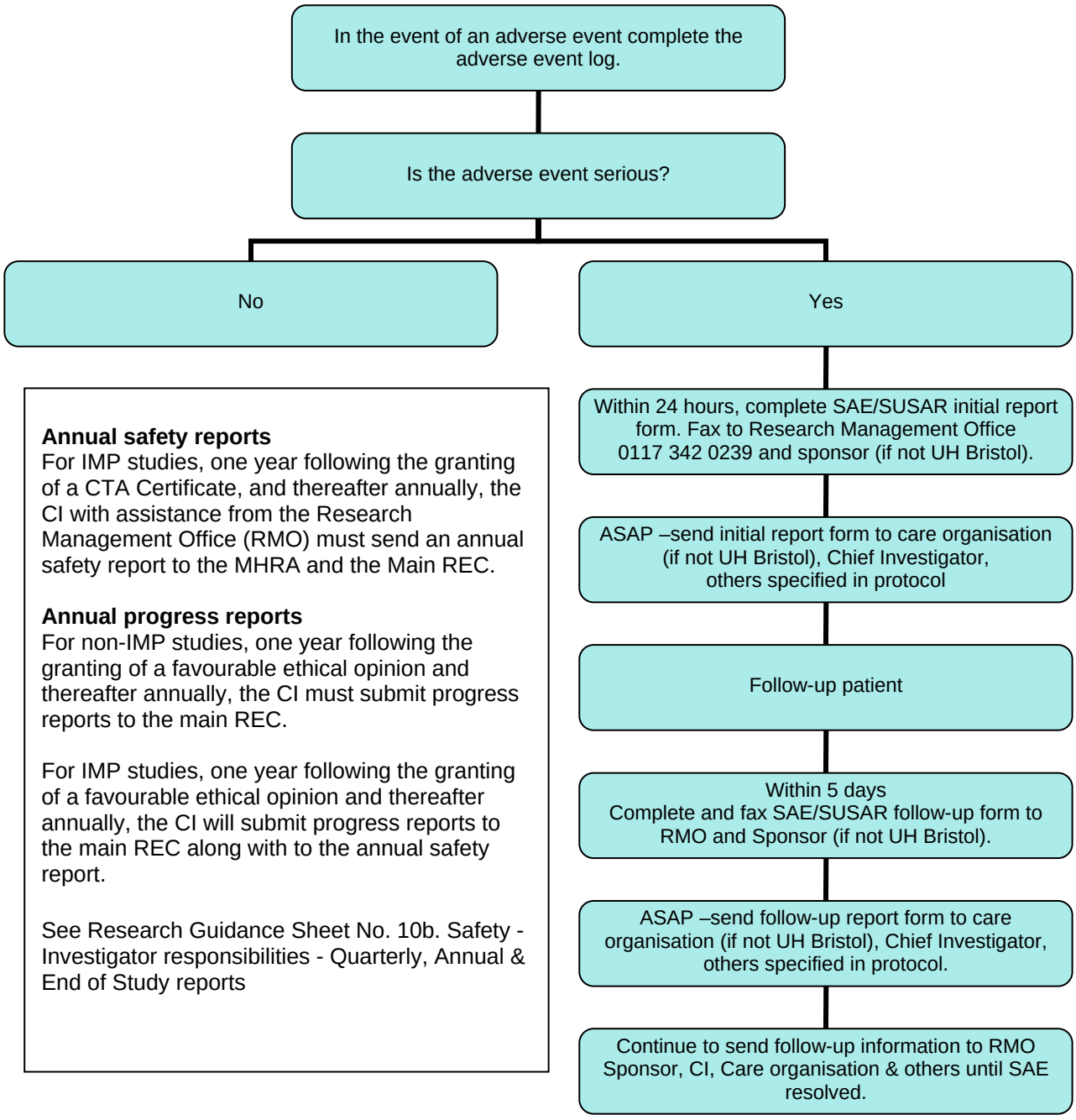
University Hospitals Bristol NHS
NHS Foundation Trust

Research Guidance Sheet No. 10a
Safety - Investigator responsibilities
V1.6 15.09.2010

Adverse event (AE) - any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product.
Serious adverse event (SAE) – an adverse event that results in: death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect.



More detailed information and forms for assessment and reporting of SAEs can be found in the Trust's Research Related Adverse Event Reporting Policy available on the Research website.