**Governance team sponsorship review for Medicines and Healthcare products Regulatory Agency (MHRA) regulated studies**

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| **Chief Investigator (CI)** |  |
| **Full Title:** |  |
| **Short Title/Acronym**  |  |
| **Study Type:** | CTIMP ATMPCombination  | [ ] [ ] [ ]  | **Sponsor:** | **Research Database Application** **ReDA Ref No:****EDGE Ref No:** |
| **Phase** |  | **# Sites:** |  |
| **MHRA Risk category** |  | **Funder:** |  |
| **Investigational Medicinal Product (IMP) name(s)** |  | **WorkTribe number:** |  |
| **Integrated Research Application System (IRAS) Number** |  |
| **Finance Ref:** |  | **Research Ethics Committee(REC) Ref No:** |  |
| **EudraCT:** |  | **National Institute for Health Research (NIHR) (UK Clinical Research Network (UKCRN)) No:** |  |

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| **Section 1- Application for Sponsorship** |  |
|  | **Date review & completed**  | **Comments**  | **QC completed and approved** |
| Valid submission received via the checklist  |  |  |  |
| Sponsor to CI agreement, review and signed  |  |  |  |
| IRAS form review |  |
| Filter questions correct? |  |  |  |
| All fields completed and correct wording used |  |  |  |
| Consistent with all study documents  |  |  |  |
| Sites listed |  |  |  |
| Key collaborators |  |  |  |
| Study documentation review  |  |
| Protocol on Joint Research Management Office (JRMO) template and protocol signed  |  | Specify if waiver logged with Quality Assurance (QA) Manager |  |
| Protocol review & template text removed  |  |  |  |
| Final submitting set received  |  |  |  |
| Data protection review |  |
| Data to be collected from NHS | Staff, Patients or Healthy volunteers |  |  |
| Personal Identifiable Data (PID) collected? | YES/NO  |  |  |
| PID being shared outside Sponsor? | YES/NO | If yes specify with whom & where |  |
| Recruitment and Consent appropriate |  | IRAS A27-1 to A34 |  |
| Confidentiality arrangements  |  | IRAS A36 – A40 |  |
| Storage and use after End of trial |  | IRAS A41- A45 |  |
| Management of research |  | IRAS A71-2 |  |
| Costing  |  |
| Costings available Health Research Authority (HRA) Statement of Activities Document (multicentre)Schedule of Events Cost Attribution Template (SoECAT) |  |  |  |
| Funding |  |
| Funding letter supplied |  |  |  |
| Contracts  |  |
| Contract checklist completed and available |  |  |  |
| Risk assessment received |  |  |  |
| Peer review |  |
| Scientific peer review |  | By whom and date |  |
| Departmental peer review  |  | By whom and date |  |
|  |  |
| Genetic Modification (GM) committee approval received | Date  | Name |  |
| Clinical/Medical physics approval received | Date  | Name |  |
| Pathology approval received  | Date  | Name |  |
| Pharmacy approval received | Date  | Name |  |
| Radiology approval received | Date | Name |  |
| Good Clinical Practice (GCP) manager approval received  | Date  | Name |  |
|  |  |
| Quality Control (QC) performed and approval given | Date  | Name |  |
| IRAS signed | Date  | Name |  |
| Sponsorship with Conditions issued | Date  | Name |  |
| Documents uploaded to REDA and Indemnity | Date  | Name |  |

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| **Section 2- Checks for Governance approval**  |  |
|  | **Date review & completed**  | **Comments**  | **QC check completed and approved** |
| REC |  |
| REC Acknowledgement of submission |  |  |  |
| REC Approved with conditions received |  |  |  |
| CI response approved & submitted |  |  |  |
| REC approval letter |  |  |  |
| MHRA -Regulated Studies |  |
| MHRA acknowledgment of submission  |  |  |  |
| MHRA Approved with conditions received |  |  |  |
| CI response approved & submitted |  |  |  |
| MHRA approval letter |  |  |  |
| MHRA (Clinical investigation) |  |
| MHRA acknowledgment of submission |  |  |  |
| MHRA No objection letter received |  |  |  |
| HRA |  |
| HRA approval letter |  |  |  |
| HRA full document set received |  |  |  |
| Any other regulatory approval |  |  |  |
| *List additional approvals or delete if n/a* |  |  |  |
|  |  |
| Contracts checklist completed |  |  |  |
| Final pharmacy approval | Date | Name |  |
| QC check completed and approved  | Date | Name |  |
| Governance agreement issued | Date | Name |  |
| Documents & correspondence uploaded to ReDA and Indemnity | Date | Name |  |
| Paper file updated and passed to GCP team**FINAL GOVERNANCE MEETING ACTIONS COMPLETED** | Date | Name |  |

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|  | **Name**  | **Signature** | **Date** |
| **Governance Officer** |  |  |  |
| **Governance Team Leader** |  |  |  |