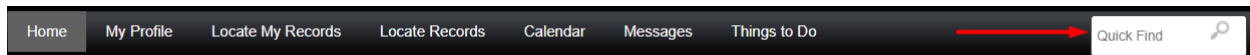
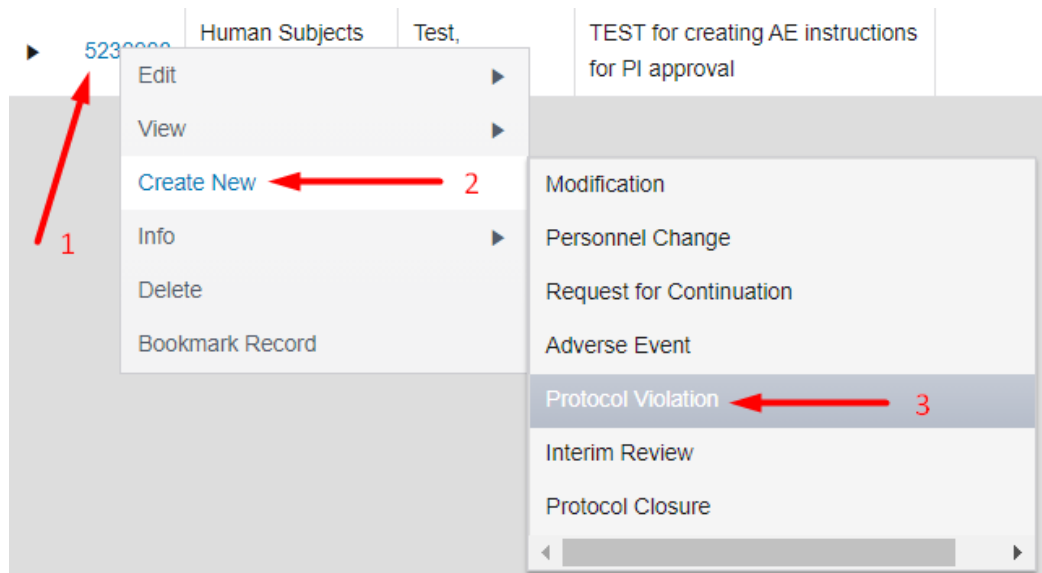


Protocol Violation - General guidance for electronic submission

- 1) If opening a study from **era.illu.edu**:
 - a. Log into InfoEd using your unique username and password.
- 2) In the upper right corner, enter the IRB number of the study in the Quick Find – Enter

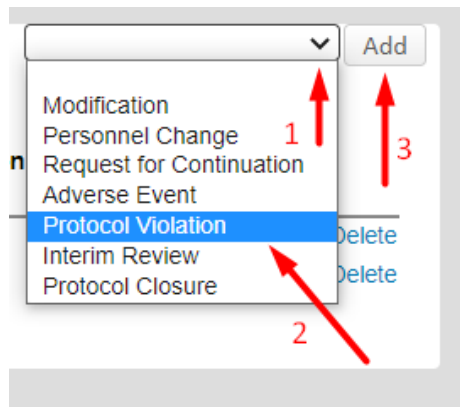


- 3) Once that number populates the screen, follow the below guidance.
 - 1) Click on the IRB number
 - 2) Click on Create New
 - 3) Click on Protocol Violation
 - 4) Go to #5 on this guidance document

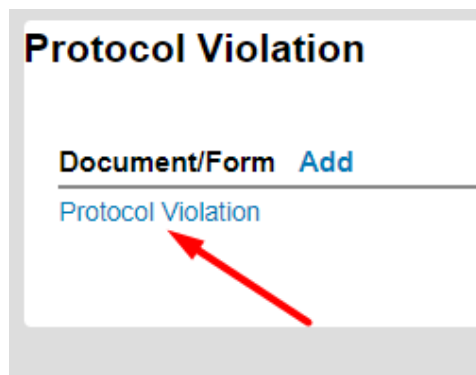


- 4) If opening a study from the **Investigator Portal** “My Projects” tab:

- 1) Click on the  icon under the IRB number
- 2) Click on Submissions in upper black bar
- 3) Click on pull-down arrow in upper right empty box
- 4) Click on Protocol Violation
- 5) Click Add
- 6) Go to #5 on this guidance document



5) Click on the blue [Protocol Violation](#) under “*Document/Form*”



6) Read the definitions (especially the first time) and confirm the project summary at the bottom of the instruction page is correct.

7) Click on 2 *Sponsor Notification* tab at the top of the page.

a. Answer and fill in appropriate – SAVE (upper right)

8) Click on 3 *Description* tab at the top of the page

a. Fill in all applicable areas – SAVE (upper right)

9) Click on 4 *Prevention* tab at the top of the page

a. Fill in all applicable areas – SAVE (upper right)

10) Click on 5 *Additional Instructions* at the top of the page.

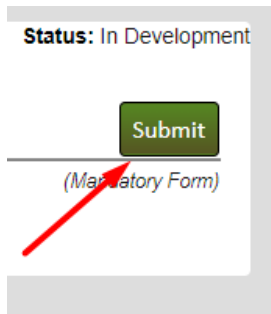
a. Read and save copy

11) Click on the *ALL PAGES* tab – SAVE (upper right). Review for accuracy and make any applicable changes.

12) Click Print box in upper right corner to save as PDF or print.

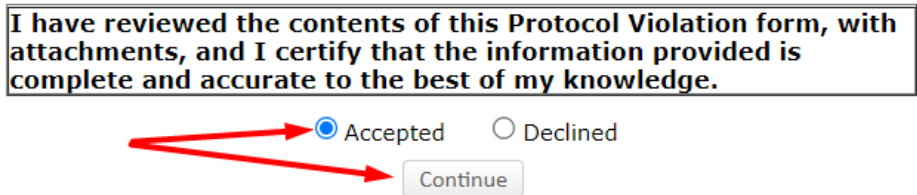
13) Click Completed in upper right corner; Close

14) Click Submit in the green box to the right.

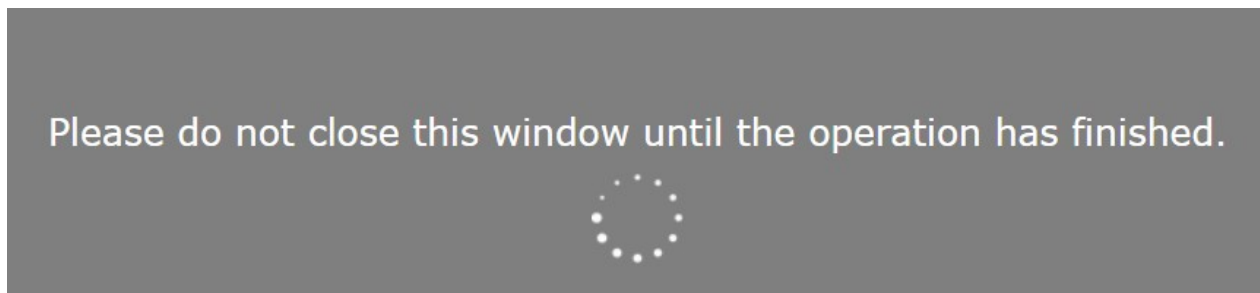


A screenshot of a web form. At the top, it says "Status: In Development". Below this is a green rectangular button with the word "Submit" in white text. Underneath the button, the text "(Mandatory Form)" is displayed in a smaller, italicized font. A red arrow points from the bottom left towards the "Submit" button.

15) Click Accepted then Continue – wait for page to refresh.



A screenshot of a certification statement enclosed in a black-bordered box. The text reads: "I have reviewed the contents of this Protocol Violation form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge." Below the box are two radio buttons. The first is labeled "Accepted" and is selected (indicated by a blue dot). The second is labeled "Declined" and is unselected. Below the radio buttons is a grey "Continue" button. Two red arrows originate from the left: one points to the "Accepted" radio button, and the other points to the "Continue" button.



16) The green box changes to red with caption – “Recall Submission”

17) Your submission is now routed for review. You may close the study in the upper left corner by clicking on “Done” - (DO NOT click the X to close the study, as this leaves it open and running in the background).