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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**  |
|  |  |  |  |  |  |  |
|  |  **Sponsor Representative Signature** |  | **Position** |  | **Date** |  |
| **Once all required approvals are in place the Sponsor Representative must sign and date and issue authorisation email.** |