## Appendix 3 - List of amendments requiring REC Favourable Opinion

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| 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 in 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 |