

11. Reporting Adverse Events in Research

What is an adverse event or incident in research?

An incident is an untoward event or omission that could give rise to, or has the potential to produce, unexpected or unwanted effects that could be to the detriment of the safety of research participants, students or staff of Northumbria University.

An incident includes, but is not limited to, breaches of security, violence, physical injury and psychological distress. It includes 'near misses', where an incident had the potential to cause injury, harm or disruption had intervention or evasive action not been taken. Some examples of possible adverse events that may occur within research include:

- An incident involving violence or intimidation during a research interview
- Theft or damage to property during a research activity
- Accidental injury to a research participant or to a student or member of staff during a research activity.

Why do adverse events/incidents need to be reported?

The reporting of all incidents, however minor, allows Northumbria University to build up a profile of all the risks to staff, students and research participants and can help to develop good practice and create a safer working environment. It is important to ensure that lessons are learned from any events and that the safety of staff, students and participants is maintained.

You should complete a report on any incident, including a near-miss, as soon as possible after the event. This should include clear information about the location, timing and personnel involved in the incident, as well as its nature and impact and any immediate actions taken. A copy of the report should be received by the Faculty Associate Pro Vice-Chancellor (Research and Innovation) in your faculty on behalf of the Faculty Research Ethics Committee as soon as possible.

In the event of an accident or near miss the University's Incident Reporting Policy must be followed. This policy has been developed to detail the standards to be applied following an accident or incident at Northumbria University or involving a member of staff or student away from the University on official business or as part of their studies.

The purpose of accident/incident investigation is to identify the cause of all work related accidents, injuries, near misses, ill health conditions and violence at work incidents in order to prevent or reduce the likelihood of recurrences.

Incidents are also recorded to allow the University to identify any common trends and to measure performance.

Staff are required to report all work related accidents or incidents to their manager or supervisor who will then investigate the circumstances leading to the accident or incident.

An Incident Report form should be completed for all incidents and accidents and forwarded to the University Health & Safety Team. In the event of a serious incident a report should be made by telephone as soon as possible.

The immediate responsibility for managing an incident falls to the most senior person associated with the project available at the time. Wherever possible, the member of staff involved in the incident should complete the [Incident Report Form](#).

Incidents are graded as follows, and actions taken accordingly. Near misses are to be graded according to the potential severity of the incident.

Level 1 Incidents:

- Result in death or are life-threatening or lead to permanent total disablement that may prevent the person from following his or her normal occupation, or the occupation for which the person is suited by virtue of his/her education, background and abilities
- Cause damage to property or equipment that results in a cost to the University of over £1m
- Attract media attention for more than three days.

Level 2 Incidents:

- Result in injury or distress requiring medical attention or more than 3 days' sick leave
- Cause damage to property or equipment that result in a cost to the University of £100k-£1m.

Level 3 Incidents:

- Result in injury or distress requiring medical attention or 3 days' sick leave
- Cause damage to property or equipment that results in a cost to the University of £10k-£100k.

Level 4 Incidents:

- Result in minor injury or offence requiring less than 3 days' sick leave
- Cause damage to property or equipment that results in a cost to the University of £1k-£10k.

Level 5 Incidents

- Result in no, or very minor, injury
- Cause damage to property or equipment that results in a cost to the University of less than £1k.

The Faculty Associate Pro Vice-Chancellor (Research and Innovation) is responsible for ensuring that the incident is graded, and that the Incident Report is passed immediately to the Executive Dean of Faculty and the University Research Support Office. The Research Office will ensure level 1, 2 and 3 incidents will be passed to the Pro Vice Chancellor (PVC) (Research and Innovation), the University Health and Safety Adviser and the Insurance Advisor.

If the research has been approved by an NHS Research Ethics Committee (or other external ethics approval body) the Principal Investigator is also responsible for ensuring that a copy of the Incident Report is sent to the approving committee.

Anyone wishing to make a complaint about the conduct of research, or about University staff or students in relation to research activity, should approach the Faculty Associate Pro Vice-Chancellor (Research and Innovation) in the relevant faculty. The complaint procedure should be on the copy of the consent form that is given to the participant.