Creating, Completing and Submitting a Reportable Event Report in InfoEd

1. **Chief Investigator (CI):** Login to InfoEd. Select the '*My Items*' tab and find the record requiring a Reportable Event. Hover the cursor over the record number and select '*Edit > Master Record*'.

2. **Co-Investigator (Co-I) or Student:** Login to InfoEd. Search for the record by Title or Personnel under the '*Search for Items*' tab, or enter the approval number into the 'Quick Find' box which is located to the right of the screen. When you locate the record, hover the cursor over the record number and select '*Edit > Master Record*'.
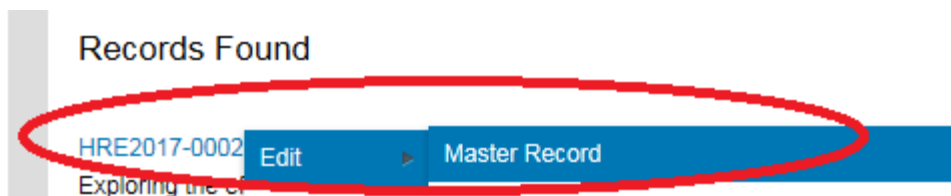
3. Select '*Submissions'* from the left hand side of the black banner. Here you will see the list of submissions associated with this record. Select '*Reportable Event*' from the dropdown menu to the right of the screen and click 'Add'.
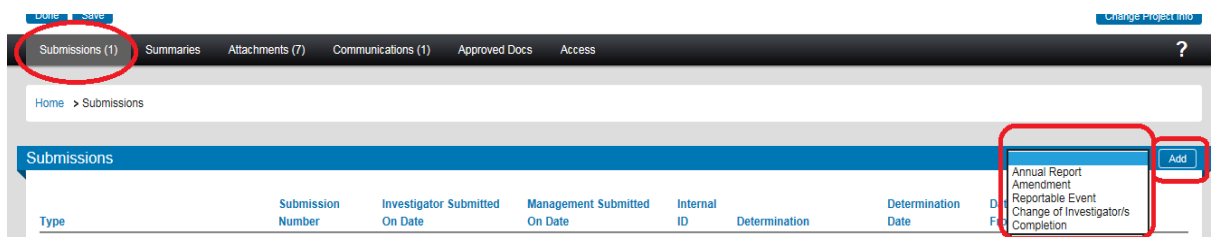
4. Under the heading '*Reportable Event*' click on '*Add*' (next to the '*Show Existing Protocol Attachments*').

5. Scroll to the lower section of the screen where you will see 3 forms to choose from (Major protocol deviation; Serious adverse event report; Unanticipated problem report). Select the applicable form by ticking the check box opposite and then click the 'Add' button above the check box. This window will close and you will be back at the 'Reportable Event' window.

6. Under the heading '*Reportable Event*' click on the name of the form you have added to open the form.

7. Complete the form, click '*Save*' which is located to the top right hand side of the screen and then tick the box next to '*Complete*'. If any questions have not been answered an error message '*Incomplete mandatory field(s) found*' will appear and a box in the left hand corner will list questions/fields still to be completed.

8. Click 'Close' to close the form and exit the window.

9. You should now be back at the '*Reportable Event*' window. Click the '*Submit*' button which is located to the right of the screen.

10. If you are the CI, a separate window displaying the researcher declaration will appear, asking whether you accept or decline the declaration. Click '*Accepted > Continue > Submit*'.

11. If your Reportable Event submission is successful, the determination should read '*Completed*' (if you are the CI) or '*Submitted*' (if you are the Co-I or Student).

12. The CI will receive an automated email from InfoEd notifying the Reportable Event report has been submitted. The same message will also appear under the '*Messages*' tab on the InfoEd main screen.

How to Attach Supporting Documents to Your Reportable Event report

1. In the 'Reportable Event' window, click on the 'Add' button.
2. A new window titled 'Add Components' will appear on your screen.
3. In the 'Upload' section, click on 'Browse' to locate the file you wish to attach with this report.
4. Once you have located and selected the document, click 'Open' to continue.
5. The location of the selected document should now be listed in the 'Location' field of the 'Upload' section in the 'Add Components' window. If applicable, select a 'Category' from the dropdown box.
6. Click on 'Upload' and then 'Close'.
7. The 'Add Components' window will close and you should see your document listed in the 'Reportable Event' window.