8.1 - Standard Operating Procedure – Study Drug Accountability

SCOPE

These guidelines apply to all protocol of which UT M.D. Anderson Cancer Center (MDACC) is the FDA Sponsor of Record.

PURPOSE

To ensure the investigational product(s) documentation is maintained by the research team according to sponsor/regulatory guidelines.

REFERENCE

ICH GCP 4.6; 5.0

PROCEDURES

- The responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution. The investigator should maintain records that adequately document that subjects were provided the dosage specified in the protocol and reconcile all investigational product(s) received from the supplier. The investigator should maintain records indicating the products delivery to the trial site, inventory at the site, the use by each subject, and the return to supplier or alternative disposition of unused product(s).

- Subject diaries may be utilized to assist in assessing the subject compliance. The Sponsor will provide a Drug Accountability Log that must be maintained separately for each individual subject and filed in the Regulatory Binder. The Drug Accountability Log is to be use for protocols involving self-administered study drugs (i.e. p.o., subcutaneous injections). Research teams that desire using a Drug Accountability Log other than that provided by the Sponsor may do so at the discretion of the Clinical Research Monitor. Documentation should be maintained by the investigator adequately documenting the participant’s assigned identifier, date and quantity of drug dispensed, date and quantity of drug returned and disposition of returned drug. The investigator or designated person should explain the correct use of the investigational product(s) to each subject and should ensure, during each return visit that each subject is following the instructions properly.

- The clinical research monitor will review the drug accountability log(s) for all enrolled subjects during each scheduled monitoring visit and the following will be verified:

  1. The storage conditions are acceptable.
  2. The investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).
3. Subjects should be provided with necessary instructions on properly using, handling, storing, and returning the investigational product(s).
4. Disposition of used/unused investigational product(s) at the trial site complies with applicable regulatory requirement(s) and is in accordance.

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