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| **SPONSOR ADDITION OF SITE/CHANGE OF PI AMENDMENT CLASSIFICATION & AUTHORISATION** | |
| **Title:** | **Trial Title** |
| **Sponsor Ref:** | **AC REC Ref:** |
| **Classification Reference:** | **e.g. Non-Substantial 2.0 – 19 April 2016** |
| **Chief Investigator:** | **CI Name** |

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| **THIS AMENDMENT MAY BE IMPLEMENTED ONCE THE**  **CONDITIONS SET OUT IN THIS EMAIL ARE MET.** |

Dear **[Chief Investigator],**

I have reviewed your proposed changes as outlined in our previous correspondence.

I can confirm that in the opinion of the Sponsor's representative the following changes comprise a **non-substantial** amendment:

1. **Addition of the following sites: List sites and name PIs**
2. **Change of PI at the following sites: List sites and name the old and new PIs**

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| **What to do next…** | |
| **REC** | There is no requirement to notify the REC of this amendment. |
| **MHRA** | [Delete if not applicable] There is no requirement to notify the MHRA of this amendment.  *Please note, whilst there is no requirement to submit the amendment to the competent authority* ***at this time,*** *at such time where an amendment to the MHRA is deemed necessary by the Sponsor, all previous amendments (including this one) must be summarised as part of that submission.* |
| **NHS R&D** | The proposed changes will need to be submitted to NHS R&D.  You should now submit the IRAS Amendment Tool (signed and locked by myself), and all updated documentation **(with changes highlighted or tracked)** to via IRAS as outlined in the submission Tab of the Amendment Tool.  The Local Information Pack is made up of;  ·         Covering email using standard template format (the correct template needs to be used)  ·         Localised OID  ·         Schedule of Events or SoECAT  ·         Delegation Log (where any of first 4 categories in IRAS ticked) - The delegation log should include known research team names but not signatures.  We need to specify that they should use the ACCORD template (not the one on IRAS).  ·         Relevant supporting documents - these will include some of the documents that have been submitted/approved with the IRAS Form submission and other documents to support study set up at the participating NHS/HSC organisation(s). Information about the documents to include is provided alongside the covering email templates provided.  For Scottish sites;  You should localise the OID and email it, along with the ACCORD delegation log for the site, to NRS PCC: gram.nrspcc@nhs.scot  For English/Welsh sites;  You should localise the OID and email it together with the other documents that make up the [UK LIP](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack) to the R&D office and study delivery team (Principal Investigator or Local Collaborator, as applicable) at participating NHS organisation(s).  If the study is an NIHR portfolio study, you should copy the Local Information Pack to the LCRN of participating organisations in England.  This should take place after the Sponsor/CI receives the Initial Assessment Letter or the Approval Letter from HRA/HCRW.  For NI sites;  You should localise the OID and email it together with the other documents that make up the [UK LIP](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack) to the R&D office and study delivery team (Principal Investigator or Local Collaborator, as applicable) at participating HSC organisation(s).   There are country specific e-mail templates on IRAS (and guidance).  R&D office contacts can be found at [R&D Contacts Directory - NHS R&D Forum (rdforum.nhs.uk)](https://rdforum.nhs.uk/rd-contacts-directory/)  **Please copy me into this correspondence.** |
| **Contracts** | The proposed amendment(s) will require changes to be made to existing contracts.  Please contact the Research Contracts, Governance and Integrity Team by submitting the relevant Contract Request Form (CRF) to [ERO.Contracts@ed.ac.uk](mailto:ERO.Contracts@ed.ac.uk). Forms can be accessed at [Setting up research contracts (sharepoint.com)](https://uoe.sharepoint.com/sites/EdinburghResearchOffice/SitePages/Setting-up-research-contracts.aspx). |
| **Sponsor** | I can now authorise implementation of this amendment.  Please note the following terms of this authorisation:   1. Local approval of the amendment (i.e. NHS R&D approvals) must be obtained for each participating site and a copy forwarded to the Sponsor prior to implementation of the amendment. 2. The CI (or delegate) must maintain a log of the implementation dates of this amendment at each of the sites. 3. The sponsor has already received a signed CV and GCP certificate for each new PI and has received a feasibility report for each new research site.   **Please ensure copies of these approvals are sent to** [**resgov@accord.scot**](mailto:resgov@accord.scot) **in a timely manner.** |

Please contact me if you have any further questions.

Wishing you every success with your research,

[Lead Sponsor Representative]