Reporting of Adverse Events on studies approved by a University Research Ethics Committee

Studies which have a Sponsor

> For guidance on the requirements for adverse event reporting on studies which require approval from the University's Sponsorship Committee, please see the Procedure for Safety Reporting for University of Liverpool Sponsored Research (SOP007).[1]

It is recognised that the process for managing and advising on the safety aspects arising from Sponsored studies rests with the Sponsor and the Independent Data Monitoring Board (or equivalent body – such as a Drug Safety Review Board / Independent Steering Committee etc.).

The University Research Ethics Committee does not need to be notified of any ***unrelated*** adverse events on studies that have a Sponsor.

However, the University Research Ethics Committee (ethics@liverpool.ac.uk) should be copied into notifications which are sent to the Sponsor and the Independent Data Monitoring Committee (or equivalent body) that relate to:

- serious adverse events (SAE) ***which are related to the study***; and,
- suspected unexpected serious adverse reactions (SUSAR).[2]

The University Research Ethics Committee expects to be notified of the above adverse events types **within 24 hours** of the discovery of the event. The role of the

[1] Available on the University Sponsorship webpages

[2] The Principal Investigator or Supervisor is responsible for assessing the adverse event in the context of the study and determining the classification of the adverse event; but should consult the Sponsor and the University Research Ethics Committee where in doubt.

University Research Ethics Committee shall be to assess whether the adverse event affects the ethical approval for the study. The Research Ethics Committee shall have the option to suspend or revoke the University ethical approval of the research; or to recommend modification to the protocol or study design, if it is considered to be in contravention of the University's policies and procedures on research ethics. If this option is revoked, the Research Ethics Committee Chair will discuss this with the Sponsor and the Independent Data Monitoring Board (or equivalent body).

Where the Sponsor takes appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety, the Research Ethics Committee must be notified immediately and in any event within three days, in the form of a substantial amendment, that such measures have been taken and the reasons why.[3]

Research which do not require approval from the University's Sponsorship Committee have a Sponsor

Serious adverse events (SAEs)

A serious adverse event can include[4] an untoward occurrence that:

i. results in death or is life threatening;

ii. requires hospitalisation or prolongation of existing hospitalisation;

iii. results in persistent or significant disability or incapacity or;

[3] Health Research Authority, *Safety Reporting* (2018) https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/
[4] Note: this is not intended to be an exhaustive list. The Principal Investigator or Supervisor should assess the adverse event in the context of the study and consider whether this would constitute a Serious Adverse Event.

iv. consists of a congenital anomaly or birth defect;

v. results in physical, psychological, or socio-economic harm to a participant;

vi. significantly deviates from the ethically approved protocol or study plan;

vii. affects the consent process;

viii. involves a breach of the confidentiality of personal data without the participant's consent.

Serious adverse events occurring during or as a consequence of a research project involving human participants, their tissues, or their data which has been ethically approved by a University Research Ethics Committee must be reported by the Principal Investigator or Supervisor to the University's Research Ethics and Integrity team (ethics@liverpool.ac.uk) **within 24 hours** of the discovery of the event.

It is expected that the study will normally be halted while the serious adverse event is considered.

The information to be provided to the Research Ethics and Integrity team should include:

- Research Ethics Committee Reference
- Study Title
- Principal Investigator / Supervisor and Student Investigator details
- Participant's details
- Date and time of the adverse event

- Details of the adverse event

- Assessment of adverse event (reason for seriousness, and suspected cause)

- Confirmation of whether the study has been halted and proposed future action

The Research Ethics and Integrity team will then inform the Chair of the relevant Committee of receipt of the report within a further 24 hours. The Chair shall then assess whether to suspend or revoke ethical approval of research; or to recommend modification to the protocol or study design if it is considered to be in contravention of the University's policies and procedures on research ethics.

Adverse events

Even the most rigorously planned research can encounter adverse events – it is important that adverse events are treated as learning opportunities, both for researchers and the institution.

Examples that may constitute a non-serious adverse event include minor, inconsequential deviations from the study protocol; minor accidental injuries sustained as a result of participation in the study etc.

The Principal Investigator should inform the Research Ethics and Integrity team as soon as practicable and at least **within ten days** of an adverse incident occurring and should provide a written report detailing the nature and consequences of the event. The report should include any proposed amendments to the participant information sheet, study protocol and/or other study materials. The Chair of the Central University Research Committee will confirm that the incident is non-serious and report to the Committee at its next meeting. The final view of the Chair will be communicated to the Principal Investigator or Supervisor.

Contacts

This procedure will be regularly reviewed in the light of experience and revisions to codes of practice laid down by any relevant professional or learned society. Any comments should be sent to ethics@liverpool.ac.uk.