Human Research Ethics Adverse Event Form

* denotes mandatory

Project number *

Project title *

Reporting Researcher or Student*

Research team members

Date of the incident* 01-Jan-2019

Where did the incident occur?

Category*

- ○ Injury/harm to participant(s)
- ○ Informed consent issues
- ○ Participant upset or distressed
- ○ Confidentiality issues
- ○ Injury/harm to researcher
- ○ Researcher upset or distressed
- ○ Other – please explain below

Description of incident*
(be specific, list all aspects event if they seem unrelated to incident)

Relationship to research procedures*

- ○ Directly related
- ○ Probably or possibly related
- ○ Unrelated
- ○ Unknown
- ○ Other cause

Rationale:

Any other information

What action has already been taken by the research team i.e. follow up with participant*

Has this event been resolved to the satisfaction of all parties?*

- ○ Yes
- ○ No – If no, what follow-up has occurred post-adverse event (add details below)

What further follow-up is required? Be specific*

What was the individual doing prior to incident?

Describe the participant's condition following the incident*

List any other information you may have regarding the participant (e.g. meds, complaints prior to incident)

Has this been reported as an OSH incident?*

- ○ Yes
- ○ No
- ○ N/A (please explain why below)

Have the ECU Risk and Assurance team been advised?*

- ○ Yes
- ○ No
- ○ N/A (please explain why below)

Type of Adverse Event*

- ○ Expected Adverse Event
  - If yes, where was the event risk acknowledged:
    - ☐ Anticipated in research protocol
    - ☐ Described in participant information letter
- ○ Unexpected Adverse Event
- ○ Expected Serious Adverse Event
  - If yes, where was the event risk acknowledged:
    - ☐ Anticipated in research protocol
    - ☐ Described in participant information letter
- ○ Unexpected Serious Adverse Event

Is recruitment or contact with participants still ongoing?*

- ○ Yes
- ○ No

Actions needed to prevent recurrence

Implications for Research Project

- ☐ None

Rationale:

- ☐ Changes to protocol

Details:

- ☐ Changes to materials (e.g. information letter, consent form)

Details:

- ☐ Other changes

Details: