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| **Study Title** | Facilitating AcceLerated Clinical evaluation Of Novel diagnostics for COVID-19 (FALCON C-19) |
| **Abbreviated Title** | FALCON C-19 |
| **Chief Investigator** | Prof Rick Body |
| **Sponsor Reference (Research Office PIN)** | B00944 |
| **Protocol Number** | N/A |

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| **Site Name** |  |
| **Principal Investigator** |  |

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| **Sponsor** | Manchester University NHS Foundation Trust |
| **Sponsor Contact Details** | Dr Eloïse Cook (Study Co-ordinator)  [Eloise.cook@mft.nhs.uk](mailto:Eloise.cook@mft.nhs.uk); 0161 701 7540  Emma Columbine (Sponsor Representative)  [research.sponsor@mft.nhs.uk](mailto:research.sponsor@mft.nhs.uk) |

The following list of documents is not exhaustive; the specific documents to be filed will differ according to the particular nature of the study. Documents should be filed in reverse chronological order (i.e. with the most recent version or dated document filed at the front of each section).

|  |  |
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| **At Front of Each File** | Study information and contact page |
| Contents page |

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| **SECTION 1** | **File \_\_ of \_\_** | **N/A** |
| **Protocol** | Current protocol, signed by site PI |  |
| Previous version(s) of protocol |  |
| Site protocol deviation log and correspondence |  |
| Study specific SOPs |  |

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| **SECTION 2** | **File \_\_ of \_\_** | **N/A** |
| **Health Research Authority (HRA)** | Letter of HRA approval |  |
| Signed IRAS form |  |
| Notices of substantial amendments |  |
| Notification of non-substantial/minor amendments |  |
| HRA amendment documentation (categorisation e-mails and approvals) |  |
| HRA correspondence |  |
| **NHS R&D** | Trust confirmation of capacity and capability |  |
| Statement of activities and schedule of events for site |  |

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| **SECTION 3** | **File \_\_ of \_\_** | **N/A** |
| **Case Report Form (CRF)** | Sample CRF |  |
| CRF completion guidelines |  |

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| **SECTION 4** | **File \_\_ of \_\_** | **N/A** |
| **Financial Documentation** | Funding arrangements and award letter (including any requirements of the award) |  |

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| **SECTION 5** | **File \_\_ of \_\_** | **N/A** |
| **Signed Agreements and Contracts** | Sponsorship letter | X |
| Material transfer agreements |  |
| Insurance/indemnity documentation | X |
| Clinical site agreement | X |

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| **SECTION 6** | **File \_\_ of \_\_** | **N/A** |
| **Research Staff** | Delegation of duties log |  |
| Training log |  |
| Site principal investigator current CV (signed and dated) |  |
| Research team current CV(s) for all entries on the delegation of duties log |  |
| Evidence of GCP training for required research staff (to cover whole study period) |  |
| Previous research team CV(s) and GCP certificate(s) – expired or team members who have left |  |
| Evidence of training (other than GCP) |  |
| Copies of honorary contracts/letters of access |  |

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| **SECTION 7** | **File \_\_ of \_\_** | **N/A** |
| **Research Ethics Committee** | Ethics favourable opinion letter |  |
| Ethics favourable opinion letter with conditions |  |
| Correspondence (including response to conditions) |  |
| **Amendments and Reports** | Ethics favourable opinion for substantial amendments |  |
| Annual progress reports |  |
| Correspondence |  |

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| **SECTION 8** | **File \_\_ of \_\_** | **N/A** |
| **Approved Information for Participants** | Participant information leaflet(s) with local header |  |
| Informed consent form(s) with local header |  |
| GP letter with local header |  |
| Other approved written information for participants with local header |  |
| Previous versions of the above (clearly marked as superseded) |  |

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| **SECTION 9** | **File \_\_ of \_\_** | **N/A** |
| **Procedures and Tests** | Normal value(s)/range(s) for procedures and tests |  |
| Lab accreditation certificate(s) | X |
| Application to Trust labs |  |
| Lab manual |  |
| Record of locally retained body fluids/tissue samples |  |

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| **SECTION 10** | **File \_\_ of \_\_** | **N/A** |
| **Adverse Event Reporting** | Study specific reporting procedures |  |
| Master SAE form | X |
| Master AE form | X |
| Completed SAE forms | X |
| Completed AE forms | X |
| AE log | X |
| Notifications from investigator to sponsor of SAEs | X |
| Sponsor correspondence |  |
| Notification from sponsor to investigators of safety information |  |
| Urgent safety measures |  |

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| **SECTION 11** | **File \_\_ of \_\_** | **N/A** |
| **Monitoring** | Monitoring log |  |
| Site initiation report |  |
| Monitoring visit reports |  |
| Monitoring close-out report |  |
| Remote monitoring documentation |  |
| Source data location document\* |  |
| Audit reports |  |
| Related correspondence |  |

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| **SECTION 12** | **File \_\_ of \_\_** | **N/A** |
| **Sponsor Oversight** | Sponsor green light e-mail for site |  |
| Sponsor green light e-mail(s) for amendments |  |
| Sponsor correspondence regarding amendments |  |
| Completed SIV form |  |

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| **SECTION 13** | **File \_\_ of \_\_** | **N/A** |
| **Data Management** | Filenote confirming location of completed CRFs |  |
| Documentation of data corrections at site i.e. data query forms |  |
| Related communications |  |

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| **SECTION 14** | **File \_\_ of \_\_** | **N/A** |
| **Other Communications** |  |  |

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| **SECTION 15** | **File \_\_ of \_\_** | **N/A** |
| **Close Out** | End of study notification form |  |
| Final report |  |

**Filed Separately**

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| **CONSENT FILE** | **Filed with Local Research Team** | **N/A** |
| **Records of Informed Consent** | Screening, enrolment and withdrawal log for site |  |
| Completed consent forms for all recruited participants at site |  |
| Completed GP letters for all recruited participants at site |  |

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| **PAPER CRFs** | **Filed with Local Research Team (Separate to ICFs)** | **N/A** |
| **Completed Paper CRFs** | Completed paper CRFs for each participant recruited at site |  |
| Redacted source data |  |