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| **AMENDMENT IMPLEMENTATION AUTHORISATION** | |
| **Title:** | Trial Title |
| **REC Reference** | REC Reference |
| **Sponsor Ref** | AC |
| **Classification Reference:** | e.g. Substantial Amendment 1 – 24 March 2016 |
| **Chief Investigator:** | CI Name |

Dear **[Chief Investigator],**

I can confirm that the required approvals have been obtained for the amendment detailed above:

1. **[**

As a representative of the Co-Sponsors (University of Edinburgh and NHS Lothian), **I hereby authorise implementation of the aforementioned amendment.**

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| Please note the following terms of this authorisation:   1. Local approval of the amendment (i.e. NHS R&D approval) must be obtained for each participating site and a copy filed in the TMF. [Delete if not applicable] 2. The Chief investigator (or delegate) must maintain a log of the implementation dates of this amendment at each of the sites. [Delete if not applicable] 3. The Chief Investigator (or delegate) must ensure that all investigators are instructed that participant re-consent is required [insert particular circumstances, e.g. sub-group only, time limit for re-consent]. [Delete if not applicable] 4. [Any additional trial specific conditions] |

Please contact me if you have any further questions.

Wishing you every success with your research,

[Lead Sponsor Representative]