

IRB Policy 31: Storage of Investigational Test Articles

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I. Summary Policy

It is the policy of the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA) IRB that all investigational 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, labeling, and control of investigational drugs, agents, or biologics.

II. Definitions:

- A. Test article** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the FD&C Act or under the Public Health Service Act.
- B. Investigator** means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.
- C. Sponsor-investigator** means an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under FDA regulations include those of an investigator and those of a sponsor.
- D. Investigational device** means a device, including a transitional device, that is the object of an investigation.
- E. 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).

III. PI Responsibilities

Protocols involving an investigational test article 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). It is the PI's responsibility to assure that systems and procedures for control of the investigational test articles comply with FDA and other applicable regulations, including ensuring personnel who may use the test articles are appropriately trained and qualified to do so safely, and documenting delegation to qualified study staff, where the test articles will be shipped to and stored, the procedures for the release of the test article (e.g., with a written physician's order), and how inventory will be maintained.

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 the research sites' 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 and labeled 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 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 PI is responsible for maintaining records of receipt, use, dispensing, and disposal for all test articles. Upon completion or termination of a clinical investigation or the PI's part in an investigation, or at the sponsor's request, the PI must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

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

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IV. 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). Sponsor-investigators must submit an attestation xform that documents his/her understanding of the applicable responsibilities.

V. VA 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.

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

References:

21 CFR 50, 56, 312, 812
FDA Information Sheets
VHA Directive 1200.05
VHA Handbook 1108.04