**Note: Some of the SOPs listed below only apply to High Risk Trials, CTIMPs and Medical Device Clinical Investigations (MDCIs). The SOP title shall reflect this as appropriate.** **Where a box is shaded the SOP is not relevant to the role and need not be read, although staff may choose to do so if they wish or CI/Sponsor directs.**

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| **Document** | **Title** | **CI** | **PI** | **TM** | **RN** | **Stat** | **Dat** | **Pha** | **Lab** | **Initial** | **Version****number** |
| **ST-1** | Quality Statement |  |  |  |  |  |  |  |  |  |  |
| **QM-1** | Quality Manual |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-1** | Management of SOPs |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-2** | Training Record |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-3** | Protocol Guidance for High Risk Trials & CTIMPs  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-4** | Applying for Sponsorship  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-5** | Sponsorship review & risk assessment |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-6** | Study start-up  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-7** | Trial Master File |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-8** | Investigator Site File  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-9** | Receiving informed consent  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-10** | Applying for REC ethical opinion  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-12** | Case Report Forms  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-13** | Generation of contracts |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-14** | SmPC, IB and IMP Dossier  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-15** | Management of Medicinal Products used in research  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-16** | Selection & management of contracted third parties |  |  |  |  |  |  |  |  |  |  |

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| **Document** | **Title** | **CI** | **PI** | **TM** | **RN** | **Stat** | **Dat** | **Pha** | **Lab** | **Initial** | **Version****number** |
| **SOP-QA-17** | Project committees  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-18** | Randomisation and blinding for controlled trials |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-19** | Amendments |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-20** | Data management |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-21** | APRs and DSURs |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-22** | Adverse Event in CTIMPs |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-23** | Statistical analysis plans for clinical trials |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-24** | Managing a change in CI of a CTIMP or Medical Device Clinical Investigation |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-25** | Deviations and Breaches  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-26** | Sponsor file (CTIMPs and Medical Device Clinical Investigations) |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-27** | Good documentation practice |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-28** | Monitoring  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-29** | Audit  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-30** | MHRA inspection |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-31** | Research project closure  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-32** | Archiving  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-33** | Research project publications and dissemination  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-34** | Good Clinical Practice/Good Research Practice training  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-35** | Unblinding  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-36** | Retention of health records of clinical trial patients |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-37** | Management review |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-38** | Equipment and Facilities |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-39** | Adverse Events in Medical Device Clinical Investigations |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-40** | Multi-centred site selection |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-41** | Genetically Modified Micro-organism research  |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-42** | Urgent Safety Measures |  |  |  |  |  |  |  |  |  |  |
| **SOP-QA-43** | Suspected Serious Breaches |  |  |  |  |  |  |  |  |  |  |

CI – Chief Investigator PI – Principal Investigator TM – Trial Manager RN – Research Nurse/Researcher

Stat – Statistician Dat – Data Programmer/analyst Pha – Pharmacist Lab – Laboratory staff