|  |  |  |  |
| --- | --- | --- | --- |
| Form number | **Form 52.009A** | Version  | **6.0** |
| Title | **Checklist of documents required for R&I submission** |

|  |  |
| --- | --- |
| Study Title: |  |

|  |  |
| --- | --- |
| R&I Ref: |  |

All documents must be submitted electronically. Please rename as below. If document is not applicable to type of study, please state not applicable (N/A)

|  |  |  |
| --- | --- | --- |
| Documents: | Yes/ N/A | Document file name: |
| IRAS -R&I form fully signed (in xml and pdf format) |  | R&I\_form\_last signature date |
| Protocol  |  | Protocol\_date\_version |
| CV (for all personnel in the site study team)  |  | Surname first name\_CV\_date |
| Research Passport |  | Research Passport\_date\_version |
| GP/Consultant Information sheet |  | GP Information sheet\_date\_version |
| Letters of invitation to participants |  | Letter of invitation\_date\_version |
| Investigator Brochure |  | IB\_date\_version |
| Participant Information Sheet |  | PIS\_date\_version |
| Consent Form |  | Consent form\_date\_version |
| Questionnaire |  | Questionnaire\_date\_version |
| Funding Application (for GG&C sponsored studies) |  | Funding application\_date\_version |
| Funding Award Letter |  | Funding Award letter\_date |
| ARSAC Authorisation  |  | ARSAC certificate\_date |
| MHRA Clinical Trial authorisation  |  | MHRA authorisation\_date |
| REC favourable opinion and all correspondence |  | REC (Opinion)\_date |
| Trial Agreements |  | Agreement (type)\_date\_version |
| Evidence of Insurance or Indemnity |  | Insurance Certificate\_date |
| REC favourable opinion for any substantial amendments and all correspondence |  | REC (opinion)\_Amendment(ref)\_date |
| Confirmation of authorisation from MHRA for any substantial amendments |  | MHRA authorisation\_Amendment(ref)\_date |
| Completed copy of this checklist |  | SubmissionChecklist\_R&I\_date |

Please Note: The below local documents can be requested/submitted at a later stage.

|  |  |  |
| --- | --- | --- |
| Local Documents | Yes/ N/A | Document file name: |
| OID |  | OID\_last signature date |
| OID appendix |  | OID\_appendix\_date |
| *Email from the site Head of Department (confirmation from the HoD that he/she is aware and happy for the study to proceed within their service)* |  | HoD\_authorisation |

Please Note: Applications with blank signatory sheets unfortunately cannot be accepted as valid document set.

Please Note: Data Protection Impact Assessment (DPIA) and/or Data agreements may also be required.

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website. Any copy reproduced from the website may not, at time of reading, be the current version. |