Appendix 2 - List of amendments requiring MHRA & REC authorisation

Change to the main objective of the trial
Change of the primary or secondary end-points likely to have a significant impact on the safety or scientific value of the trial
Use of a new measurement for the primary end-point
New toxicological or pharmacological data or new interpretation of toxicological or pharmacological data which is likely to impact on the risk-benefit assessment
Addition of a trial arm or placebo group
Significant change of inclusion or exclusion criteria (for example, age range) likely to have a significant impact on the safety or scientific value of the trial
Change of a diagnostic or medical monitoring procedure likely to have significant impact on the safety or scientific value of a trial
Withdrawal of an independent data monitoring committee
Change of investigational medicinal product(s)
Change of dosing/mode of administration of investigational medicinal product(s)
Any other change to trial design likely to have a significant impact on primary or major secondary statistical analysis or on the risk-benefit assessment
Change of the Sponsor or Sponsor's legal representative
Temporary halt of the trial or temporary halt at a trial site, and re-start of the trial following a temporary halt
Change of the definition of the end of the trial