Human Research Ethics RIMS User Guide Creating an Adverse Event Report



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.

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

Figure 1

RIMS						
Home My Profile	Locate My Records	Locate Rec	ords Calendar Me	ssages Actio	on Items	
	Posulta	found: 6	Switch (Durner Ven et		Function Funct
Research Grants	Results					
Human Ethics	Drag a	column header a	and drop it here to group by t	hat column		
Animal Ethics		Record Number	Record Type	Record Owner	Record Primary Sponsor	Record Status
My Projects		H-2021-0029	Humarl Subjects Protocol	Skene, Jarrod		Approved
		Dev-008600	Human Subjects Protocol	Skene, Jarrod		In Development
SPIN	•	Dev-008575	Human Subjects Protocol	Skene, Jarrod		In Development
	+	Dev-008570	Human Subjects Protocol	Skene, Jarrod		In Development
	•	Dev-008544	Human Subjects Protocol	Skene, Jarrod		In Development
	•	Dev-008543	Human Subjects Protocol	Skene, Jarrod		In Development

- 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

	te my Records	Locate Record	ds Calendar Me	ssages Actio	n Items	
Research Grants	Results	found: 6	Switch (Owner You 🗸		Export to Exce
Human Ethics	Drag a	column header and	d drop it here to group by t	hat column		
Animal Ethics		Record Number F	Record Type	Record Owner	Record Primary Sponsor	Record Status
My Projects	•	H-2021-0029	Human Subjects Protocol	Skene, Jarrod		Approved
	-	Edit	an Subjects Protocol	Skene, Jarrod		In Developmen
SPIN		View	an Subjects Protocol	Skene Jarrod		In Developmen
	2	Create New	Progress Report / R	enewal arrod_		In Developmen
		Info	Variation	3		In Developmen
		Delete	Adverse Event	inoc		in Developmen



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

Submissions (3) Link	ages Summaries Attachments (4) Communications (33) Access	?
Home > Submissions >	Adverse Event > Submission	
	Adverse Event	Submission Number H2021-0330.02 Created on: 22.Nov.2021 Status In Development
Submission		
AE Detail	Add Document/Form Show Existing Protocol Attachments	
Reviews	Document/Form	Type Status 3 Submit
Communications	Adverse Event Submission v3	Adverse event report Incomplete (Mandatory Form)
Personnel (3)		
Departments (1)		
Attachments (1)		
Status History (1)		
Assignments		

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

	Updated By: Jarrod Skene @ 22-Nov-2021 12:16:41 PM
Marka Save	
U Table of Contents	Please Note: The eForm will timeout after 2 hours of inactivity
Quest Hist	When to use this form
S Form Hist	
Print	This form is to be used to notify the Human Research Ethics Committee (HREC) of adverse events/reactions occurring in the course of the conduct of your research.
Ø validate	Types of adverse events/reactions:
	Expected adverse reactions:
	• Report to the HREC if it is considered the event will impact the research and action is planned as a result, eg protocol amendment.
	Serious adverse events (SAEs) at sites covered by the HREC approval:
	To be reported to the HREC within 72 hours.

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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

Submission Number: H-2021-0	039-02 Created on: 22-Nov-	2021 Status: In Development
Туре	Status	Submit
Adverse event report	Completed	PDF (Mandatory Form)
	Submission Number: H-2021-0 Type Adverse event report	Submission Number: H-2021-0039-02 Created on: 22-Nov- Type Status Adverse event report Completed

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

Document/Form Type Status Show Route (Route History) Adverse Event Submission v3 Adverse event report Completed PDF (Mandatory Form)	dverse Event		Submission Number: H	I-2021-0039-02	Created on: 22-Nov-2021	Status : E	thics Office Review
Adverse Event Submission v3 Adverse event report Completed PDF (Mandatory Form)	Document/Form	Туре	Status		Sh	ow Route	(Route History)
	Adverse Event Submission v3	Adverse event report	Completed	PDF			(Mandatory Form)

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 <u>human-ethics@newcastle.edu.au</u>.

END of document