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| **SUBSTANTIAL AMENDMENT CHECKLIST** | | | | |
| **Study Title:** |  | | | |
| **REC Number:** |  |  | |  |
| **Chief investigator:** |  | **Sponsor Reference:** | | AC |
| **Amendment Number and Date:** |  | | **Reviewer:** |  |
| **Required approvals** | **REC  R&D  CA  ARSAC  Other** | | | |

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| Detail any trial specific requirements here for example; *(delete section if no specific requirements):*  *☐ Manufacturer must approve any amendments to the protocol* | | | |
| **Summary of Proposed Changes** | | | |
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| **For all Risk Assessed Substantial Amendments** | | | |
| IRAS Amendment Tool reviewed, signed off and locked? | | | **Yes  No  N/A** |
| Country-specific amendment application form reviewed and authorised as necessary? | | | **Yes  No  N/A** |
| For addition of UK sites, OID and SoE or SoECAT provided? | | | **Yes  No  N/A** |
| Supporting documentation (with track changes/highlighting) reviewed and approved? | | | **Yes  No  N/A** |
| Signatures obtained for amended documents with signature pages (e.g. protocol, investigator brochure)? | | | **Yes  No  N/A** |
| Does the amendment impact the RSI (Pharmacovigilance team notified)? | | | **Yes  No  N/A** |
| Existing agreement(s) updated/new agreement(s) initiated and authorised as necessary? | | | **Yes  No  N/A** |
| Does this amendment have any impact on the Risk Assessment (Risk Assessment Committee notified)? | | | **Yes  No  N/A** |
| Requirement to notify Phase I Committee of this amendment? | | | **Yes  No  N/A** |
| Requirement to notify ATGMSC of this amendment? | | | **Yes  No  N/A** |
| **Substantial Amendments for Regulated Trials** | | | |
| Amendment to Competent Authority (CA) – are there any previous amendments to be summarised with this submission? | | | **Yes  No  N/A** |
| **Submissions** | | | |
| Copy of Submissions to relevant bodies filed electronically? | **Combined review  REC  R&D  CA  ARSAC  Other [specify]** | | |
| Sponsor amendment classification email sent and filed electronically? | | **Yes  No  N/A** | |

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| **Sponsorship Considerations** | | | | | | | | |
| **Consideration** | | | | | **Response** | **Details and Actions** | | |
| **Participant Group**  Does the amendment involve a new participant group or an existing patient group in a new country that may affect UoE indemnity/insurance arrangements? *If yes, consult insurers to ensure the new group is covered.* | | | | | **Yes  No  N/A** |  | | |
| **Statistician**  Are there any statistical implications resulting from the amendment? If so, the trial statistician should be involved with the review of the amendment. ***For regulated trials, the statistician will be required to re-sign the protocol.*** | | | | | **Yes  No  N/A** |  | | |
| **Intervention**  Does this amendment involve a change to / addition of an intervention which could impact on UoE indemnity/insurance arrangements? *If yes, consult insurers to ensure the new intervention is covered*. | | | | | **Yes  No  N/A** |  | | |
| **Monitoring**  Could this amendment impact the level of monitoring required for the study? e.g. new country added. *If, yes, Inform the Senior Clinical Trials Monitor(s) or designee.* ***For regulated trials, the trial monitor must be notified of all amendments.*** | | | | | **Yes  No  N/A** |  | | |
| **Quality Assurance**  Could this amendment impact the level of auditing required for the study? *If, yes, Inform the Quality Assurance Manager or designee.* | | | | | **Yes  No  N/A** |  | | |
| **Pharmacovigilance / Vigilance**  Could the amendment impact on Pharmacovigilance / vigilance arrangements? e.g. new country added. *If yes, discuss with PV team* | | | | | **Yes  No  N/A** |  | | |
| **Support Departments**  Will any support departments be affected by this amendment? Consider most common e.g. WTCRF, labs, pharmacy, radiology, tissue governance, Edinburgh Imaging, *If yes, seek input from necessary department.* Are any new labs/facilities proposed as part of the amendment? *If so, have they been accredited / audited / vendor assessed by ACCORD QA?* | | | | | **Yes  No  N/A** |  | | |
| **Risk Benefit**  Does this amendment impact on the risk/benefit ratio of the study? Is there an impact on participant safety and/or data integrity? Any changes to the RSI for a trial may result in changes to the Risk/Benefit and should be discussed internally (e.g. at Sponsorship meeting) to determine if the risk assessment should be re-opened. *If yes, determine/justify whether continued Sponsorship is appropriate.* | | | | | **Yes  No  N/A** |  | | |
| **Scientific Value**  Does this amendment impact on the scientific value of the study? *If yes, determine/justify whether continued Sponsorship is appropriate.* | | | | | **Yes  No  N/A** |  | | |
| **Contract/Agreement**  Does the amendment impact an existing clinical trial agreement(s) or require a new agreement(s)? *e.g.. Change of PI, recruitment, financial implications, new countries added or new services required.* | | | | | **Yes  No  N/A** |  | | |
| **New Site(s)**  If the amendment entails opening a new site(s) or expansion (in time or resources) of participation of an existing site(s), are additional resources and/or feasibility questionnaires required? | | | | | **Yes  No  N/A** |  | | |
| **Information Governance/Data Protection**  Does the amendment include new requirements for sharing data with other organisations or use of new software or mobile devices. *If yes, consider whether advice should be sought from the R&D Information Governance Lead and/or Information Governance within NHS Lothian and/or the University of Edinburgh.* | | | | | **Yes  No  N/A** |  | | |
| **Approvals** | | | | | | | | |
| Once approved, amended documentation and associated approvals must be forwarded to [include trial specific third parties] | | | | | | | | |
| Approvals required and obtained prior to implementation authorisation (*copies must be electronically filed)*. | | | | **REC  CA  ARSAC  R&D (HRA)  Other** | | | | |
| Approved, clean documents saved as PDF in “Current Approved Documents” and hard copy filed in Sponsor File/Trial Master File. | | | | | | **Yes  No  N/A** | | |
| RSI Tracker updated | | | | | | **Yes  No  N/A** | | |
| **Sponsor Representative Sign-Off** | | | | | | | | |
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|  | **Sponsor Representative Signature** |  | **Position** | | |  | **Date** |  |
| **Once all required approvals are in place the Sponsor Representative must sign and date and issue authorisation email.** | | | | | | | | |