**Governance team sponsorship review for Interventional studies**

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| **CI** |  |
| **Full Title:** |  |
| **Short Title/Acronym**  |  |
| **Study Type:** |  | **Sponsor:** |  |
| **Phase** |  | **EDGE Ref No:** |  |
| **# Sites:** |  | **REC Ref No:** |  |
| **Funder:** |  | **NIHR (UKCRN) No:** |  |
| **Finance Ref:** |  | **IRAS Number** |  |
| **WorkTribe number:** |  |  |  |

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| **Section 1- Application for Sponsorship** |  |
|  | **Date review & completed**  | **Comments**  | **QC completed and approved** |
| Valid submission received |  |  |  |
| CI-Sponsor agreement review and signed  |  |  |  |
| IRAS form review |  |
| Filter question correct? |  |  |  |
| Artificial intelligence (AI) study? |  | Contact Sarah Palmer-Edwards |  |
| All fields completed and correct wording used |  |  |  |
| Consistent with all study documents  |  |  |  |
| Sites listed |  |  |  |
| Key collaborators |  |  |  |
| Study documentation review  |  |
| Protocol on JRMO template |  | Specify if waiver logged with QA |  |
| Protocol review & template text removed  |  |  |  |
| Final submitting set received  |  |  |  |
| Data protection review |  |
| Data to be collected from NHS | Staff, Patients or Healthy volunteers |  |  |
| 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 study |  | IRAS A41- A45 |  |
| Management of research |  | IRAS A71-2 |  |
| Registered on CT.GOV or ISRCTN?  |  |  |  |
| Data Protection Impact Assessment (DPIA) pre-screening form submitted | YES/NO | Specify date and Queen Mary of Barts Health |  |
| DPIA/IG team response received | YES/NO |  |  |
| DPIA completed )If requested) and signed off the Data Protection Officer (DPO) | YES/NO | Specify DPIA requested/ No DPIA needed  |  |
| Costing  |  |
| Costing available  |  |  |  |
| Funding |  |
| Funding letter supplied |  |  |  |
| Funding letter uploaded to EDGE and saved to Indemnity |  |  |  |
| Declaration of no cost form (if applicable)  |  |  |  |
| Investigator’s own account |  |  |  |
| Contracts  |  |
| Contract checklist completed and available |  |  |  |
| Risk assessment  |  |  |  |
| Vendor agreement  | If applicable  |  |  |
| 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 |  |
|  |  |
| Risk Assessment |  | Version, Risk score and category |  |
| Reviewed by the team leader and approval given (only applicable if scored medium or high on risk assessment)  | Date  | Name |  |
| IRAS signed | Date  | Name |  |
| **Sponsorship with Conditions issued** | Date  | Name |  |
| Documents uploaded to EDGE; attributes / workflows / notes created as per the current version of EDGE manual. Indemnity folder. | 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 |  |  |  |
| HRA |  |
| HRA approval letter |  |  |  |
| HRA full document set received |  |  |  |
| Any other regulatory approval |  |  |  |
| *List additional approvals or delete if n/a* |  |  |  |
|  |  |
| Contracts checklist completed |  |  |  |
| Review check completed and approved (if medium/high risk) | Date | Name |  |
| Governance agreement issued | Date | Name |  |
| Documents & correspondence uploaded to EDGE and Indemnity | Date | Name |  |
| Confirmation of Sponsorship with C&C issued | Date | Name |  |

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