Human Research Ethics

RIMS User Guide

Creating an Adverse Event Report

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Purpose of this guide

The human research ethics committee that approves an ethics application is responsible for monitoring the project. This includes any negative impacts the research activities may have on participants or others involved in the research.

Serious or unforeseen events need to be reported to the approving ethics review panel through an Adverse Event Report. This allows the approving body to confirm that the approved risk management strategy for the project is appropriate and that the research is being conducted in accordance with the ethics approval.

Examples of adverse events include:

- the reaction of a potential participant during recruitment
- a participant being impacted during data collection (e.g., unforeseen impact during the administration of a survey or an interview)
- related or unrelated reaction to being exposed to a substance or intervention
- a participant being impacted due to a departure from an approved ethical protocol.

For additional guidance on what constitutes 'serious' adverse events, refer to the approval certificate issued when your project was initially approved.

Serious or unforeseen adverse events must be reported in RIMS within 72 hours of the occurrence of the event or the chief investigator receiving advice of the event.

Details of adverse events which are not serious or unforeseen can be included in the project's next annual progress report.

Creating an adverse event record

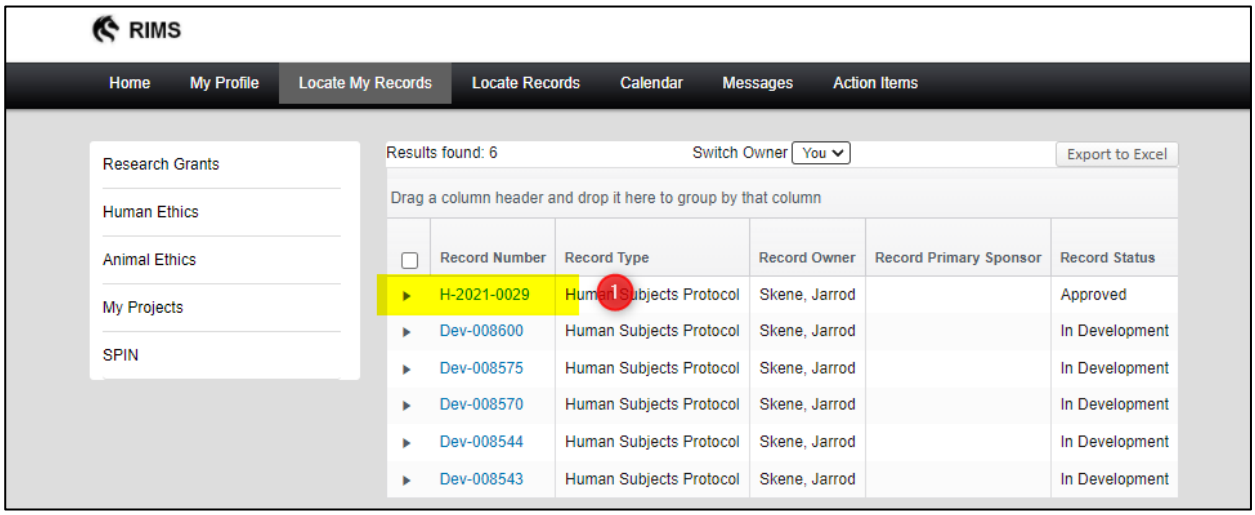
Adverse event reports can only be created for an already-approved ethics protocol, so the first step is to locate the desired ethics protocol record in RIMS.

Refer to the *RIMS User Guide – Getting Started and Locating Records* to learn how to find records for research projects you're listed on.

Once you have located the appropriate record, follow the steps below to create an adverse event report.

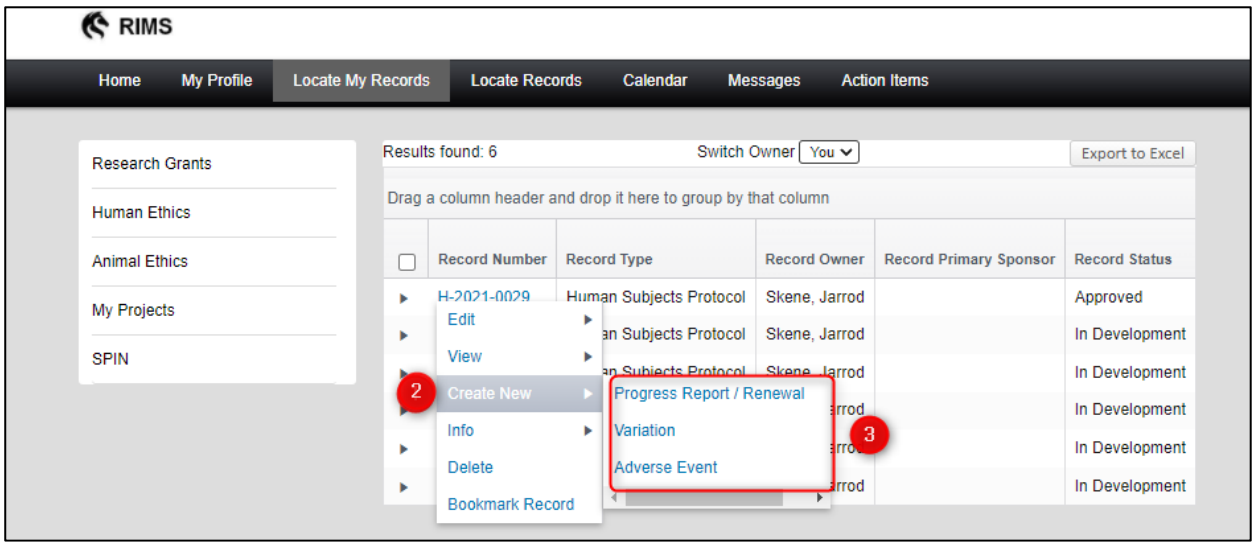
1. Click on the **Record Number** to access the desired protocol as shown in Figure 1.

Figure 1



2. A menu will appear as shown in Figure 2. Click the **Create New** option.
3. Then click on the **Adverse Event** option.

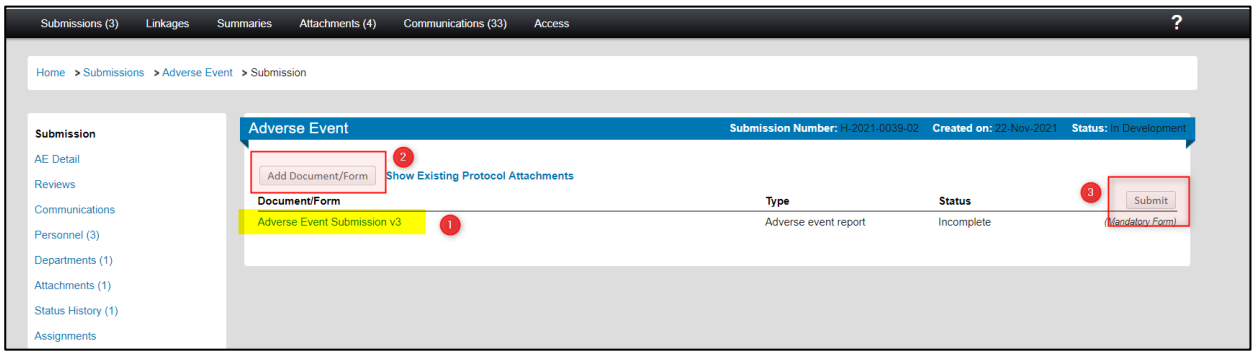
Figure 2



Completing the adverse event eForm

After creating your adverse event record, you will move to a new screen, as shown in Figure 3.

Figure 3



From this screen, you will need to:

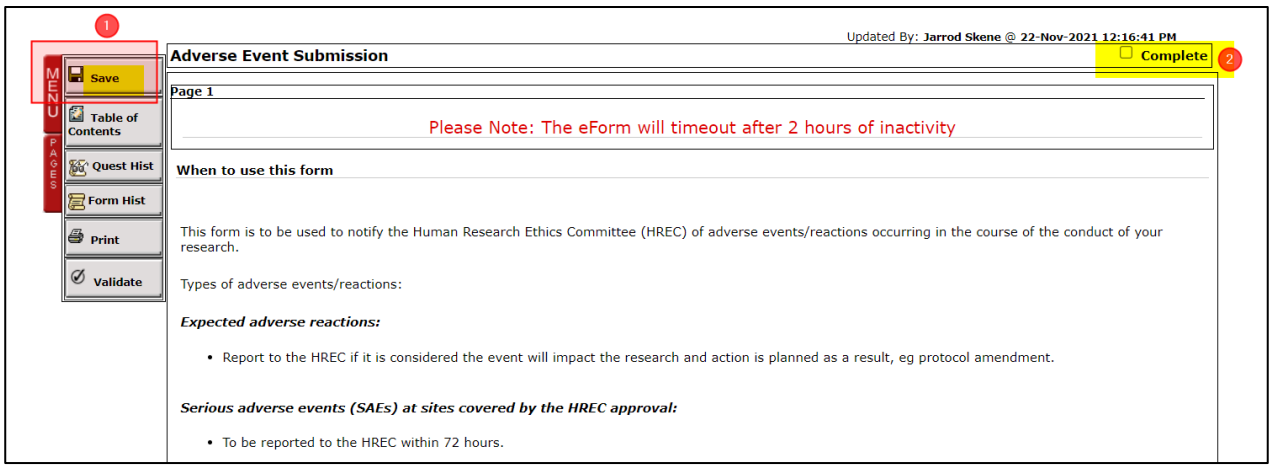
1. access the adverse event eForm
2. add any relevant supporting documentation
3. select the **Submit** button to move to the next stage.

Nex, you need to complete the required fields in the eForm.

Save your work often to avoid losing important data.

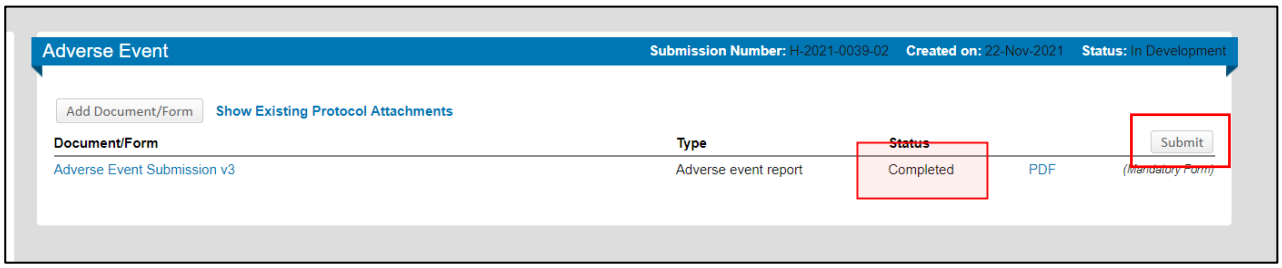
One you have completed all the mandatory fields, tick the **Complete** box at the top right of the screen, as shown in Figure 4. You will not be able to submit the eForm if this box is not ticked.

Figure 4



Once you have completed the details in the eForm as per Figure 4, your submission summary will change to indicate the eForm has been completed. See Figure 5 below.

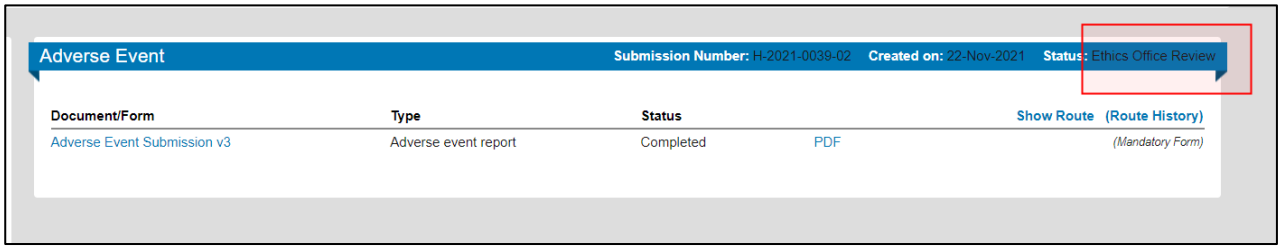
Figure 5



Next, hit the **Submit** button.

This will see the status of your eForm change from 'In Development' (Figure 5) to 'Ethics Office Review' (Figure 6).

Figure 6



Your Adverse Event Report has been submitted.

For questions or support

If you have questions about this guide or need additional support, please contact the Human Research Ethics team on human-ethics@newcastle.edu.au.

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