Adverse Event - General guidance for electronic submission
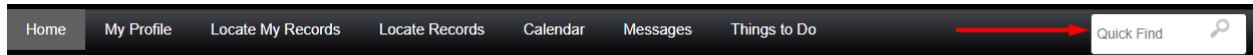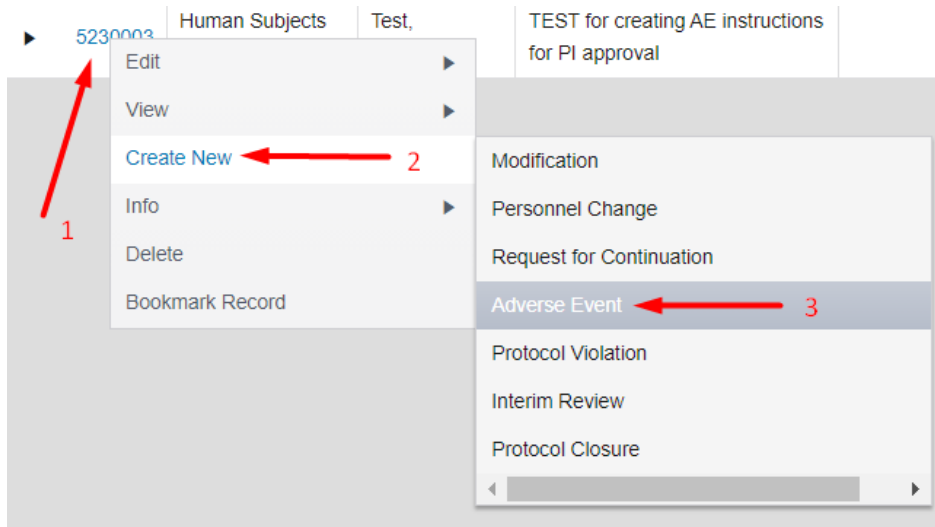
1) If opening a study from **era.llu.edu**:

      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
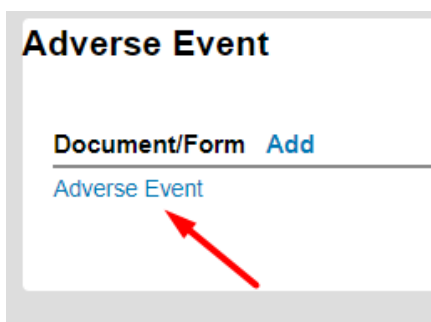   4) Go to #5 on this guidance document

4) If opening a study from the **Investigator Portal** "My Projects" tab:

      1) Click on the [icon] 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
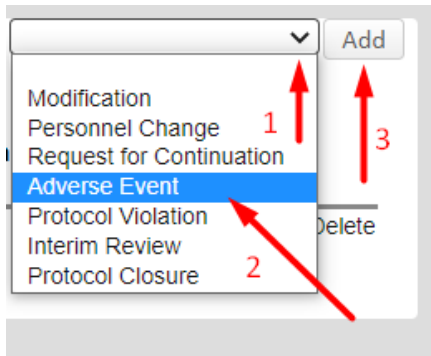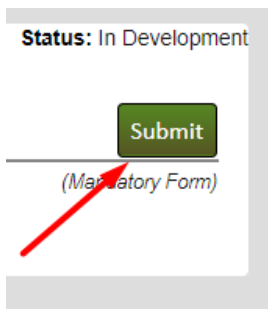
5) Click on the blue Adverse Event under "*Document/Form*"

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)

Adverse Event

Document/Form **Add**
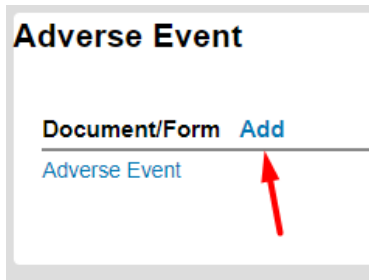
Adverse Event

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

Status: In Development

Submit

(Mandatory Form)

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

I have reviewed the contents of this Adverse Event form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge.

◉ Accepted   ○ Declined

Continue

Please do not close this window until the operation has finished.

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).