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| Form number | **Form 52.009D** | Version  | **14.0** |
| Title | **Project File Checklist** |

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| Completed by (Research Administrator’s name): | Quality checked by (Coordinator / Facilitator’s name): |
| R&I Ref: |  |
| CI name: |  |
| PI name: |  |
| NRS PCC Ref: (*if applicable)* |  |
| NRS Review type: (*if applicable)* |  |
| Funder Type (e.g. Eligible, NEF, Extended Review):  |  |
| Sponsor: |  |
| Additional Information: (e.g. CTIMP, Basic Science, s student, staff, GP or PIC) |  |
| Full document set  | Date rec’d or N/A |
| Protocol Version:  | Protocol Date:  |  |
| Participant Information Sheet & Consent form |  |
| Other Study Documents (GP letters, Questionnaires etc) |  |
| IRAS Form (fully signed including sponsor sign off) |  |
| IRAS applications in XML Format |  |
| Insurance certificate  |  |
| Commercial Budget Information agreed  |  |
| Funder award letter  |  |
| Agreements: Draft ready datemNCA/mCTA/OID as agreement |  |
| Study ARSAC Licence |  |
| Musketeer Studies only – Schedule 1 |  |
| Governance Report for Lead Nation (if not Scottish Lead) |  |
| Outline OID |  |
| SoECAT or Schedule of Events |  |
| **Full Generic Document Set Declared** (Record FDS on SReDA Local Clock) |  |

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| R&I Local Approval  | Date rec’d or N/A |
| CI CV/GCP  |  |
| Approvals e.g. Caldicott Guardian /PBPP/DPIA/LPAC/SafeHaven |  |
| Localised LIP:Localised OIDOID appendix emailHofD approvalDelegation Log template (CTIMPs) |  |
| Submitted Local Information Pack to NRS PCC (N/A for databases/tissue banks/single centre) |  |
| Support department approvals (E.g. CRF, respiratory lab/ophthalmology/radiology if needed) |  |
| CTEC Approval Date (Beatson studies) |  |
| Costings Update to Facilitator (Commercial Only) |  |
| Finance Review Completed |  |
| Project sent to Pharmacy  |  |
| Pharmacy approval  |  |
| Project eligible for registration on public database (e.g. clinicaltrials.gov) (Top 4 categories on IRAS only) |  |
| Imaging support Form 58.004B completed/SReDA imaging tab updated by the research co-ordinator (Imaging will QC & correct errors/update as study progresses) |  |
| Agreements:- [delete as appropriate] – fully signed datemNCA/mCTA/OID as agreement |  |
| Local ARSAC compliant |  |
| Research Passports/HRCs/LOAs Date valid documents and pre-engagement checks received:Date documents were signed/issued: |  |

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| Extended Sponsor Process | Date rec’d or N/A |
| Sponsor Oversight Checklist sign off date (For CTIMPS)  |  |
| Is adoption considered for NIHR CRN Portfolio (Non Eligible Funded (NEF) projects only)  |  |
| Peer Review (For Sponsored NEF studies – done alongside Protocol review, SOP 51.003)Two independent peer reviews are required for NIHR CRN adoption\*  |  |
| Risk Assessment completed by the research co-ordinator and final risk outcome completed on SReDA (By the SRA/RA)  |  |
| Sponsor Finance Review (If N/A provide justification) |  |
| Data Protection Impact Assessment (DPIA) |  |
| Agreements:- [delete as appropriate] – fully signed datemNCA/OID as agreementCollaboration AgreementData Sharing AgreementShared Award Letter (back to back agreement)Material Transfer AgreementOther (Refer to contract crib sheet) |  |
| Required Documents | Date rec’d or N/A |
| Ethics Favourable Opinion  |  |
| HRA approval |  |
| MHRA clinical Trial Authorisation  |  |
| Governance Report  |  |
| R&I Approval and Post Approval | Date rec’d or N/A |
| GG&C Board Approval issued |  |
| Clock Permanently Stopped |  |
| Research Facilitator sent R&I approval to prompt completion of finance distribution (Commercial Only)Date Sent:Date Concluded (within 7 days of approval date): |  |
| Costings sent to Finance (Commercial Only) |  |
| RGL date updated on SReDA  |  |
| CTRE date updated on SReDA (Eligible/Extended review and Commercial) |  |
| Key Recruitment Contact & Recruitment Source updated on SReDA (Eligible/Extended review and Commercial)  |  |
| Site Visit Information updated on SReDA |  |
| GG&C Board Approval letter uploaded onto SReDA |  |
| CPMS Minimum Dataset sent to Information Officer (Eligible/Extended review for GG&C led studies only) |  |
| NRS Finance System updated  |  |
| Updates for CPMS Record (Eligible/Extended review for GG&C led studies only) e.g. changes to CTRE (Closed to Recruitment End) dates. |  |

\* Department of Health and Social Care Eligibility Criteria definition of high quality peer review:

**Peer review must be independent, expert, and proportionate:**

Independent: At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators’ host institution and not involved in the study in any way. Reviewers do not need to be anonymous.

**Expert:** Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service based aspects of the protocol, and/or have the expertise to assess the methodological and statistical aspects of the study.

**Proportionate:** Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review.

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