

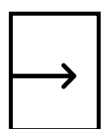


# How to Create and Submit a Reportable Event

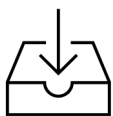
## QUICK STEPS



- A **Reportable Event** can be submitted for an approved study when an unanticipated problem arises (i.e., theft of laptop containing participant information, breach of confidentiality, participant complaint, participant adverse reaction), which may require changes to the methodology or data management/security.
- From the Manage Protocols window, select the application that requires a reportable event.
- Click on the **Title** to open the application.



- Click the **Reportable Event** option along the top header, then click the **Report an Event** button on the right-hand side of the screen.
- The event form will appear.
- Choose the event type and complete the event form.



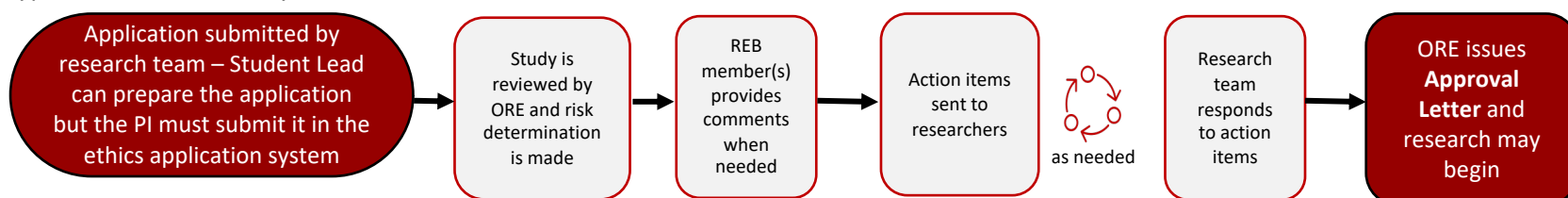
- On completing the event information, click the **Save** button on the right-hand side of the screen. This is important, as there is **NO** automatic saving in Reportable Events so this must be done to retain the changes.
- Click the **Submit for Review** button.
- Submitted requests will trigger an email notification. Click the **Activity Log** button to see a log of the activities and notifications related to that event.



- Click on **View Protocol** to return to the main application.
- Click again on **Reportable Events** along the top header. Your reportable event will be listed: Status = **Submitted**
- Your reportable event request has been submitted - Press the **←Back** button within the application to return to the home page.
- Once the event is reviewed and approved by ORE, the status will change to = **Resolved**

## APPROVAL PROCESS

For a typical minimal risk study...



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Close Request



Unanticipated Problem