ELEMENT I.7.B.: The organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

This Element applies only to an organization that conducts research with investigational or unlicensed test drugs or devices or an independent IRB or EC that reviews a researcher's plan to control test articles.

An organization should describe the process for handling investigational or unlicensed test articles so that they are used only in approved protocols and under the direction of approved researchers. Possible methods organizations can use to control investigational drugs and devices are:

- Protocol-by-protocol review and approval of the researcher's plan to control test articles along with training or evaluation of researchers on knowledge and compliance with the plan.
- Organizational control of test articles. For example, organizations can control investigational drugs by having a pharmacy store them and dispense them only under the prescription of an approved researcher.

Procedures for the control of investigational drugs and devices should apply to all settings in which the organization uses investigational drugs and devices, such as inpatient, outpatient, on-site, and off-site settings.

Regulatory and guidance references

- **FDA:** 21 CFR 312.61, 21 CFR 312.62, 21 CFR 312.69, 21 CFR 812.100, 21 CFR 812.110, 21 CFR 812.140(a)
- **ICH-GCP:** 2.12, 2.13, 4.6.1, 4.6.2 – 4.6.4
- **VA:** Handbook 1108.04
- AAHRPP Tip Sheet: Following the Guideline of the International Conference on Harmonisation – Good Clinical Practice (E6)

Required written materials

1. Essential requirements:
    1. Policies and procedures describe the control of investigational drugs.
    2. Policies and procedures describe the control of investigational devices.
2. When following the ICH-GCP (E6) guideline:
    1. Policies and procedures include:
        1. A description of the manufacturing, handling, and storage in accordance with applicable good manufacturing practice.

2. Where allowed or required, the researcher or organization assigns some or all duties for investigational articles accountability at the clinical trial sites to an appropriate pharmacist or another appropriate individual who is under the supervision of the researcher or organization.
3. The researcher, pharmacist, or other designated individual maintains records of the product's delivery to the clinical trial site, the inventory at the site, the use by each participant, and the return to the sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial participants.
4. The researcher maintains records that document adequately that the participants are provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.

Outcomes

- Investigational test articles are used only in approved research protocols and under the direction of approved researchers.
- The organization has a process to ensure the proper handling of investigational test articles.