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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Chief Investigator (CI)** |  | | | | | |
| **Full Title:** |  | | | | | |
| **Short Title/Acronym** |  | | | | | |
| **Study Type:** | CTIMP  ATMP  Combination | |  | **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:** | | |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |  |

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