|  |  |
| --- | --- |
| **Study Title:** |  |
| **CI/PI Name:** |  |
| **Sponsor Number:** |  |
| **REC:** |  |
| **R & D** |  |

|  |  |  |
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| **1** | **Contact Information** | **Notes** |
|  | Contact details sheet |  |
| **2** | **Draft Documents** |  |
|  | Sponsor registration form/RA |  |
|  | IRAS |  |
|  | Protocol |  |
|  | All participant documents |  |
|  | Evidence of peer review |  |
|  | Correspondence |  |
| **3** | **Submission documents** |  |
|  | Final approved version of all documents |  |
|  | Signed IRAS Form |  |
|  | Letter confirming sponsorship |  |
|  | File Note re location of Insurance |  |
|  | Correspondence |  |
| **4** | **Ethics** |  |
|  | Copy of correspondence between CI & REC |  |
|  | Approval letter from REC |  |
| **5** |  **R & D** |  |
|  | Copy of correspondence between CI & R&D |  |
|  | Approval letter from R & D |  |
| **6** | **Amendments** |  |
|  | Copy of all documents prior to submission |  |
|  | Copy of final approved amendment(s) |  |
|  | Approval letters from relevant parties |  |
| **7** | **Funding** |  |
|  | Evidence of funding |  |
| **8** | **Study Staff** |  |
|  | CVs |  |
|  | GCP |  |
|  | GLP |  |
| **9** | **Safety Reporting** |  |
|  | Any relevant safety issues |  |
| **10** | **Laboratories** |  |
|  | Accreditation Certificates or location of same |  |
| **11** | **End of Study** |  |
|  | Details of archiving if not in protocol |  |
|  | Declaration |  |
|  | Report |  |