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| **GLOBAL HEALTH SUBSTANTIAL AMENDMENT CHECKLIST** | | | | | |
| **Study Title:** |  | | | | |
| **In-country Ethics Number:** |  | **UK Ethics Number:** | | |  |
| **Chief investigator:** |  | **Sponsor Reference:** | | | AC |
| **Amendment Number and Date:** |  | | **Reviewer:** |  | |
| **Required approvals** | **In-country Ethics  UK Ethics**  **In-country CA**  **Other (please specify below)** | | | | |
|  | **------------------------------------------** | | | | |

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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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| **Justification for Substantial Classification and Rationale for the Selection of Bodies to be Notified of the Amendment at This Time** | | | | |
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| **For all Global Health Risk Assessed Substantial Amendments** | | | | |
| In-country amendment application form reviewed and authorised as necessary? | | | | **Yes  No  N/A** |
| UK ethics amendment form reviewed and authorised as necessary? | | | | **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** |
| Does the amendment require due diligence for any new organisation/institution? (Research Funding Specialist notified?) | | | | **Yes  No  N/A** |
| Does the amendment require a vendor assessment for any new potential vendor? (QA 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? | | | | **Yes  No  N/A** |
| Has the ACCORD amendment tracker been updated? | | | | **Yes  No  N/A** |
| **Global Health Substantial Amendments for Regulated Trials** | | | | |
| Amendment to Competent Authority (CA) in the country where the study is being conducted? | | | | **Yes  No  N/A** |
| **Submissions** | | | | |
| Copy of Submissions to relevant bodies filed electronically? | | **In-country CA  UK Ethics  In-country \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Other [specify]** | | |
| Date Amendment submitted to In-country Competent Authority. | c c / c c c / c c c c | | | |
| Date Amendment submitted to In-country Ethics Committee. | c c / c c c / c c c c | | | |
| Date Amendment submitted to UK Ethics Committee. | c c / c c c / c c c c | | | |
| 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 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, CRIC, BRIC, *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 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 RA 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** |  | | |
| **New Vendor(s)**  Does the amendment entail a potential new vendor or expansion of vendor services? *If yes, inform the Quality Assurance Manager or designee to initiate vendor assessment.* | | | | | **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)*. | | | | **In-country CA  In-country Ethics  UK Ethics**  **Other (please specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | |
| 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** |  |