Sponsor-Investigator (IND/IDE) Applications

VCU/VCUHS CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

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1. PURPOSE

This Standard Operating Procedure provides guidelines for Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) requirements for sponsor-investigator research projects at VCU/VCUHS.

2. REQUIREMENTS

It is the policy of VCU/VCUHS that all research involving investigational agents (drug, biologic, or device) be reviewed and approved for use in compliance with all federal, state, and institutional regulations and policies. Approval may require review by the Food and Drug Administration (FDA) in the form of an IND or an IDE application.

3. DEFINITIONS

Food and Drug Administration (FDA)

The United States regulatory authority which oversees the pharmaceutical and medical device industries and is responsible for ensuring that the drugs and medical devices marketed in the U.S. have a greater benefit than risk when used according to manufacturer's directions.

Investigational Device Exemption (IDE) – Prescribed documents/application submitted to the FDA and approved to allow for the conduct of a clinical study using a significant risk device that is new or not approved for that use. Non-significant risk IDEs are not submitted to FDA but do have other IDE responsibilities.

Investigational New Drug (IND) – Prescribed documents/application submitted to the FDA and approved to allow for the conduct of a clinical study using a drug that is new or not approved for that dosage, form, or indication.

Investigator

An individual who actually conducts a clinical investigation. See IRB Written Policies and Procedures (WPP) IX-1 – Principal Investigator Eligibility and Statement of Responsibilities for additional information about who can be an investigator.

Sponsor

A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution,

private organization, or other organization. At VCU a faculty member (not the institution) may be a sponsor.

Sponsor-investigator - An individual VCU faculty member who both initiates and conducts an investigation, and under whose immediate direction the investigational drug or device is administered or dispensed. A sponsor-investigator complies with all the FDA-prescribed obligations of both a sponsor and an investigator.

4. PROCESS

A. VCU offers a website and guidance for sponsor-investigators in meeting the requirements for FDA submission for an IND or IDE. As soon as possible in the process, the VCU Faculty-Held IND – IDE Resource Website should be consulted and the VCU FDA Regulatory Resource Program Manager should be contacted.

B. Application for an IND or IDE for a sponsor-investigator research project should adhere to the following:

- Prior to initiation of a sponsor-investigator research project, a determination must be made as to whether an IND or IDE application should be submitted to the FDA per 21 CFR 312 (IND) and/or 21 CFR 812 (IDE). The PI should consult with the VCU FDA Regulatory Resource Program Manager during the evaluation process and prior to preparation of the regulatory package to the FDA. The potential sponsor-investigator may also consult with the FDA to determine if an IND or IDE application is required.
- If it is determined that an IND is required, an IND submission package should be assembled per 21 CFR 312 and submitted via the VCU FDA Submission Portal per VCU Policy – Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE). The VCU FDA Regulatory Resource Program will review the submitted initial FDA package and consult with the sponsor or sponsor-investigator as appropriate or by request. Once reviewed, the IND package should be submitted to the FDA.
- If it is determined that an IDE is required, an IDE submission package should be assembled per 21 CFR 812 and submitted via the VCU FDA Submission Portal per VCU Policy – Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE). Once the initial submission is reviewed, the IDE package should be submitted to the FDA.
- Upon receipt of the IND/IDE application package, the FDA will respond with an acknowledgement letter including the assigned IND/IDE number. All future correspondence with the FDA must include this assigned IND/IDE number.
- If the FDA determines the study is exempt, assignment of exempt status will be communicated from the FDA by letter.
- The Sponsor-Investigator must wait 30 days after the receipt date on the FDA's IND/IDE acknowledgement letter or email. An IND application may go into effect 30 days after the FDA receives the application, unless the FDA notifies the sponsor-investigator that the investigations described in the application are subject to

Clinical Hold, or on earlier notification by the FDA that the clinical investigations in the IND may begin. AN IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor via email prior to 30 calendar days from the date of receipt that the IDE is approved, approved with conditions, or disapproved. In cases of disapproval, a sponsor-investigator has the opportunity to respond to the deficiencies and/or to request a regulatory hearing under 21 CFR Part 16.

- Should the FDA require modification(s) to the application, a letter will be received within the 30 day post acknowledgement window. All concerns raised by FDA must be fully addressed and an acknowledgement received from FDA that all issues have been satisfactorily addressed before the study can be initiated.
- The Sponsor-investigator must comply with all reporting obligations per applicable federal regulation.
- Some amendments to the protocol must be submitted to the FDA for review. The Sponsor-investigator should consult 21 CFR 312.30-31 (IND) and/or 21 CFR 812.35 (IDE) to determine if an amendment should be submitted to the FDA.
- An annual progress report must be submitted to the FDA within 60 days of the anniversary date that the IND/IDE went into effect.
- After initial submission through the VCU portal, most subsequent correspondence/ submissions to/from the FDA should be uploaded to the VCU FDA Submission Portal within 5 business days. Notices of clinical holds must be submitted within 24 hours of receipt. Serious unanticipated adverse effects should be submitted concurrent with FDA submission.
- The Sponsor-investigator (or delegated individuals) should confer with the FDA Regulatory Resource Program Manager regarding questions, FDA reporting requirements, FDA correspondence, and other study-specific requirements.

5. REFERENCES

A. Code of Federal Regulations

- 21 CFR 312 – Investigational New Drug Application
- 21 CFR 812 – Investigational Device Exemption

B. Good Clinical Practice

- ICH E6: Harmonized Tripartite Guideline for GCP
    - Section 4 – Investigator
        - Section 4.1 – Investigator's Qualifications and Agreements
        - Section 4.4 – Communication with IRB/IEC
        - Section 4.5 – Compliance with Protocol
        - Section 4.9 – Records and Reports
    - Section 5 – Sponsor
        - Section 5.10 – Notification/Submission to Regulatory Authority(ies)

C. VCU

- VCU Faculty-Held IND – IDE Resource Website

- VCU Policy – Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE)
- VCU IRB Written Policies and Procedures
    - Section #IX-1 – Principal Investigator Eligibility and Statement of Responsibilities
    - Section #XVI-1 – Review of Devices – IDE Requirements (SR vs. NSR Determination)
    - Section #XVI-3 – Emergency Use of an Investigational Drug, Device, or Biologic
    - Section #XVI-6 – Review of Drugs – IND Requirements

Review/Revision History CR-RE-350

Version No.	Effective Date	Description
CR-RE-350.2a	07-01-2020	● Links updated
CR-RE-350.2	07-01-2020	● Biennial review performed ● Minor formatting edits ● Definitions updated ● References and reference links updated
CR-RE-350.1	02-03-2018	● Original