

**CIRBI™ Site QuickSteps:  
Submitting a Serious Adverse Event /  
Unanticipated Adverse Device Effect Report**

1. Log on to [www.cirbi.net](http://www.cirbi.net)
2. In the upper left hand corner of the screen, click on **“Dashboard”**
3. Click the **“My Studies”** tab
4. Click on the appropriate PI’s name for the appropriate study
5. On the very left hand side of the screen click on **“SAE Report”**

**SERIOUS ADVERSE EVENTS /  
UNANTICIPATED ADVERSE DEVICE EFFECTS Page**

1. Section #1: Choose the appropriate ‘Enrollment Status’ for the study [at this site](#)
2. Section #2: Choose the appropriate ‘Report Type’
3. Provide the appropriate and correct answers to the questions. Make sure your description of the event, outcome/resolution, and Principal Investigator’s rationale for the determination of relationship to study drug/device are complete and accurate.
4. Click “Continue

## **END OF APPLICATION Page**

1. Select either 'Submit Application' or 'Save Application, but DO NOT submit'.
2. Click "**Continue**".
  - a. If you choose, 'Submit Application', you will see the "Acknowledgement of Receipt" page.
  - b. If you choose 'Save Application, but DO NOT submit', you will see the "Not Submitted Notice" page.
3. Click "Finish" to exit

**NOTE:** You will receive an Acknowledgement Email once you have submitted, which you must retain for your study files.

v.04/2018