How to Create and Submit a Reportable Events and New Information Form (RENI)
After logging into INSPIR II, from your Home page, click on “My Studies” and proceed to the next slide.
Locate the study and click on the “Open” icon.
This opens the “Submissions/Study Management” page for the study.

If you see the “Reportable Events and New Information Form” link here, this means that someone else had already created the Reportable Events and New Information Form and you can open it by clicking on the link.

If you don’t see the Reportable Events and New Information Form link here, click on “Reportable Events and New Information Form” under “Available Forms” to create one (red arrow).
If you see a pending “Reportable Events and New Information Form” here, this means that someone else had already created the Reportable Events and New Information Form and you can open it by clicking on “Edit/View”.

If you don’t see the Reportable Events and New Information Form, click on the “Add a New Form” button to create one (red arrow).
This will bring you to a Section by Section view of the Reportable Events and New Information Form. Complete Section 1 and then click on SAVE AND CONTINUE (yellow arrow) to proceed to the next section. As you complete each section, the sections will be added to the left hand column (green arrow). Use the scroll bar (red arrow) to scroll through each section of the form. Answer all questions.

Reportable Events and New Information Form - (Version 9.0)

1.0 Reportable Events and New Information

For information about reporting requirements, click here

1.1 Study Information:

IRB Number:
H-31000

Study Title:
Testing

Principal Investigator:
Administrator

1.2 Report Type

☐ Unanticipated Problem associated with fatal or life-threatening event - Initial Report

**must be submitted within 2 days of investigator learning of event

☐ Unanticipated Problem NOT associated with fatal or life-threatening event - Initial Report

**must be submitted within 7 days of investigator learning of event

☐ Unanticipated Problem - Follow-up Report
Once you complete all sections, the system will take you to this page.

Click on "Exit Form" to exit this form and come back later.

Click on "Signoff and Submit" or "Notify PI for Signoff" if you're ready to submit to the IRB.

If you want to go back into the Reportable Events and New Information Form, click on any of the sections on the left.

Note: Your Reportable Events and New Information Form might look different and might have less or more sections than this example depending on your answers and type of study.
The PI will then receive a Submission Sign-off sheet (that looks like this).

1. The PI can review the Reportable Events and New Information Form by clicking on it (yellow arrow).
2. Then clicks on the “Approve” radio button. (orange arrow)
3. Then enters User ID and password. (red arrows)
4. Then clicks “Save Signoff” to authenticate, signoff, and submit to the IRB. (blue arrows)