Protocol Violation - PI Guidance for reviewing a PV submitted on their behalf
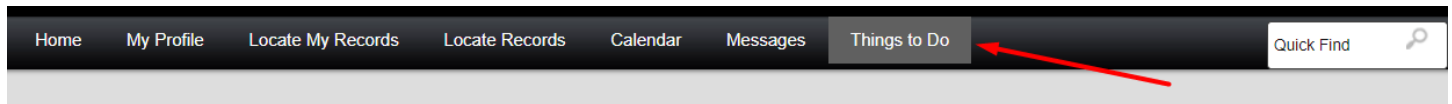
1) Log into InfoEd with your unique username and password (if you need help email IRB@llu.edu)
2) Click on *Things to Do* in the Black bar

Home	My Profile	Locate My Records	Locate Records	Calendar	Messages	Things to Do		Quick Find

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

Assignments

Open ▾ Test, Investigator ▾

Drag a column header and drop it here to group by that column

☑	Module	LLeRA	PI	Object	Assignment Type	Status	Subject	Assigned
▶	Human Subjects	5230003	Test, Investigator	Protocol Violation	Dashboard	New Submission	IRB # 5230003 Protocol Violation Approval Required	02-Aug-2023 11:25:08 AM

4) Review the Protocol Violation (PV) submission created on your behalf by clicking on either the blue wording Protocol Violation (to click page by page) OR the blue PDF (entire document combined).

Accessing item as Delegate for Investigator Test

Human Subject Protocol - *Protocol Violation*
Number: 5230003
Title: TEST for creating AE instructions for PI approval
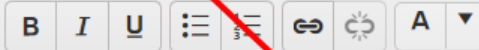**PI:** Test, Investigator
Submitted: 02-Aug-2023 11:25:00 AM

Form/Document	Document Type	Added		Review Status
Protocol Violation	Protocol Deviation	02-Aug-2023 11:25:06 AM	PDF	Un-Reviewed ⌄

Add Comments:
To be shared with everyone

B *I* U

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*.

Accessing item as Delegate for Investigator Test

Human Subject Protocol - *Protocol Violation*
Number: 5230003
Title: TEST for creating AE instructions for PI approval
PI: Test, Investigator
Submitted: 02-Aug-2023 11:25:00 AM

Form/Document	Document Type	Added		Review Status
Protocol Violation	Protocol Deviation	02-Aug-2023 11:25:06 AM	PDF	Un-Reviewed ⌄

Un-Reviewed
Reviewed
Not Applicable

Add Comments:
To be shared with everyone

B *I* U

Select a decision:

Approved

Disapproved

Abstain

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

Accessing item as Delegate for Investigator Test

Human Subject Protocol - *Protocol Violation*
Number: 5230003
Title: TEST for creating AE instructions for PI approval
PI: Test, Investigator
Submitted: 02-Aug-2023 11:25:00 AM

Form/Document	Document Type	Added		Review Status
Protocol Violation	Protocol Deviation	02-Aug-2023 11:25:06 AM	PDF	Reviewed ⌄

Add Comments:
To be shared with everyone

B I U ☰ ☰ ⊝ ⊝ A ▼

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.

OK   Cancel

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).

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

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

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 6 ▶ ⏭   Select ☑   Delete

IRB # 5230003: Protocol Violation   Institutional Review Board, IRB   Mon 07-Aug-2023 07:09 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: **07-Aug-2023**

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

CC:

Subject: **IRB # 5230003: Protocol Violation**

This is a test alert from InfoEd Certification

This is to inform you that the Protocol Violation 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 #: 5230003
PI: Dr. Investigator Test
Sponsor:
Title: *TEST for creating AE instructions for PI approval*
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 protocol violation 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.