**Checklist for Study Initiation**

**Are you ready to start enrolling PARTICIPANTS?**

|  |  |  |  |
| --- | --- | --- | --- |
| HREC Ref No |  | Principal Investigator |  |
| Protocol NO |  | Study Title |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Complete the following checklist prior to initiating a clinical research project. Do not start the study until all questions are answered YES or NA and the signature section is complete.  A research compliance officer is available to discuss these issues with you if required and the discussion will be documented on the following page. | | | |
| 1. **ETHICS COMMITTEE & GOVERNANCE APPROVAL OBTAINED**   *Do you have written and dated approval from the Research Ethics & Governance Office for the research application, current protocol, informed consent form, participant recruitment procedures and any other material to be provided to participants (diary cards, Participant card)?*  *NOTE: No participants can be enrolled in study until both ethics and governance approvals are obtained.* | | | YES |
| 1. **Budget finalised**   *Have you finalised the study budget and ensured that you have available adequate funds, adequate time, an adequate number of qualified staff and adequate facilities for the foreseen duration of the study to conduct it properly and safely?* | | | YES |
| 1. **Study Files established**   *Have all forms (including CRFs) and all procedures necessary to ensure protocol and regulatory compliance is documented been finalised? Have the study-level files been established, and all required documentation filed?*  *Have you set up participant-level files? Is the CRF ready and available with appropriate training completed?* | | | YES |
| 1. **STUDY TEAM ROLES AND RESPONSIBILITIES FINALISED**   *Have you ensured that all staff with responsibilities in the study are adequately trained and have an adequate understanding of the protocol, the investigational products, and their study-related duties and functions? Have you documented this (e.g. training log)?*  *Have all study staff completed the “Signature Log and Delegation of Duties Form”?* | | | YES  YES |
| 1. **OTHER PERSONNEL NOTIFIED**   *Have you notified all personnel who will be affected in any way by the study (such as nurses) with relevant information, such as when and where the study will be conducted?* | | | YES  N/A |
| 1. **Provisions for SUPPORT and services FINALISED**   *If the study involves the services or support of other departments, research enablers or external service providers (such as labs or radiology) have you finalised agreements and arrangements necessary for this study?* | | | YES  N/A |
| 1. **adequate EQUIPMENT AND supplIES ARE AVAILABLE**   *Have you confirmed the receipt or availability of all equipment and supplies crucial to the study including the study drug or device and sample collection/processing equipment?* | | | YES  N/A |
| 1. **Good Clinical practice**   *Have you reviewed the investigator responsibilities pertinent to study conduct, data and document management in accordance with GCP? Do you agree to adhere to these guidelines?* | | | YES |
| **DRUG/DEVICE TRIALS ONLY** | | | |
| 1. **SPONSOR/ORGANISING GROUP APProvAL GRANTED FOR INITIATION OF study**   *If your study is an externally sponsored/coordinated trial, do you need a written, dated statement approving commencement of the study? Have you received this?* | | | YES  N/A |
| 1. **Clinical trials notification complete (regulatory)**   *Have you completed and printed the CTN form to the Therapeutic Good Administration (TGA) and received acknowledgment from the TGA***?** *Do you have a copy printed in your files?* | | | YES |
| 1. **Investigational drug/device supplies AVAILABLE**   *Have you received the study drug or device?* | | | YES |
| By signing below, you are indicating that the study is ready to commence.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Principal Investigator** |  |  |  |  |  | |  | Name |  | Signature |  | Date | | | | |
| Research Compliance: Discussion points regarding practical aspects of trial management in relation to study initiation checklist.  Not compulsory to complete this page. | | | |
| **Ethics/Governance** | Ongoing responsibilities: SAE reporting/AR/protocol Amendments and ICF updates PD reporting | | |
| **Budget** | Confirm any concerns | | |
| **Study Files** | Who will maintain; All documents on file at study start | | |
| **Study Team/Responsibilities** | ICF process confirmed; Randomisation procedure; PE; Review of results; SAE reporting; Data entry; Delegation of duties | | |
| **Other personnel** | Copy of ICF in notes; Availability of further info if required | | |
| **Support Services** | Communication channels | | |
| **Equipment and Supplies** | Expiry dates; Ongoing order process; Sample shipment process | | |
| **GCP** | Awareness of ongoing responsibilities; Monitoring process | | |
| **Sponsor/Organising Group** | Monitoring/inspection readiness | | |
| **CTN** | Confirm acknowledgment on file | | |
| **IMP** | Expiry dates awareness; Training of staff to review/check regularly | | |
| **General/Follow up required** | Discuss patient flow and difference with SOC to minimise risks of PD | | |
| **Compliance assessor:**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | |  | Name |  | Signature |  | Date | | | | |