Grand Valley State University Institutional Review Board (IRB)	
Title: *Research Involving a Sponsor-Investigator*	
Section: 940	
Approved by IRBPPC: 10/04/2024	Approved by IO: 11/06/2024
Effective Date: 11/06/2024	
Related documents: IRB Policy 310: *Researcher Responsibilities, Qualifications and Training* IRB Policy 901: *IRB Protocol Review: Expedited Protocols* IRB Policy 902: *IRB Protocol Review: Full Board Protocols* IRB Policy 920: *Significant Risk, Nonsignificant Risk, and Exempt Medical Device Studies* IRB Policy 930: *Requirements for Research Involving Investigational New Drugs* IRB Policy 1020: *Reportable Events: Protocol Deviations, Unanticipated Problems and Adverse Events* IRB Guidance G-20: *ClinicalTrials.gov Registration*	

Policy

The purpose of this policy is to outline the requirements and review process for research studies where the investigator will also serve as the sponsor for a research study. As defined in Food and Drug Administration (FDA) regulations (21 Code of Federal Regulations [CFR] 312.3 and 812.3(o)), a sponsor-investigator is an individual who both initiates and conducts a clinical investigation, and under whose immediate direction a test article (i.e. an investigational drug, device, or biologic) is administered, dispensed or used. The requirements of a sponsor-investigator include both those applicable to an Investigator and those applicable to a Sponsor.

This policy does not apply to industry-sponsored research, or research where a funding agency is acting as a sponsor. This policy does not apply to investigator-initiated research that does not use a test article in a clinical investigation, as defined by FDA regulations.

As with all human subjects research, prior to initiating a clinical trial involving a test article, the sponsor-investigator must obtain approval from the IRB, and approval or clearance from the FDA when applicable.

Definitions

1. *Clinical investigation*. Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to the requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. [21 CFR 50.3(c)]

2. *Investigator*. 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). [21 CFR 50.3(d)]

3. *Human subject*. An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be a healthy human or a patient. [21 CFR 50.3(g)]

4. *Sponsor*. A person who initiates a clinical investigation, but who does not actually conduct the investigation. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators. [21 CFR 50.3(e)]

5. *Sponsor-investigator*. An individual who both initiates and actually conducts, alone or with others, a clinical investigation. The term does not include any person other than an individual (e.g., corporation or agency). [21 CFR 50.3(f)]

6. *Test Article*. 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 act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n). [21 CFR 50.3(j)]

Procedures

1. Responsibilities of the Sponsor-Investigator
    a. In addition to the requirements of 21 CFR 312 and 21 CFR 812, investigators who hold an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), Premarket Approval (PMA), or 510(k) must also meet all regulatory requirements pertaining to sponsors, appearing in other Food and Drug Administration parts, as applicable to the test article used in the research and must also meet,
        i. 21 CFR 54 for requirements related to financial disclosures by clinical investigators, and,
        ii. 21 CFR Part 11: Electronic Records; Electronic Signatures.

        Researchers are encouraged to contact the Office of Research Compliance and Integrity prior to submitting their protocol to determine if an IND, IDE, PMA, or 510(k) will be needed.

    b. The sponsor-investigator is responsible for ensuring that the clinical investigation is conducted according to:
        i. Sound research design and generally acceptable scientific methods;
        ii. All the terms of contracts and/or signed agreement(s);
        iii. The obligations specified in the signed Form FDA 1572, if applicable;
        iv. The protocol as approved by the IRB; and,
        v. All applicable regulations and laws.

    c. Specific responsibilities include:
        i. Ensuring the institutional review process is followed, as outlined in this policy.

ii. Selecting qualified study team personnel, who have appropriate training and expertise to assist in the conduct of the proposed research according to regulatory requirements.
iii. Providing study team members with the necessary information and training to conduct the clinical investigation. All study team members must be trained by the sponsor-investigator on the methods detailed in the protocol including but not limited to, the method of obtaining consent, process of reporting adverse events, data collection and data monitoring plan. The sponsor-investigator is responsible for submitting evidence of the required education and training for all study team members to the IRB.
iv. Personally conducting or supervising the proposed clinical investigation, including:
    1. Conducting the clinical investigation in accordance with agreements, contracts, the protocol as filed with the FDA and IRB, and any other applicable FDA regulations, and conditions of approval imposed by the IRB;
    2. Supervising the use of the test article at their site and administering the test article only to subjects under the PI's personal supervision or under the supervision of a person whom the PI has formally delegated that authority to in the delegation log;
    3. Obtaining the legally effective informed consent of the subject or the subject's legally authorized representative prior to the administration of a test article;
    4. Protecting the rights, safety, and welfare of subjects under the investigator's care; and,
    5. Understanding FDA guidance on FDA expectations regarding supervision and task delegation to other research team members.
v. Ensuring IRB approval is obtained before the clinical investigation activities begin, and again prior to the expiration of IRB approval (at the time of each periodic continuing IRB review of the research).
vi. Preparing, submitting and maintaining an IND or IDE application to FDA, as applicable, and that these regulatory documents are also maintained by the IRB as part of the submission processes.
vii. Registering and maintaining the clinical investigation on Clinicaltrials.gov and providing the ORCI with the National Clinical Trial (NCT) number prior to beginning the clinical investigation.
viii. Ensuring compliance with all applicable FDA labeling requirements, as applicable.
ix. Maintaining adequate records of the disposition of the test article, including dates, quantity, and use by subjects; return of the unused supplies of the test article to the manufacturer or other disposition of unused supplies, and complying with any other applicable record-keeping and retention requirements for the test article, as set forth by the FDA.
x. The sponsor-investigator and the involved institution(s) are required to permit and facilitate monitoring and auditing, at reasonable times, by the IRB, its designee, funding agencies, and federal and state regulatory agencies as appropriate.
xi. For research involving more than minimal risk to subjects, the sponsor-investigator is responsible for submitting a data and safety monitoring plan or standard operating procedures to the IRB describing how the sponsor-investigator will fulfill

all the requirements of a Sponsor and ensuring proper monitoring of the clinical investigation in accordance with the plan submitted to the IRB.

xii. The sponsor-investigator must ensure prompt reporting of any unanticipated problem involving risk to subjects or others to the IRB, appropriate institutional officials, and state and federal regulatory agencies as appropriate in keeping with IRB Policy 1020: *Reportable Events: Protocol Deviations, Unanticipated Problems and Adverse Events*.

2. Review and approval process for sponsor-investigator research
    a. Review by the institution
        i. The proposed clinical investigation may require additional institutional reviews prior to IRB submission, or these reviews may be required by the IRB as a condition of approval. These reviews may evaluate the objectives, sound scientific methods and study design, resources (people, test article acquisitions and storage, costs), plans for management and oversight of the clinical investigation including data and safety monitoring, and other relevant aspects. They are in addition to review by the IRB; they do not replace IRB review and do not constitute approval/disapproval of the IRB protocol. The additional institutional reviews may include, but are not limited to, the following:
            1. Institutional Official review
            2. Legal counsel review
            3. Risk management and institutional insurance review
            4. Office of Sponsored Programs
            5. Scientific review
            6. Research operations review
            7. Privacy and security review

    b. Review by the IRB
        i. In addition to reviewing the clinical investigation following the approved IRB policies and relevant FDA regulations, the IRB will also make the following determinations:
            1. Determining if the sponsor-investigator has the medical expertise, qualifications, training, support, and facilities necessary to conduct the research that protects the human subjects; fulfills the scientific purpose of the clinical investigation; and meets federal, state, and local laws and regulations. If necessary, additional staff or an outside consultant may be required to complete this review.
            2. Determining if there is an adequate and effective data and safety monitoring board or plan. An outside data safety and monitoring board may be required or requested by the IRB.
            3. If using an investigational device, determining if it meets the FDA definition of significant risk by considering the proposed use of the investigational device as well as any protocol-related procedures and tests in making their determination.
            4. Ensuring investigators who assume sponsor functions are knowledgeable about the regulatory and institutional requirements involved.

Relevant FDA Regulations

- 21 CFR 11: Electronic Records, Electronic Signatures
- 21 CFR 50: Protection of Human Subjects
- 21 CFR 54: Financial Disclosure by Clinical Investigators
- 21 CFR 58: Good Laboratory Practices for Nonclinical Laboratory Studies
- 21 CFR 211: Good Manufacturing Practices for Finished Pharmaceuticals
- 21 CFR 312: Investigational New Drug Application
- 21 CFR 812: Investigational Device Exemptions