

Investigator Responsibilities for Drug Supplies



Your signature on the 1572 indicates that you are agreeing to "maintain adequate drug accountability" for drug supplies for this study.

This includes:

- 1. Acknowledgement of receipt of supplies according to sponsor's instructions.
- 2. Storage of the study drug supplies in a locked limited access facility.
- 3. Accurate records of dispensing of study drug to properly enrolled/consented subjects for this protocol only.
- 4. Maintain appropriate storage according to the sponsor's instructions.
- 5. Document in writing any damaged, missing, lost, or unaccounted for study drug.
- 6. Document the return to the sponsor or destruction of any unused study drug during the conduct of the trial or at the end of the trial.
- 7. Document in writing any recall of study drug, any relabeling of study drug or any other event as notified by the sponsor.

If the study sponsor is providing a monitor to inspect and monitor your site on a periodic basis, please forward a copy of the written monitor report provided after each visit and at the close out of the study.

If the study sponsor is not providing a monitor to inspect or monitor your site, then provide a plan for maintaining accurate and complete drug accountability for your study.

This may include copies of your drug accountability form (or see sample form FOR236 <u>Investigational Agent Accountability Record</u> on UAB IRB web page under FORMS), and a final summary of drug accountability at the end of the study (see sample FOR237 <u>Overall Drug Accountability Record</u>).