

Appendix 3 - List of amendments requiring REC Favourable Opinion

Significant changes to information provided to subjects – for example, subject information sheets, consent forms, diaries, letters to GPs or other clinicians, letters to relatives/carers (whether generic to the whole trial or specific to particular trial site).
Significant changes to recruitment and consent procedures, including the inclusion of adults lacking capacity in the trial
Significant increase to the radiation exposures to subjects from the protocol
Change of insurance or indemnity arrangements for the trial
Change to the payments, benefits or incentives to be received by subjects or researchers in connection with taking part in the trial, or any other change giving rise to a possible conflict of interest on the part of any investigator/collaborator
Change of the Chief Investigator
Change of Principal Investigator at a trial site
Addition of new trial site not listed with the original request for authorisation and REC application
Change to the definition of a trial site
Any other significant change to the conduct or management of the trial at particular trial sites
Early closure or withdrawal of a site
Any other significant changes to the terms of the REC application