|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: General Preparation for Clinical Conduct** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

1. **Purpose/scope**

To describe the procedure for ensuring that stock, equipment, template documentation, staff and venue for trials conducted by the Malaria Clinical Research Group are adequately prepared.

1. **Templates/forms**

AD02.1 Stock check-list

AD02.2 Bed plan

AD02.3 Equipment servicing schedule

AD02.4 Timelines

AD02.5 Assessment schedules

1. **Glossary/definitions**

None

1. **Responsibilities and procedure**
   1. **Medical stock and equipment**

A suitably trained member of the trial team should be delegated responsibility for facilitating the checking, ordering and labelling of medical stock and equipment.

* + 1. Stock check-lists (AD02.1) are developed for general medical consumables and equipment (including items for out-patient visits and in-patient days), based on the protocol’s requirements. NB these lists may be combined with ward set up check lists found in AD05.
    2. Any existing stock (from previous trials) is checked, and expired items destroyed as appropriate. In-date stock is placed in a trial-specific secure storage area.
    3. New stock and any identified additional trial-specific supplies/equipment are ordered through the appropriate purchasing method. On receipt, stocks and requisition forms are checked for protocol compliance before secure storage in the ward.
    4. Participant-specific packs, if required, are prepared from the general medical consumables stock, and placed in a trial-specific secure storage area.Packs and their contents are labelled according to trial requirements, and a quality control check conducted by designated members of the trial team (or contract employees) as documented in a note to file. Unless otherwise specified in the protocol or elsewhere, sample containers will be labelled with the trial number, participant number, trial period and sample time-point. NB very small items (such as cryovials and eppendorfs) may only include participant information, as long as the boxes they are stored in indicate the trial.
    5. If required, participant-specific identity bands (or equivalent) are sourced and prepared, together with the bed plan and associated bed labels (AD02.2).
    6. Equipment is serviced according to manufacturers’ recommendations throughout the trial. During a trial the defibrillator and suction equipment is kept charged and relevant staff should be proficient in its workings prior to trial start.All records relating to stock and equipment (including check lists, quality control, calibration records and servicing documentation) will be filed in the Investigator Site File throughout the trial (or a note to file indicates where they are stored). It is recommended that a trial-specific equipment servicing schedule be developed (AD02.3).
    7. Drugs other than the Investigational Medicinal Product (IMP) are sourced according to the protocol or Principal Investigator (PI) requirements (e.g. for symptomatic relief of subjects’ minor ailments and anti-retroviral for HIV post-exposure prophylaxis). These may be stored in the pharmacy or a ward medicine trolley depending on a particular trial’s requirements. There should be controlled access to such other drugs while participants are in the facility.
    8. Expiry dates for all stock are checked regularly during the pre-trial phase to ensure the integrity of stock at the study start, as documented on the stock check-lists.
    9. During the trial general medical stocks are checked regularly against the stock lists for general consumables with expired stocks removed and re-ordered as above. Any stock that has been re-packaged into subject-specific boxes is also checked and replaced as above.
    10. Stock-takes of the resuscitation equipment are made according to Clinical Research Centre/Unit requirements. However, these should be such that there is enough time to re-stock if required before trial participants are expected. During admission periods, the trolley and equipment (including the suction and AED) will be checked twice daily (at the start of each shift) and daily at the start of screening/follow-up days. Ultimate responsibility for adequate function and stock of the resuscitation equipment remains with the senior investigator on site.
  1. **Staff**
     1. The PI should ensure the allocation, or recruitment, of suitably qualified staff to make up the trial team. Trial timelines and schedules will be arranged to ensure the trial is conducted according to the protocol (AD02.4 and 5).
     2. All relevant staff should attend relevant meetings and training as necessary prior to their start with the trial, documenting qualifications and training as per regulatory and SOP requirements.
  2. **Venue, including catering and entertainment**
     1. If utilising the ward, prior to and during the trial a member of the trial team will be tasked with liaising with the ward management for it to be cleaned and organised as per the enrolment schedule.
     2. By the time of trial start a member of the trial team will be tasked with planning for and source on-going catering supplies as per protocol requirements for trial participants, and also for the trial team, according to the schedule of clinical conduct. A stock list specific to such consumables may be used as above.
     3. Adequate entertainment will be planned.
  3. **Template documentation**
     1. A member of the trial team will be tasked with coordinating the production of adequate template documentation including, but not limited to, participant folders including source documents, SOP forms/templates and trial-specific instructions. See relevant SOPs for details.

1. **Document history:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |