Safety Reporting (Research other than Clinical Trials of Investigational Medical Products (CTIMPs)) for UK Health Departments' Research Ethics Service (RES)

Serious adverse event

In research other than CTIMPs, a serious adverse event (SAE) is defined as an untoward occurrence that:

a) results in death;
b) is life-threatening;
c) requires hospitalisation or prolongation of existing hospitalisation;
d) results in persistent or significant disability or incapacity; or
e) consists of a congenital abnormality or birth defect; or
f) is otherwise considered medically significant by the investigator.

A SAE occurring to a research participant should be reported to the REC where in the opinion of Chief Investigator (CI) the event was:

- related – that is, it resulted from administration of any of the research procedures, and
- unexpected – that is, the type of event is not listed in the protocol as an expected occurrence.

What?	Who	When	How	To Whom
SAE	Chief Investigator (CI) or sponsor.	Within 15 days of the CI becoming aware of the event.	SAE report form for non-CTIMPs, available from the HRA website.	The REC which issued the favourable ethical opinion.
Urgent safety measures	Chief Investigator or Sponsor. Or exceptionally by the local Principal Investigator (PI).	Immediately (by telephone) Within 3 days (in writing)	By telephone Noting in writing setting out the reasons for the urgent safety measures and the plan for further action.	The REC which issues the favourable ethical opinion. Approvals Officer/REC Manager will acknowledge within 30 days.

Progress reporting (Research other than CTIMPs)

Type	Who	When	How	To Whom
Progress reports Note: There is no requirement to submit a progress report for Proportionate Review studies or for studies where the duration of the study is two years or less.	To be submitted by sponsor, sponsor's legal representative or Chief Investigator (CI). Must always be signed by CI.	Annually (starting 12 months after the date of the favourable opinion). **The REC may exceptionally request more frequent reports**.	Annual progress report form (non-CTIMPs), available from the HRA website.	The REC which issued the favourable ethical opinion.
Declaration of the end of study	Sponsor or CI.	Within 90 days (conclusion). Within 15 days (early termination). **The end of the trial should be defined in the protocol.**	End of study declaration form, available from the HRA website.	The REC which issued the favourable ethical opinion.
Summary of final report	Sponsor or CI.	Within one year of the conclusion of the research.	No standard format. The summary should include information on whether the study achieved its objectives, the main findings and arrangements for publication or dissemination including feedback to participants.	The REC which issued the favourable ethical opinion.

All reports will be acknowledged within 30 days by the Approvals Officer/REC Manager. If any issues are raised, the REC may write to the Chief Investigator or sponsor for further information or clarification.