SAFETY REPORTING (Research other than CTIMPs)

In other 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;
(e) consists of a congenital anomaly or birth defect; or
(f) is otherwise considered medically significant by the investigator.

An SAE occurring to a research participant should be reported to the main REC where in the opinion of the Chief Investigator 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.

	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 NRES website.	Main REC for the trial.
Urgent safety measures	Chief Investigator or sponsor. *Or exceptionally by local Principal Investigator (PI).*	(i) Immediately. (ii) Within 3 days.	(i) By telephone. (ii) Notice in writing setting out the reasons for the urgent safety measures and the plan for further action.	Main REC for the trial. REC Co-ordinator will acknowledge within 30 days. *If notified by PI, relevant local REC should also be informed.*

PROGRESS REPORTING (Research other than CTIMPs)

Type	Who	When	How	To Whom
Progress reports	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) *Main REC may exceptionally request more frequent reports.*	Annual progress report form (non-CTIMPs), available from NRES website.	Main REC for the study.
Declaration of the conclusion or early termination of the research	Sponsor or CI.	Within 90 days (conclusion). Within 15 days (early termination). *The end of the study should be defined in the protocol.*	End of study declaration form, available from the NRES website.	Main REC for the study.
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.	Main REC for the study.

All reports will be acknowledged within 30 days by the REC Co-ordinator. If any issues are raised, the main REC may write to the Chief Investigator or sponsor for further information or clarification.