Investigator Responsibilities

According to the Code of Federal Regulations, you, as Investigator, are responsible for ensuring the research study is conducted according to the protocol and in compliance with applicable regulations. You agree to assure human subjects are protected, risk is minimized, and you assure any investigational product being used during the study is accountable and secure. By signing on as an investigator for human research study, you agree to:

1. Provide evidence of your qualifications through up-to-date CV or other relevant documentation requested by the MHSIRB, Sponsor or regulatory authority.
2. Protect the rights, safety, and welfare of the human research subjects, in accordance with the Belmont Report and other guidance on protection of human subjects.
3. Conduct the study in compliance with the MHSIRB approved study protocol and applicable regulations and guidelines governing the conduct of clinical studies, including state and local laws and MHSIRB policies and procedures. This includes understanding and applying the definitions of legally authorized representative (LAR), assent documents and guardian in your state. Delegate significant study-related duties only to qualified personnel, **directly oversee these personnel** to ensure they are performing their duties in compliance with applicable standards and in the best interest of the human subjects. Ensure these individuals have completed an on-line human subject's protection education program. Maintain a list of these qualified persons to whom you have delegated these significant clinical trial-related duties.
    a. Where allowed or required, you may assign some or all duties for investigational articles accountably at your site to an appropriate pharmacist or another appropriate individual who is under your supervision.
    b. You, the pharmacist, or other designated individual will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused products. You will supervise the administration of the investigational product (IP) to the research subjects, as applicable, and maintain full accountability of the IP. This includes being familiar with appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.
    c. These records will include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects. You should maintain records that document adequately that the subjects are provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.
4. Only use the current approved version of the consent and HIPAA authorization approved by MHSIRB.
5. Protect the privacy of the study participants and maintain the confidentiality of the personal health information and study data.
6. Submit and obtain **MHSIRB approval** for all advertisements, other subject recruitment or retention materials and all study-related material that will be provided to subjects.
7. Obtain MHSIRB approval for any amendments to the protocol prior to implementation of the changes.
8. Report to the MHSIRB all **unanticipated** problems involving risks to research subjects or others within **48 hours upon learning of them.** Report deaths to the MHSIRB and sponsor immediately or no later than **24 hours upon learning of them.**
9. Provide Continuing Review at defined intervals (at least annually) and Principal Investigator Site Closeout Report Information should be submitted within 30 days after completion or termination of the study to MHSIRB. Upon completion of the clinical trial, you should inform MHSIRB by submitting a summary of the trial's outcome and the regulatory authority, by submitting any required reports.
10. As requested, agree to appear in person before the MHSIRB to address questions regarding the study protocol before or following approval.

Federal Regulations

The Department of Health and Human Services (DHHS), having adopted the common Federal policy for the protection of human research subjects, is responsible for ensuring that institutions conducting research involving human subjects meet the requirements mandated by the federal policy. This includes, but is not limited to, the composition of and procedures of the institutional human subjects committee, criteria for institutional review of research protocols, and adequacy of informed consent, etc.

Applicable Regulations:

(1) Office of Human Research Protection (OHRP) regulations regarding the protection of human subjects in research, 45 CFR 46 (Common Rule)

The Department of Health and Human Services / Food and Drug Administration (FDA) regulates but does not, for the most part, support or conduct research. Its regulatory mandate, therefore, differs substantially from other DHHS agencies and other federal departments and agencies that conduct and support a significant amount of research. While the structural and functional requirements for IRBs in the FDA regulations are identical to the DHHS regulations, the substantive provisions differ in several significant aspects. Where a protocol is subject to review under both FDA and DHHS human subject regulations, both sets of regulations apply, and the requirements of both sets of regulations must be met.

Food and Drug Administration (FDA)

Applicable Regulations:

(1) FDA regulations regarding the protection of human subjects in research 21 CFR 50 and 56;
(2) FDA regulations regarding investigational new drugs 21 CFR 312;
(3) FDA regulations regarding investigational device exemptions 21 CFR 812

Belmont Report

1. Respect for persons
2. Beneficence
3. Justice

As the Investigator I understand the responsibility and I will comply with the standards and requirements to protect the rights and welfare of human subjects involved in research.

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Investigator Dated

Printed/signed