Adverse Event in Research
Report Form

This form must be used to report any adverse event or near miss occurring during a research project conducted by Lancaster University staff or research students, unless a regulator requires a different process. It should be completed by the Principal/Chief Investigator or the student's supervisor and reported to the Head of Department.

An **adverse event** is an unexpected incident during research that causes physical or psychological harm, accidental data disclosure, regulatory or legal breach, environmental harm, or reputational risk to the University. A **near miss** is an unplanned event that did not cause harm but had the potential to do so.

All adverse events and near misses must be reported to the Chair of the Faculty Research Ethics Committee (FREC) and the Head of Department as soon as possible, and within 48 hours, with all available details. Reports must be updated and resubmitted within 48 hours of further information becoming available, until the incident is fully understood. Copies should also be sent to **ethics@lancaster.ac.uk**, including the REAMS approval reference number. If the first report is submitted after 48 hours, an explanation must be provided in Part 13. A copy of the final report must be kept in the project site file.

1. Research Project or Thesis title:	
2. ACP number or REAMs reference number or IRAS ID:	
3. Principal/Chief Investigator or Supervisor:	
4. Student's name (if applicable)	
5. Department	
6. Who initially discovered the adverse event?	
7. When did the adverse event occur (date and time)?	
8.When was the adverse event reported to the Principal/Chief Investigator or Supervisor?	
9. When was the adverse event reported to the Head of Department/School?	
10. Where did it happen?	

11. Describe the event, its impact?
12. Outline the causes or possible causes of the adverse event.
13. What action(s) have been taken to address the impact of this event. Specify whether the project has been stopped and detail any communications with other organisations involved or the funders.
14. Describe what action(s) have been taken, or are planned to prevent re-occurrence of this event in the future?
Agreed and authorised by:

Principal/Chief Investigator: *Name:* Signature:	Date:
Head of Department: Name: Signature:	Date: