**HREC Guide and Notification form for**

**Adverse Events or Incidents arising in the course of research**

It is a requirement of ethics approval that researchers inform the Ethics Committee of any accidents, incidents or adverse events that arise during the course of research as soon as possible.

Such an event or incident might include an injury or accident resulting from the research, either to a person (who could be a participant, a member of the research team or a member of the public), a complaint or involve some other harm such as inadvertent release of personal data.

If a complaint is received by the research team:

* + where the researcher is a student, they must immediately inform their supervisor who should then contact the Research Ethics Manager.
  + the researcher must contact the Research Ethics Manager as soon as possible (Phone: 02 9739 2519 or [ResEthics.Manager@acu.edu.au](mailto:ResEthics.Manager@acu.edu.au)) with details of the complaint.
  + the Research Ethics Manager in conjunction with the HREC Chair and researcher will decide how best to respond to the complaint.

If an accidental release of data or breach of privacy occurs:

* + data should be recalled immediately where possible.
  + where the researcher is a student, they must inform their supervisor as soon as possible.
  + The responsible researcher should refer to the University’s [Privacy Breach Procedure](https://policies.acu.edu.au/governance/privacy_policy_and_procedure/privacy_breach_procedure) and notify the Research Ethics Manager (Phone: 02 9739 2519 or [ResEthics.Manager@acu.edu.au](mailto:ResEthics.Manager@acu.edu.au)).

If an adverse event/incident/accident occurs, then the researcher must:

* + immediately deal with the situation to the best of their ability. For example, if someone is injured, then first aid should be rendered and assistance sought (e.g. Call an ambulance, take them to a doctor/clinic/hospital as appropriate).
  + where the researcher is a student, they must inform their supervisor as soon as possible.
  + the responsible researcher should contact the Research Ethics Manager (Phone: 02 9739 2519 or [ResEthics.Manager@acu.edu.au](mailto:ResEthics.Manager@acu.edu.au)) with details of the incident.

In the event of an injury which involved a company asset or property, the researcher should complete a [Riskware](http://www.acu.edu.au/staff/human_resources/news_and_events/reporting_accidents_and_incidents) report on line in accordance with ACU’s Risk Management Policy and Procedure [Log into Riskware](https://staff.acu.edu.au/human_resources/your%20safety%20and%20wellbeing/whs_risk_management/reporting%20incidents%20and%20injuries%20on%20riskware).

Researchers should also complete the ACU Adverse Event or Incident Report Form and submit it to [resethics.manager@acu.edu.au](mailto:resethics.manager@acu.edu.au) as a priority.

**ACU Adverse Event or Incident Report Form**

**Do not use this form to report safety events relevant to clinical trials.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section 1: Project Details** | | | | | | | |
| 1. **HREC reference number:** |  | | | | | |
| 1. **Project title:** |  | | | | | |
| 1. **Chief Investigator** |  | | | | | |
| 1. **Approving HREC:** |  | | | | | |
| 1. **Type of report** | **Initial**  **Follow up** | | | | | |
| **Section 2: Details of the event** | | | | | | |
| 1. **Date of occurrence** |  | | | | | |
| 1. **Location of occurrence** |  | | | | | |
| 1. **Has the event or incident been resolved** | **Yes**  **No** | | | | | |
| 1. **Who was affected by the event or incident** | **Party Affected** | **Yes** | **No** | **If yes, provide further detail such as number of participants/records, names of researchers etc.** | | |
| Research Participants |  |  |  | | |
| Researchers |  |  |  | | |
| Research Records, Data or Property |  |  |  | | |
| 1. **Did the event result in or cause any of the following?** | * Death * Life-threatening * Hospitalisation * Prolongation of existing hospitalisation * persistent or significant disability or incapacity * congenital anomaly or birth defect | | | | | |
| 1. **Describe the incident using lay language. Include details of any negative consequences, harm or damage that has occurred because of the incident.** | | | | | | |
|  | | | | | | |
| 1. **What has been identified as the cause of the incident?** | | | | | | |
|  | | | | | | |
| 1. **Describe the corrective steps that have occurred and those that are to occur following this report.** | | | | | | |
|  | | | | | | |
| 1. **Describe the preventative steps to stop reoccurrence.** | | | | | | |
|  | | | | | | |
| 1. **Has the event/incident had an impact on the ethical acceptability of the research** | | | | | **Yes** | **No** |
| 1. **Was the event/incident related to the study design and / or procedure?** | | | | | **Yes** | **No** |
| 1. **Was the event/incident anticipated in the in the risks section of the approved project description?** | | | | | **Yes** | **No** |
| 1. **Will the event/incident adverse event raise additional safety concerns for the participants of this research or affect participants’ willingness to continue participation** | | | | | **Yes** | **No** |
| 1. **If the incident involved ACU property or assets has a report been submitted via Riskware** | | | | | **Yes** | **No** |
| **Section 3: Declaration** | | | | | | |
| By submitting this form, I Chief Investigator declare that:  The information contained in this report is true and accurate. | | | | | **Yes** | **No** |