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	Any adverse event, adverse reaction or unexpected	Must be reported immediately to H&SS and the Research Ethics Committee.
unexpected	adverse reaction, respectively,	
serious adverse	that: (a) results in death; (b) is	Head of H&S Services will report
reaction	life-threatening; (c) requires hospitalisation; (d) results in persistent or significant disability or incapacity.	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	'