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| **SPONSOR AMENDMENT CLASSIFICATION AND AUTHORISATION** | |
| **Title:** | **Trial Title** |
| **REC Reference** | **REC Reference** |
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| **Sponsor Ref:** | **AC** |
| **Classification Reference:** | **e.g. Non-Substantial 2.0 – 19 April 2016 / Substantial Amendment 1.0 – 24 March 2016** |
| **Chief Investigator:** | **CI Name** |

Non- risk assessed (delete as appropriate)

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

Risk Assessed (delete as appropriate)

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| **THIS AMENDMENT MUST NOT BE IMPLEMENTED UNTIL EXPLICIT WRITTEN AUTHORISATION HAS BEEN PROVIDED BY THE SPONSOR** |

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/ substantial** amendment:

1. **Summary of changes**

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| **What to do next…** | |
| **Protocol / IB / SPC**  **Signatures** | [Delete if not applicable] Following any amendments to the [**amended document(s)**], the signature page must be re-signed by the relevant individuals prior to implementation of the amendment. |
| **REC** | [Delete if not applicable]  There is a requirement to obtain a favourable opinion from the relevant Research Ethics Committee (REC) for this amendment.  You should now submit the IRAS Amendment Tool (signed and locked by myself), and all updated documentation **(with changes highlighted or tracked)** to the relevant REC via IRAS as outlined in the Submission Tab of the Amendment Tool.  Please note that if any of the following criteria are met, a revised IRAS application form must also be submitted:   * **The appointment of a new Chief Investigator (CI)** The Notice of Substantial Amendment form should be signed by the outgoing CI. Where the signature of the outgoing CI is not possible, the sponsor’s signature is acceptable. The IRAS application form should be signed by the new CI. * Where the amendment proposes to **increase the exposure of participants to ionising radiation**, or to **include such exposure for the first time**. Part B Section 3 of the IRAS application form, including the relevant authorisations should be submitted. * Where the amendment proposes to **include adults lacking capacity in the research for the first time.** * Where the amendment seeks Section 34 approval under the **Mental Capacity Act 2005**. * Where the amendment proposes to **include existing or newly obtained tissue samples for the first time**. Part B Section 5 of the IRAS REC application form should be submitted.   **Please send me a copy of the submitted documents and any responses from the REC** |
| **REC** | [Delete if not applicable] There is no requirement to inform the REC of this amendment. |
| **MHRA** | [Delete if not applicable] There is a requirement to have these changes accepted by the competent authority.  All updated documentation (i.e. amended documents, IRAS Amendment Tool (signed and locked by myself , revised CTA, [where appropriate] this email and purchase order number for MHRA invoicing should be submitted to the MHRA via the MHRA submissions portal or via the combined review system if your study was initially submitted using that system . Please refer to the Submission Tab of the Amendment Tool for more information.  Other submissions portals should be used for submissions to authorities in other territories, as required, e.g. Common European Submission Portal (CESP) for EU member state submissions.    .  *Please note, any previous amendments to the trial (substantial or non-substantial) which were not required to be submitted to the MHRA must be summarised and submitted to the MHRA as part of the current amendment.*  For further information on amendments to the MHRA, please see:  <https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues>  **Please send me a copy of the of the documents submitted to the MHRA as well as the confirmation of submission email from the MHRA.** |
| **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 this 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.* |
| **HRA and NHS R&D** | [Delete if not applicable] 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)** 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.** |
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| **Radiation Assurance** | There is a requirement to notify the Radiation Assurance via radiation.assurance@hra.nhs.uk and provide the required documentation, including Research Exposure Form F1, protocol, PIS/CF, updated IRAS form and the IRAS Notice of Substantial Amendment form (attached; signed by myself).  Please update Part B Section 3 of IRAS following review by Medical Physics Expert (MPE) and Clinical Radiation Expert (CRE). |
| **ARSAC** | [Delete if not applicable] ARSAC must be notified for information of any changes to the **administration of radioactive materials exposure during a study**, e.g. dose changes, new modalities, new classes of study par participants.  You should provide ARSAC with a copy of the IRAS Amendment tool (signed and locked by myself), an updated PRA form (if there are changes to the number of administrations or procedures involving radioactive substances) and all relevant updated documentation **(with changes highlighted or tracked).**  In a multi-site study, it is not necessary for each ARSAC certificate holder to notify ARSAC. It is helpful if either the ARSAC certificate holder at the lead site or the trial co-ordinator can provide a single notification.  Documentation should be sent to ARSAC via the ARSAC online portal.  **Please copy me into this correspondence.** |
| **Phase I Study Review Committee (PISRC)** | [Delete if not applicable] The proposed changes will need to be reviewed and approved by the NHS Lothian Phase I Study Review Committee (PISRC).  Amended documentation (with changes highlighted or tracked) should be sent to [James.Gibson@nhslothian.scot.nhs.uk](mailto:James.Gibson@nhslothian.scot.nhs.uk).  Please note, NHS Lothian R&D cannot approve the amendment until PISRC approval of the amendment has been issued.  **Please forward a copy of the PISRC amendment approval to me.** |
| **Phase I Study Review Committee (PISRC)** | [Delete if not applicable] I have discussed the proposed amendment with the Phase I Study Review Committee (PISRC) – there is no requirement for this amendment to be reviewed and approved by the committee. |
| **Advanced Therapy and Gene Modification Safety Committee** (**ATGMSC)** | Delete if not applicable] The proposed changes will need to be reviewed and approved by the Advanced Therapy and Gene Modification Safety Committee (ATGMSC).  Amended documentation (with changes highlighted or tracked) should be sent to [lothian.atgmsc@nhs.net](mailto:lothian.atgmsc@nhs.net).  Please note, NHS Lothian R&D cannot approve the amendment until ATGMSC approval of the amendment has been issued.  **Please forward a copy of the ATGMSC amendment approval to me.** |
| **Advanced Therapy and Gene Modification Safety Committee** (**ATGMSC)** | [Delete if not applicable] I have discussed the proposed amendment with the ATGMSC – there is no requirement for this amendment to be reviewed and approved by the committee. |
| **Contracts** | [Delete if not applicable] The proposed amendment(s) may require changes to be made to existing contracts.  Please contacy 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). |
| **Third Parties** | [Delete if not applicable] Third parties must be notified of the amendment to ensure they are in receipt of the most up to date documentation. Please ensure copies of the appropriate amended documents are circulated to **[insert relevant third parties]** prior to implementation of the amendment.  **Please copy me into this correspondence.** |
| **Sponsor**  **(Non Risk assessed)** | Once **[insert appropriate (NOT R&D) – approvals]** approval is in place, I 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 filed in the TMF. [Delete if not applicable] [Delete if not applicable] 2. The CI (or delegate) must maintain a log of the implementation dates of this amendment at each of the sites. [Delete if not applicable] 3. [Any additional trial specific conditions]   **Please ensure copies of these approvals are sent to** [**resgov@accord.scot**](mailto:resgov@accord.scot) **in a timely manner.** |
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| **Sponsor**  **(Risk assessed)** | Once **[insert appropriate (NOT R&D) – approvals]** approval is in place, I can authorise implementation of this amendment.  Please note authorisation will be given in a separate email.  **Please ensure copies of these approvals are sent to** [**resgov@accord.scot**](mailto:resgov@accord.scot) **in a timely manner to minimise delay in authorisation.** |

Please contact me if you have any further questions.

Wishing you every success with your research,

[Lead Sponsor Representative]