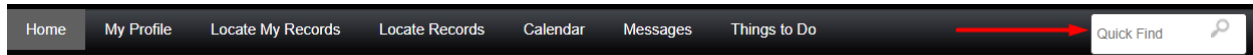
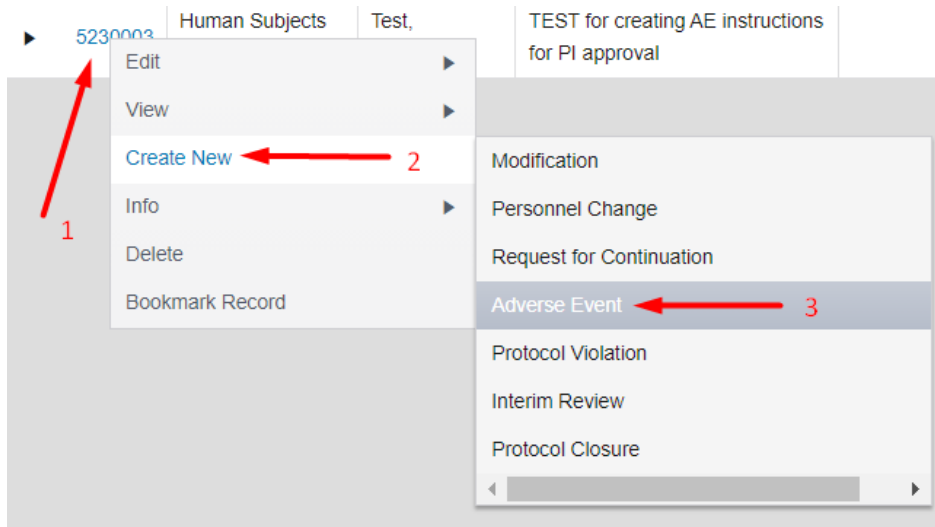


## Adverse Event - General guidance for electronic submission


- 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

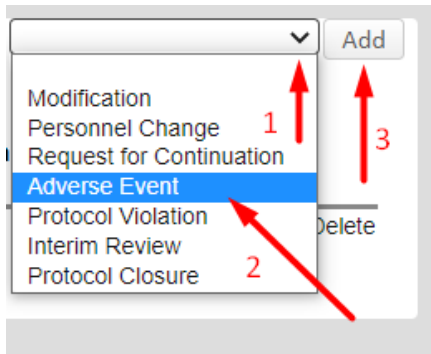


- 3) Once that number populates the screen, follow the below guidance.
  - 1) Click on the IRB number
  - 2) Click on Create New
  - 3) Click on Adverse Event
  - 4) Go to #5 on this guidance document

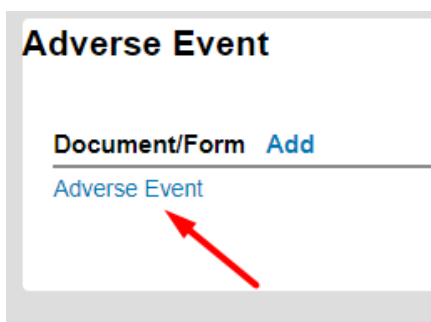


- 4) If opening a study from the **Investigator Portal** “My Projects” tab:

- 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 Adverse Event
- 5) Click Add
- 6) Go to #5 on this guidance document



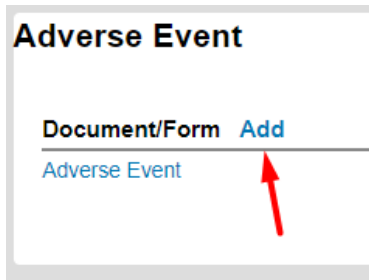
5) Click on the blue [Adverse Event](#) under “*Document/Form*”



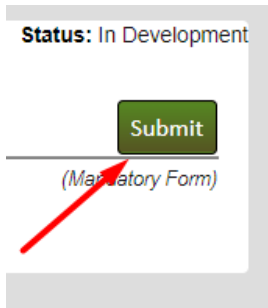
- 6) Read the instructions (especially the first time) and confirm the project summary at the bottom of the instruction page is correct.
- 7) Click on 2 *General Information* tab at the top of the page.
  - a. Fill in all applicable areas – SAVE (upper right)
- 8) Click on 3 *Subject Information* tab at the top of the page.
  - a. Fill in all applicable areas – SAVE (upper right)
- 9) Click on 4 *Event Description* tab at the top of the page.
  - a. Fill in all applicable areas – SAVE (upper right)
- 10) Click on 5 *Resolution* tab at the top of the page.
  - a. Type response in empty box – SAVE (upper right)
- 11) Click on 6 *Subject Outcome* tab at the top of the page.
  - a. Fill in all applicable areas – SAVE (upper right)
- 12) Click on 7 *Event Categorization* at the top of the page.
  - a. Fill in all applicable areas – SAVE (upper right)
- 13) Click on 8 *PI Assessment* tab at the top of the page.
  - a. Fill in all applicable areas – SAVE (upper right)
- 14) Click on 9 *Reports Filed* at the top of the page.
  - a. Click yes or no – SAVE (upper right)
- 15) Click on the *ALL PAGES* tab – SAVE (upper right). Review for accuracy and make any applicable changes.
- 16) Click Print box in upper right corner to save as PDF or print.

17) Click Completed in upper right corner; Close

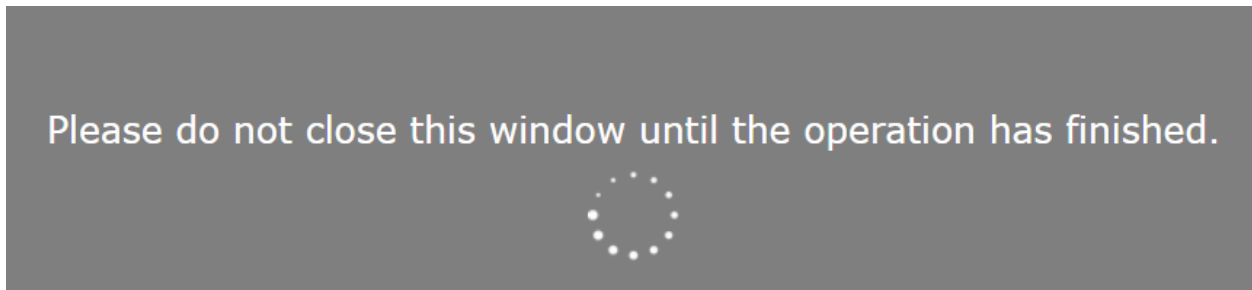
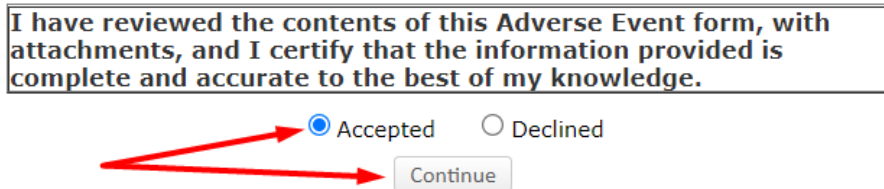
18) Add any other forms/documents that may be used as support (if applicable)



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



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



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

22) 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).