## About this Form

It is the responsibility of the Chief Investigator to ensure the Ethics Office is contacted immediately regarding any incident, serious, or unexpected adverse event. This may include adverse effects of the research on participants or problems relating to the conduct of the project. Failure to do so may result in discontinuation of approval and/or disciplinary action.

In most cases, recruitment and data collection should be paused while an Incident Report is under review.

You may be required to submit an Amendment Request alongside or shortly after your Incident Report. Amendment Request forms can be downloaded from the Federation University Human Research Ethics website, [here](https://federation.edu.au/research/internal/ethics/human-ethics#Modifying_an_approved_project_596801), under the heading ‘Forms’ and ‘Modifying an approved project.’

If you have any queries about whether or not you are required to submit an Incident Report or require urgent assistance to manage an Incident, please contact the Ethics Team via email at research.ethics@federation.edu.au.

## Completing the Form

This form can be completed on your computer using the tab key to move through the template. The response area will expand to fit the content. Click inside a checkbox to record a Yes/No response.

Please do not alter any part of the form, and answer all relevant questions.

## Submitting your Report

Complete the report form and submit via email to the Coordinator, Research Ethics research.ethics@federation.edu.au, **cc’ing all co-investigators**.

**Please delete this instruction page before submission.**

# PROJECT DETAILS

|  |  |
| --- | --- |
| **HREC Approval No:** | Click or tap here to enter text. |
| **Project Title:** | Click or tap here to enter text. |
| **Chief Investigator:** | Click or tap here to enter text. |
| **Other Researchers:** | Click or tap here to enter text. |
| **Name of the person completing this form:** | Click or tap here to enter text. |

# INCIDENT DETAIL

|  |  |
| --- | --- |
| **Date of Incident:** | Click or tap to enter a date. |
| **Location of Incident:** | Click or tap here to enter text. |
| **Details of Incident:** | Click or tap here to enter text. |
| **Probable cause of Incident:** | Click or tap here to enter text. |
| **Remedial action taken, if any:** | Click or tap here to enter text. |
| **As a result of this Incident, does this project require amendment(s)?\*\*** | [ ]  | Yes, an Amendment Request has been submitted / is attached. |
| [ ]  | Yes, an Amendment Request will be submitted at a later date. |
| [ ]  | No |
| **\*Attached supporting documentation, if applicable:** | Click or tap here to enter text. |

## Submitting your Report

This Incident Report should be submitted via email to the Coordinator, Research Ethics research.ethics@federation.edu.au, **cc’ing all co-investigators.**

**Note:**

* **\*** Any relevant documentation associated with this incident should be included in this email as **separate and unnumbered**, but clearly labelled, attachments.
* **\*\*** If the incident requires changes made to the project, an **Amendment Request** must also be submitted to the HREC for approval. Amendment Request forms can be downloaded from the Federation University Human Research Ethics website, [here](https://federation.edu.au/research/internal/ethics/human-ethics#Modifying_an_approved_project_596801), under the heading ‘Forms’ and ‘Modifying an approved project.’