

IRB Policy 31: Storage of Investigational Agents

**Revision Date: February 16, 2008, revised January 27, 2011,
revised October 15, 2015**

I. Definitions:

Investigational Drugs/Investigational Biologics (Test Articles): A new drug/agent or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used *in vitro* for diagnostic purposes. Investigational drugs or biologics may include:

- a. Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or
- b. Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency).

II. Summary Policy

It is the policy of the ETSU/VA IRB that all investigational drugs, devices, drugs, or biologics used in human subject research be stored, handled and dispensed in accordance with governing regulations and institutional policy. It is the responsibility of the investigator to comply with all institutional, state, and federal regulations in regards to storage of investigational drugs, agents, or biologics.

III. VA / MSHA Researchers

All research investigators conducting VA approved human subjects research protocols involving the use of pharmaceutical agents must be in compliance with all VHA policies/handbooks as they relate to obtaining, prescribing, and the storing of pharmaceuticals as well as addressing required record keeping. In addition, investigators using any controlled substances including Schedule II and III narcotics must be in full compliance with VHA Pharmacy Policies and Drug Enforcement Administration (DEA) Regulations. If the use of pharmaceuticals is covered under FDA Regulations, those regulations must be followed as well.

VA researchers are responsible to ensure the local Pharmacy Service or Research Service Investigational Pharmacy receives:

- Documentation of IRB and any other relevant approvals.
- A copy of VA Form 10-9012 (if applicable).
- A copy of the current approval protocol.
- A copy of the consent document for each participating participant with all appropriate signatures.
- Documentation of IRB continuing review approval.
- Copies of sponsor-related correspondence specific to the drugs as appropriate.
- Copies of all correspondence addressed to the Researcher from the FDA specific to the investigational drugs as appropriate.
- Inform the chief, pharmacy service, the research pharmacy when applicable, and the Research Development Committee and the IRB in writing with a study

- involving investigational drugs has been suspended, terminated, or closed.
- Comply with all dispensing requirements.
- Comply with all documentation requirements and make relevant records accessible to the investigational drug pharmacist when requested.

In addition, studies conducted at Mountain States Health Alliance must follow all applicable MSHA policies.

Controlled substances may not be stored outside of the pharmacy department of the involved hospital.

IV. PI Summary Responsibilities

Protocols involving an Investigational Drug (IND) or Investigational Device (IDE) require compliance with the pertinent FDA and the DHHS regulations (21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, and 45 CFR 46).

The PI is responsible for assuring the IRB that investigational drugs and devices are stored in a secure and safe manner and that the storage and safety requirements are consistent with FDA, sponsor, and affiliated research institutions' storage requirements for drugs or devices being investigated. Whenever possible, the storage of drugs and biologics should be under the supervision of a registered pharmacist and stored in the pharmacy in a limited access, locked area. Devices should be stored according to manufacturer's specifications and maintained in a limited access area. Access to the test devices must be limited only to those authorized to use the devices.

The PI is responsible for ensuring that test articles (drugs, biologics, or devices) are controlled so that they are not used outside of a research study. An investigator shall administer the drug or device only to subjects under the PI's personal supervision or under the supervision of a sub-investigator responsible to the PI. The PI shall not supply the investigational drug or device to any person not authorized to receive it.

The protocol for the study should outline the security and storage plan for the test article(s) indicating that the plan meets the sponsor's storage and security requirements. The plan should include whether or not control will be through a hospital pharmacy and under the supervision of a registered pharmacist or held in a proper and secure storage area by the investigator. The protocol should detail how the test article is used in human subjects, indicate who may have access to the test article(s) and outline the accountability plan for the test article(s) to ensure that there is no unapproved access to or use of the test article(s).

PI responsibilities related to investigational drugs are outlined in the Supplemental Form for Drugs section of the new protocol submission xform. This section is required for submission for investigational drug studies. PI responsibilities related to investigational devices are outlined in the Supplemental Form for Devices section of the new protocol submission xform. This section is required for submission for investigational device studies.

V. Additional Responsibilities for PI Acting as Sponsor

If a PI is acting as the sponsor of research involving an investigational drug, the ETSU/VA IRB requires that the PI submit documentation that the proposed drug preparation has been reviewed and determined to be in compliance with Current Good Manufacturing Practices. In addition, when an PI is acting as the sponsor of research involving an investigational drug or device, the IRB requires that the PI review the reporting and record-keeping responsibilities as stated in 21 CFR 312 and 21 CFR 314 (for investigational drugs) or 21 CFR 812 and 21 CFR 814 (for investigational devices). (also see policy 33)

References

21 CFR 50, 56, 312, 812
FDA Information Sheets
VA Investigator Handbook