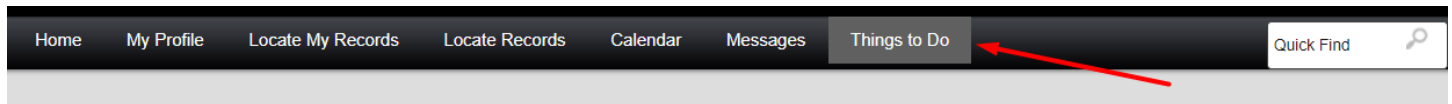


## Protocol Violation - PI Guidance for reviewing a PV submitted on their behalf

- 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



- 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

<input type="checkbox"/>	Module ▾	LLeRA ▾	PI ▾	Object ▾	Assignment Type ▾	Status ▾	Subject ▾	Assigned ▾
<input type="checkbox"/>	Human Subjects	<a href="#">5230003</a>	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).

REVIEW

## 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

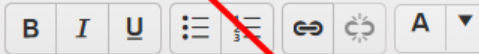
HELP

ROUTE

Form/Document	Document Type	Added	Review Status
<a href="#">Protocol Violation</a>	Protocol Deviation	02-Aug-2023 11:25:06 AM	<a href="#">PDF</a> Un-Reviewed ▾

Add Comments:

To be shared with everyone



Select a decision:

Approved

Disapproved

Abstain

OR

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 - *Protocol Violation*

Number: [5230003](#)

Title: TEST for creating AE instructions for PI approval

PI: Test, Investigator

Submitted: 02-Aug-2023 11:25:00 AM

HELP

ROUTE

Form/Document	Document Type	Added	Review Status
<a href="#">Protocol Violation</a>	Protocol Deviation	02-Aug-2023 11:25:06 AM	<a href="#">PDF</a> Un-Reviewed ▾

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**

**HELP**

**ROUTE**

### 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
<a href="#">Protocol Violation</a>	Protocol Deviation	02-Aug-2023 11:25:06 AM	<a href="#">PDF</a> <span>Reviewed</span>

**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](mailto: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 Close

**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


If comments added, they would show up here. 

**Comments I can see...**

No Comments have been recorded

Form/Document	Document Type	Added	Review Status
<a href="#">Protocol Violation</a>	Protocol Deviation	02-Aug-2023 11:25:06 AM	<a href="#">PDF</a> <span style="border: 1px solid gray; padding: 2px;">Reviewed</span>


**Add Comments:**  
Not Available in View Mode

**My Decision is:**  
Approved 

**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 PV is acknowledged:

**Messages** Inbox New Mail Switch Recipients Test, Investigator Page 1 of 5 Select Delete

 [IRB # 5230003: Protocol Violation Submission Acknowledgement](#) Institutional Review Board, IRB Wed 02-Aug-2023 11:51 AM

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:** 02-Aug-2023  
**To:** Dr. Test, Investigator - SM: Perinatal Biology  
**CC:**  
**Subject:** IRB # 5230003: Protocol Violation Submission Acknowledgement

**This is a test alert from InfoEd Certification**


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

**IRB #:** 5230003  
**PI:** Dr. Investigator Test  
**Sponsor:**  
**Title:** TEST for creating AE instructions for PI approval  
**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) • (909) 558-0131 (fax) • [irb@llu.edu](mailto: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 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](mailto: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.