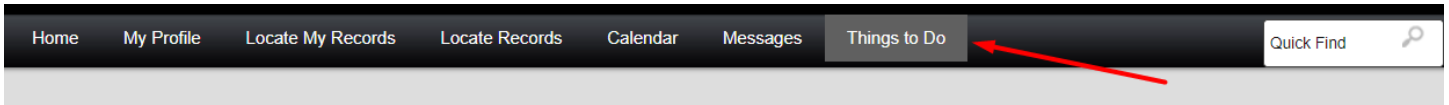
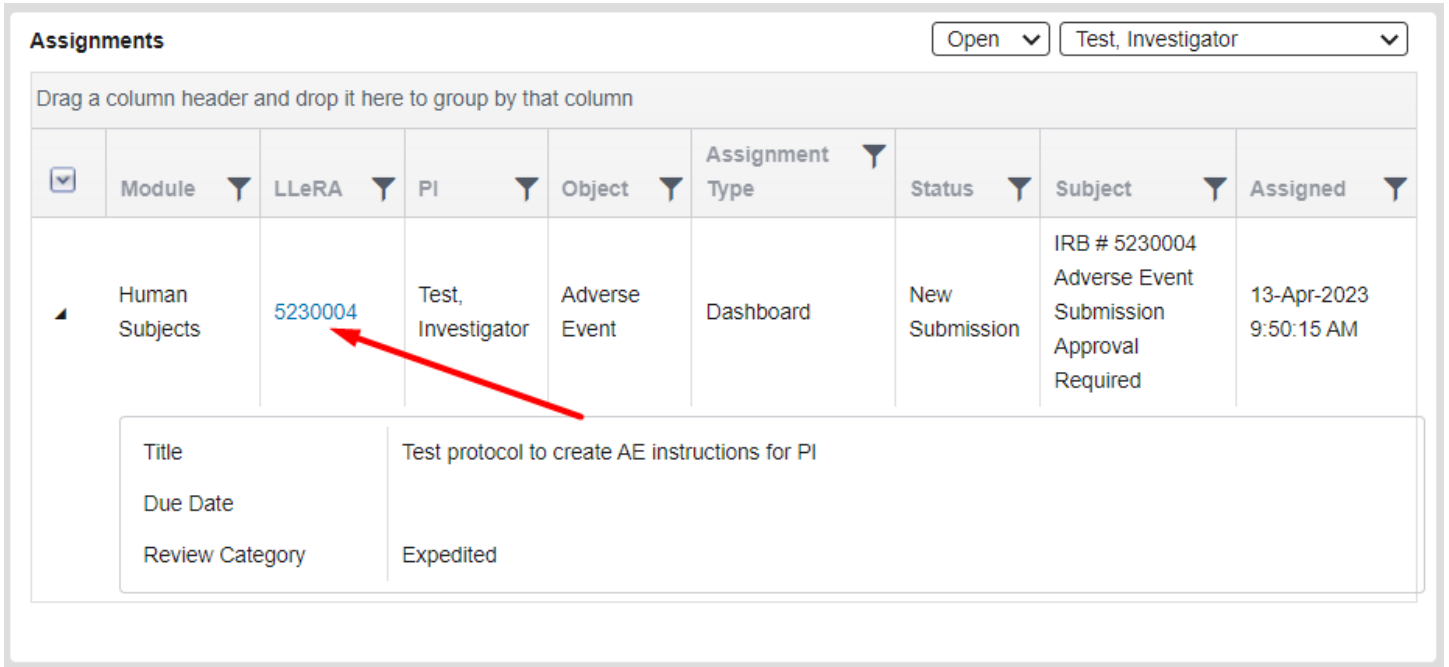


AE - PI Guidance for reviewing an AE submitted on their behalf

- 1) Log into InfoEd with your unique username and password (if you need help email IRB@llu.edu)
- 2) Click on *Things to Do* in the Black bar



- 3) In large, white box, click on the [blue](#) IRB (LLeRA) number.



The screenshot shows the 'Assignments' section of the InfoEd system. At the top right, there are two dropdown menus: 'Open' and 'Test, Investigator'. Below these is a header for the table: 'Drag a column header and drop it here to group by that column'. The table has the following columns: Module, LLeRA, PI, Object, Assignment Type, Status, Subject, and Assigned. The first row of data is for 'Human Subjects' and contains the following information: LLeRA number '5230004' (highlighted in blue with a red arrow), PI 'Test, Investigator', Object 'Adverse Event', Assignment Type 'Dashboard', Status 'New Submission', Subject 'IRB # 5230004 Adverse Event Submission Approval Required', and Assigned '13-Apr-2023 9:50:15 AM'. Below the table, there is a detailed view of the assignment with the following information: Title 'Test protocol to create AE instructions for PI', Due Date, and Review Category 'Expedited'.

Module	LLeRA	PI	Object	Assignment Type	Status	Subject	Assigned
Human Subjects	5230004	Test, Investigator	Adverse Event	Dashboard	New Submission	IRB # 5230004 Adverse Event Submission Approval Required	13-Apr-2023 9:50:15 AM

Title: Test protocol to create AE instructions for PI
Due Date:
Review Category: Expedited

- 4) Review the Adverse Event (AE) submission created on your behalf. Click on either the blue wording [Adverse Event](#) (to click page by page) OR the blue [PDF](#) (entire document combined).

REVIEW

Accessing item as Delegate for Investigator Test

Human Subject Protocol - Adverse Event
Number: [5230004](#)
Title: Test protocol to create AE instructions for PI
PI: Test, Investigator
Submitted: 13-Apr-2023 9:50:08 AM

Form/Document	Document Type	Added	Review Status
Adverse Event	Adverse event	13-Apr-2023 9:50:14 AM	Un-Reviewed ▾

HELP

ROUTE

Add Comments:
 To be shared with everyone

OR

Select a decision:

Approved

Disapproved

Abstain

5) As you review, if you'd like to make comments on anything, you may add them to the various boxes on the above screen.

6) When done reviewing the document, you can click on the X in the upper right corner.

7) Once reviewed, click on the Review Status pull-down and choose *Reviewed*.

REVIEW

Accessing item as Delegate for Investigator Test

Human Subject Protocol - Adverse Event
Number: [5230004](#)
Title: Test protocol to create AE instructions for PI
PI: Test, Investigator
Submitted: 13-Apr-2023 9:50:08 AM

Form/Document	Document Type	Added	Review Status
Adverse Event	Adverse event	13-Apr-2023 9:50:14 AM	Un-Reviewed ▾

HELP

ROUTE

Add Comments:
 To be shared with everyone

Select a decision:

Approved

Disapproved

Abstain

Un-Reviewed
 Reviewed
 Not Applicable

8) Under Select a decision, you may choose Approved or Disapproved; Abstain should not be used at this time.

REVIEW

Accessing item as Delegate for Investigator Test

Human Subject Protocol - Adverse Event
Number: [5230004](#)
Title: Test protocol to create AE instructions for PI
PI: Test, Investigator
Submitted: 13-Apr-2023 9:50:08 AM

Form/Document	Document Type	Added	Review Status
Adverse Event	Adverse event	13-Apr-2023 9:50:14 AM	PDF Reviewed ▾

HELP

ROUTE

Add Comments:
To be shared with everyone

Select a decision:

Approved

Disapproved

Abstain

9) If you choose approved or disapproved, the below shows up – click OK and move on. If you choose disapproved, the routing stops. (email IRB@llu.edu for further instructions or call ext.44531)

eracert.llu.edu says

You are about to complete your review. You will not be able to edit after this decision.



10) Screen will refresh:

Do NOT close this browser window!

**The window will close on its own when the review finishes processing.
If you close the window your review will not be saved.**

11) The screen refreshes to the below showing the decision and comments (if any).

REVIEW

Accessing item as Delegate for Investigator Test

Human Subject Protocol - Adverse Event

Number: [5230004](#)

Title: Test protocol to create AE instructions for PI

PI: Test, Investigator

Submitted: 11-Apr-2023 1:04:30 PM

If comments added, they would show up here. →

Comments I can see...
No Comments have been recorded

Form/Document	Document Type	Added	Review Status
Adverse Event	Adverse event	11-Apr-2023 1:04:38 PM	PDF Reviewed

Add Comments:
Not Available in View Mode

My Decision is:
Approved ←

HELP

ROUTE

12) You may close this window and go back to your main InfoEd login page – **Messages** - you should see the following entry that the AE is acknowledged:

Messages Inbox New Mail Switch Recipients Test, Investigator Page 1 of 3 Select Delete

IRB # 5230004: Adverse Event Submission Acknowledgement Institutional Review Board, IRB Tue 11-Apr-2023 13:11 PM

13) If you click on the blue wording you will see the following:

Reply Reply All Forward Save Next Close

From: Institutional Review Board, IRB Received: 11-Apr-2023

To: Dr. Test, Investigator - SM: Perinatal Biology

CC:

Subject: IRB # 5230004: Adverse Event Submission Acknowledgement

This is a test alert from InfoEd Certification

This is to acknowledge that your IRB Adverse Event form has been successfully submitted in InfoEd for the study referenced below:

IRB #: 5230004
PI: Dr. Investigator Test
Sponsor:
Title: Test protocol to create AE instructions for PI
Submitted By: Mrs. Deborah Rodman

Please contact us if you have any questions.

Thank you.

Human Research and Compliance
 24887 Taylor Street • Suite 201 • Loma Linda, CA 92350
 (909) 558-4531 (voice) • irb@llu.edu

14) Your submission is complete and is routed to the IRB Analyst for review.

15) Once your submission has been reviewed and accepted by the IRB Analyst, it is routed to the IRB Chair for final review. When that review is complete, you will receive an email and see the following on your **Messages** screen in InfoEd.

Messages Inbox New Mail
Switch Recipients Test, Investigator Page 1 of 3 Select Delete

[IRB # 5230004: Adverse Event](#) Institutional Review Board, IRB Thu 13-Apr-2023 08:19 AM

16) When you click on the blue wording, the window opens to show the below:

Reply Reply All Forward Save Next Close

From: **Institutional Review Board, IRB** Received: **13-Apr-2023**
To: **Dr. Test, Investigator** - SM: Perinatal Biology
CC:
Subject: **IRB # 5230004: Adverse Event**

This is a test alert from InfoEd Certification

This is to inform you that the Adverse Event on the following study has been reviewed by the IRB chairperson and will be reported to the committee at the next scheduled meeting of the IRB.

IRB #: 5230004
PI: Dr. Investigator Test
Sponsor:
Title: Test protocol to create AE instructions for PI<
Submitted By: Mrs. Deborah Rodman

Review Comments (if any):

Please contact us if you have any questions.

Thank you.

Human Research and Compliance
24887 Taylor Street • Suite 201 • Loma Linda, CA 92350
(909) 558-4531 (voice) • (909) 558-0131 (fax) • irb@llu.edu

17) This adverse event is now Complete. You may forward this to your coordinator or if no coordinator, please keep a copy for your records in the event of an audit.