**Start-up Checklist**

|  |  |  |
| --- | --- | --- |
| **Project Reference Number:** Click here to enter reference number | **Yes** | **N/A** |
| **Investigators and Study Staff** | | |
| Formal start-up meeting scheduled with all research personnel. Ensure all documentation including email correspondence and/or meeting records are stored in the Investigator File |  |  |
| A list of investigators and study staff contact details stored in the Investigator Files |  |  |
| Current signed and dated Curriculum Vitae of all investigators and study staff stored in the Investigator Files (within 2 years) |  |  |
| A training log of all investigators and study staff including:   * Good Clinical Practice (GCP) Training (within 3 years) * Study Specific Training content has been undertaken |  |  |
| A delegation and signature log signed and stored in the Investigator Files |  |  |
| If applicable, Honorary Researcher/s undertaken orientation and provided with access where required |  |  |
| **Data storage and handling**  See WH OG-GC7 Data Management in Research Guideline | | |
| For hardcopy documents: Secure and locked storage allocated for project. Access given to those approved in project. |  |  |
| For electronic files: WH SharePoint/Restricted S-Drive project folder created for project files. Access given to those approved in project. |  |  |
| If applicable: REDCap Database login and access setup for all relevant personnel |  |  |
| If applicable: For projects with external transfer of data, WH ShareFile folder created (Contact Corporate Records). |  |  |
| **Ethics Approval** | | |
| This study has been ethically approved and ethics approval letters/correspondence are stored in the Investigator Files |  |  |
| A copy of all the final approved ethics application documents is stored in the Investigator Files |  |  |
| A section is made available for storage of any ethics amendments that may occur |  |  |
| **Governance Authorisation (For SSA projects)** | | |
| The study has received WH governance approval prior to commencement |  |  |
| A copy of the governance authorisation letter and correspondences are stored in the Investigator File |  |  |
| A copy of all the final authorised governance documents are stored in the Investigator Files |  |  |
| **Finance & Agreements (where applicable)** | | |
| Approved budget and financial agreements/correspondences stored in Investigator File |  |  |
| Signed and executed Research Agreement stored in Investigator File |  |  |
| **Insurance & Indemnity (where applicable)** | | |
| For Commercial Trials: Current and valid insurance certificate & Indemnity form/s stored in the Investigator Files |  |  |
| **Participant/Recruitment (where applicable)** | | |
| Instructions for decoding available for research personnel in the Investigator Files |  |  |
| A screening log is stored in the Investigator File |  |  |
| A participant log is stored in the Investigator File |  |  |
| Inclusion and Exclusion selection criteria log regarding participant selection is stored in the Investigator File |  |  |
| Current ethics & governance authorised patient materials (e.g. PICFs, Letters, brochures etc) are marked clearly in files for use. |  |  |
| **Clinical Trials registration (where applicable)** | | |
| Have you registered your clinical trial with clinicaltrials.gov or anzctr.gov.au? |  |  |
| **Equipment and supplies (where applicable)** | | |
| Confirm the receipt or availability of all equipment and supplies crucial to the study including the study drug or device where applicable |  |  |
| **DRUG & DEVICE TRIALS ONLY** | | |
| **Sponsor Initiation** | | |
| Received written and dated statement/confirmation form Sponsor approving commencement of study. Store in the Investigator File |  |  |
| **Pharmacy/laboratories (if applicable)** | |  |
| Laboratory manuals for project stored in Investigator File |  |  |
| Pharmacy/drug manuals and correspondences stored in Investigator File |  |  |
| Instructions for handling of Investigational Product/s and project related materials stored in the Investigator File |  |  |
| **Clinical Trials Notification/Clinical Trial Exemption** |  |  |
| Clinical Trial Notification (CTN)/ Clinical Trial Exemption (CTX) acknowledgement by TGA stored in the Investigator File |  |  |
| By signing below, you are indicating that the study is ready to commence.  **Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name Signature Date | | |