Appendix 4 – Amendments not normally requiring notification

Changes to the identification of the trial (for example, change of title)
Increase in duration of the trial, provided that the exposure to treatment is not extended, the definition of the end of trial is unchanged and there is no change to monitoring arrangements
Changes to the numbers of subjects planned in the UK as a whole or at individual trial sites, provided that there is no change to the total number of subjects in the trial or the increase/decrease is insignificant in relation to the overall sample size
Change in the documentation used by the research team to record trial data (for example, case report form or data collection form)
Additional safety monitoring which is not part of an urgent safety measure but is taken on a precautionary basis
Changes to the research team other than to the Chief or Principal Investigators
Changes to contact details
Changes to the internal organisation of the Sponsor or persons to whom tasks have been delegated
Changes to the logistical arrangements for transporting or storing samples
Changes to technical equipment
Inclusion or withdrawal of another Member State or third country
Minor clarifications to the protocol
Minor clarifications or updates of subjects' information documentation
Corrections of typographical errors