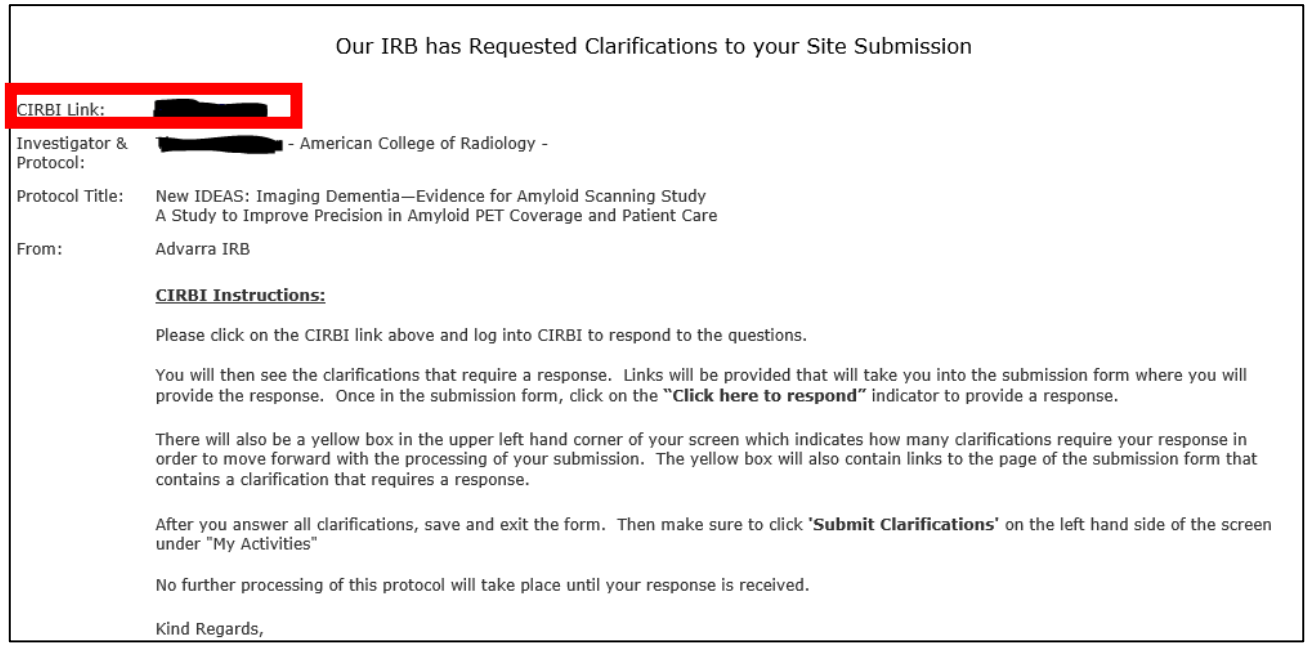
- On the bottom right-hand corner of the form there will be options to:
- **Continue** saves the form and moves you forward to the next slide.
  - Note: if all the red asterisked (*) questions are not answered, you will not be able to move forward.
- **Save** allows you to save the page in any stage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



# Responding to IRB Requests for Clarifications

- 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.

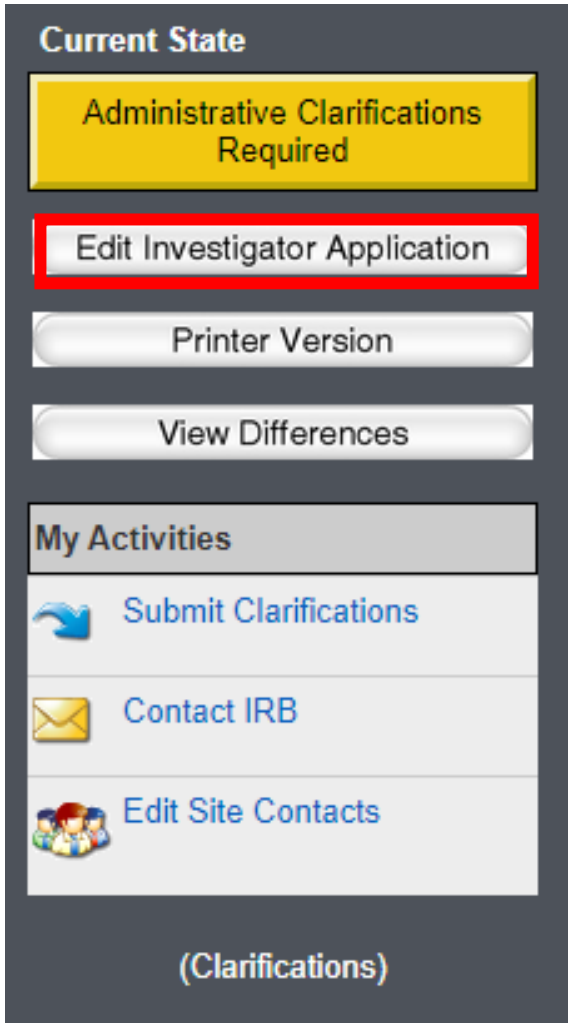
There will also be a yellow box in the upper left hand corner of your screen which indicates how many clarifications require your response in order to move forward with the processing of your submission. The yellow box will also contain links to the page of the submission form that contains a clarification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

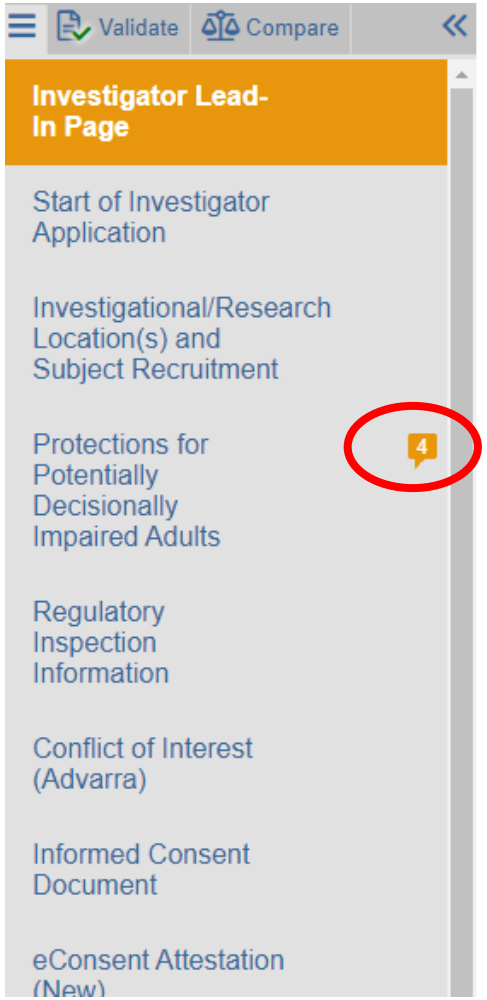
Kind Regards,

# Responding to IRB Requests for Clarifications (Cont.)



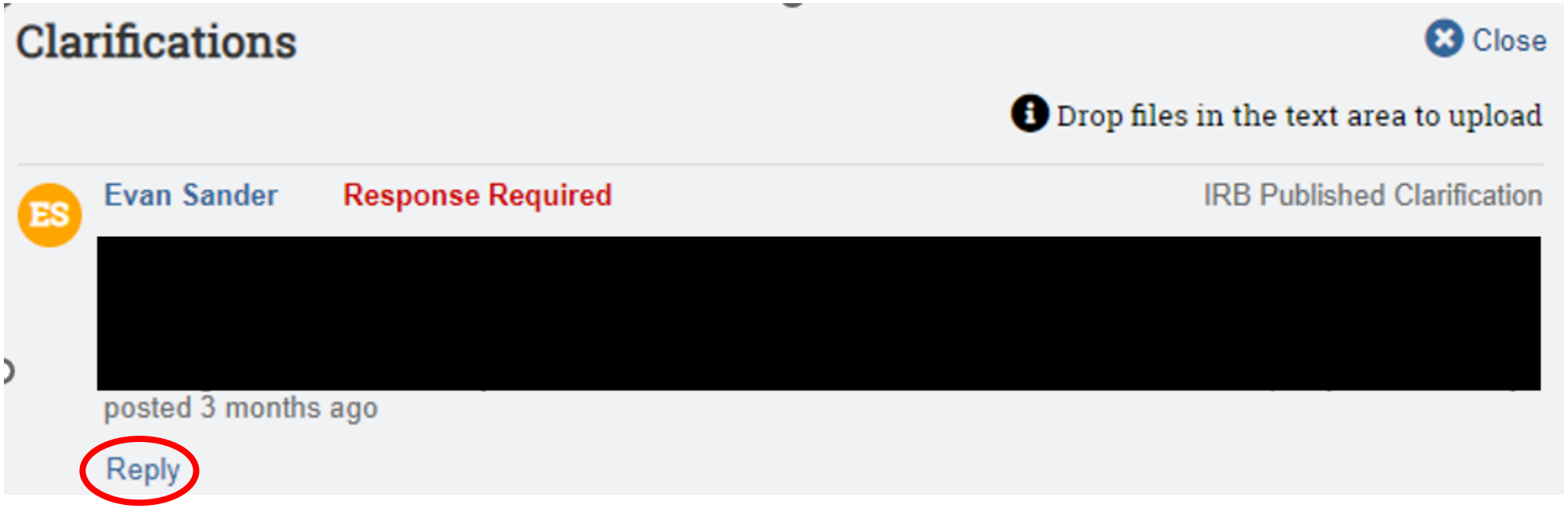

- Once you are in CIRBI, respond to each inquiry.
- Click on “Edit Investigator Application”
  - This will take you into the form.

# Responding to IRB Requests for Clarifications (Cont.)



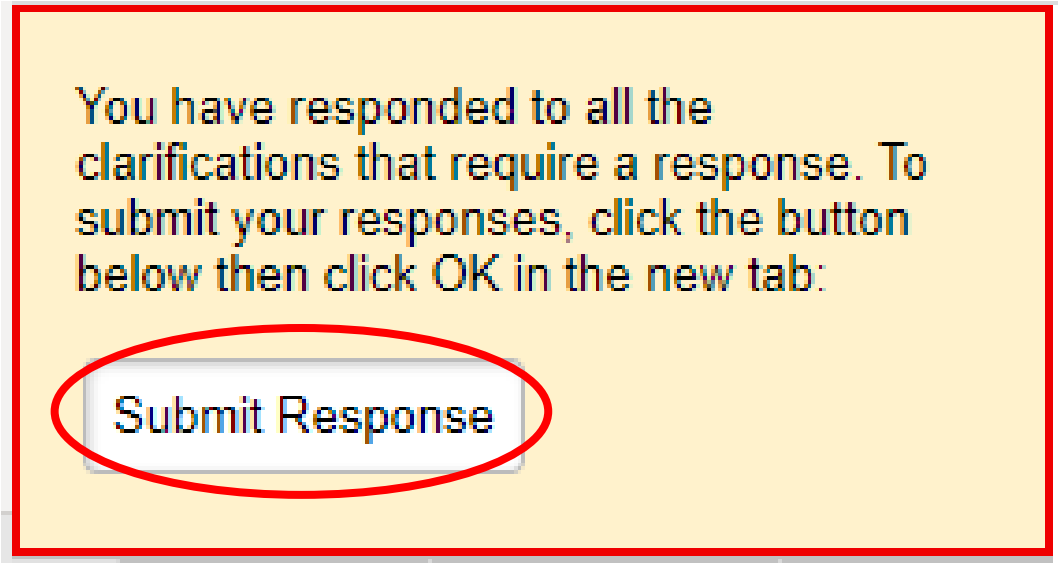

- Click on the tab on the left-hand side that has a text box (circled in red)
  - Please note that you may have more than on tab with the text box
- Click on the text box ( 1 Click here to respond )
- A pop up will open
  - Sometimes you have to scroll to the bottom of the page to see the pop-up

# Responding to IRB Requests for Clarifications (Cont.)




- In the pop-up
  - Click on the “Reply” below the question (circled in red)
  - Type in your response and click “OK”

# Responding to IRB Requests for Clarifications (Cont.)




- Once you reply to all of the questions, you must submit your responses.
- To submit responses:
  - Click the “submit responses” bottom in the upper left-hand corner (circled in red)

# ALZ-NET Regulatory

**ACR Center for Research and Innovation**

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