The following list of SOPs are to be read for staff completing Research under a Research Passport / Letter of Access (LoA).

* The following list must be read
* Additional SOPs should be added if relevant to the type of research being undertaken
* Staff with a Research passport / LoA completing a CTIMP must be added to IQM for SOP accountability
* SOPs must be read before research activity commences

Name:

Study Name:

Study PO Number:

Start date:

|  |  |  |  |
| --- | --- | --- | --- |
| **SOP number** | **SOP Title** | **Initial** | **Date** |
| FRM021  | Sponsor investigator file checklist |  |  |
| FRM038 | Protocol Non Compliance Form |  |  |
| FRM068 | Site File Index |  |  |
| FRM069 | End of Study Sample Declaration Form |  |  |
| SOP003 | Informed consent for research studies |  |  |
| SOP011 | Archiving of research studies |  |  |
| SOP012 | Adverse event reporting |  |  |
| SOP013 | Trial Master File Creation and Maintenance |  |  |
| SOP021 | Trial closure and end of trial reporting |  |  |
| SOP025 | Risk Assessment  |  |  |
| SOP031 | Patient Recruitment |  |  |
| SOP037 | Amendments  |  |  |
| SOP040  | Management of external research staff – research passport scheme |  |  |
| SOP041 | File Notes |  |  |
| SOP049 | GCP training for research staff |  |  |
| SOP050 | Handling protocol non-compliance |  |  |
| SOP060  | Version control of study documents |  |  |
| SOP080 | Study data – collection and entry |  |  |
|  |  |  |  |
|  | *Please add additional SOPs if relevant for the type of research* |  |  |

Please file the completed form in the eTMF folder