



## Safety Note 59

# Incident reporting in Human Interventional Studies at the University of Reading

### Scope

All studies involving invasive and non-invasive intervention to volunteers participating in studies carried out by the University of Reading, including:

- where diagnostic equipment such as MRI or scanners are used for the purpose of the study;
- administering foods, food supplements or other substances to volunteers as part of the trial;
- taking samples from volunteers e.g. by venipuncture

Please note: volunteers are classified as members of the public with respect to the trial irrespective of their employment status or enrolment for study at the University.

### Regulatory Environment

All activities at the University are subject to the requirements of the H&S at Work Act 1974 and associated regulations. The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 apply to events which arise out of, or in connection with, (the University's) work activities. Where the study is subject to the approval of a NHS Research Ethics Committee, the National Research Ethics Service also acts as the competent authority for incident reporting. Where the studies involve foods or nutritional supplements then additional regulations and reporting requirements under the Food Safety Act and associated regulations apply.

### University Reporting of Incidents

The University has procedures in place for the reporting of incidents arising out of, or in connection with University activities, which are administered by H&S Services. Incident reports from Human Interventional Studies approved by the University Research Ethics Committee should be reported to H&S Services and will then be copied to the Secretary of the Research Ethics Committee. In addition investigation reports will be sent to Heads of School, Insurance Office and to Mike Proven (Coordinator for Quality Assurance in Research, for NRES approved projects only). Summaries of incidents will be included in the papers for the University Health & Safety Committee and the University Research Ethics Committee.

A serious adverse event should be reported immediately to the Head of Health & Safety Services and the Chair of the Research Ethics committee, who will assess according to the guidelines below and report, where appropriate, to the Deputy Vice-Chancellor, Pro-Vice Chancellor (chair of the University H&S Committee) or the University Secretary & Director of Governance. The incident will also be reported to the Business Continuity Officer by the Head of Health & Safety Services in agreement with the Chair of the Ethics Committee.

The Head of H&S Services is responsible for deciding if onward reporting to a regulatory body (for example the Health & Safety Executive, Food Standards Agency or Local Authority Environmental Health).

The Principal Investigator is responsible for reporting the incident, if required, to the National Research Ethics Service and to the sponsor.

### What requires reporting?

Serious adverse event/reaction or unexpected serious adverse reaction	Any adverse event, adverse reaction or unexpected adverse reaction, respectively, that: (a) results in death; (b) is life-threatening; (c) requires hospitalisation; (d) results in persistent or significant disability or incapacity.	Must be reported immediately to H&SS and the Research Ethics Committee.  Head of H&S Services will report incident to appropriate senior university officer, in consultation with the Chair of the Research Ethics Committee.
Unexpected adverse reaction	An adverse reaction, the nature and severity of which is not consistent with the information about the product in question	All cases should be reported to H&SS and the Research Ethics Committee secretary within 2 days of notification. If two or more cases occur the cases should be investigated. If more than 4 cases occur the trial should be halted until investigation is completed.
Adverse reaction	Any untoward and unintended response in a subject to an investigational product which is related to any dose administered to that subject.	All cases should be reported to H&SS and the Research Ethics Committee secretary within 2 days of notification. If two or more cases occur the cases should be investigated. If more than 4 cases occur the trial should be halted until investigation is completed.
Adverse event/experience	Any untoward medical occurrence in a subject, including occurrences which are not necessarily caused by or related to the product, e.g. vomiting, diarrhoea or fainting.	Should be recorded in the study records. If two or more adverse events are reported these should be reported to H&SS and Research Ethics Committee secretary within 2 days of notification. If more than 4 cases occur the trial should be halted until an investigation is completed.
First aid treatment	Subject requiring first aid as a result of any intervention (e.g fainting).	Must be reported within 2 working days to H&SS.
Near-miss	An event which may in other circumstances have caused harm to the volunteers, for example failure of equipment, administration of an incorrect dose (even in the absence of an adverse reaction).	Must be reported within 2 working days of discovery to H&SS.

### How to report

By telephone on 0118378 8888 (for immediate reporting) or by sending a short summary of the incident by email to [safety@reading.ac.uk](mailto:safety@reading.ac.uk). For incidents occurring out of hours contact the Emergency call centre on 6300 and ask for H&SS to be informed.