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| **NHS Grampian** |  | **U:\Logos\Untitled2.png** |

**Quality Management System Matrix**

Upon commencing involvement in a Clinical Trial all researchers must read the relevant documents which make up the Quality Management System. This shall include, as a minimum, the Research & Development Quality Manual, Quality Statement and a selection of Standard Operating Procedures (SOPs). SOPs may include Sponsor SOPs, departmental SOPs or study specific SOPs, which may be added at the end of this list. Researchers should use this matrix to record which documents they have read and the version number, and retain in their training record (this may be in place of the SOP Sign off Sheet (TMP-QA-40)).

**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 |  |  |  |  |  |  |  |  |  |  |
| **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