



Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE)

Policy Type: Administrative

Responsible Office: Office of Research and Innovation

Initial Policy Approved: 12/03/2015

Current Revision Approved: 05/16/2018

Policy Statement and Purpose

The purpose of this policy is to outline reporting requirements for VCU sponsors and sponsor-investigators of an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE). In order for VCU to provide proper oversight and educational resources, the Office of the Vice President for Research and Innovation must be informed of all IND and IDE activity in a timely fashion.

Proper adherence to Food and Drug Administration (FDA) regulations is critical to managing risk; noncompliance may result in liability for the individual sponsor or sponsor-investigator and the university. When a faculty member serves as the sponsor of an IND or IDE, the FDA communicates directly with the faculty member, not the university. As such, the reporting requirements for sponsors and sponsor-investigators contained in this policy are critical to ensuring that VCU is aware of all faculty held INDs and IDEs and to assist with compliance with FDA regulations.

This policy does not apply when a faculty member serves only as the principal investigator on an IND or IDE and the sponsor is a pharmaceutical company, governmental agency, academic institution, private organization, or other organization.

Noncompliance with this policy may result in disciplinary action up to and including termination of employment. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

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Who Should Know This Policy

VCU sponsors and sponsor-investigators are responsible for knowing this policy and familiarizing themselves with its contents and provisions.

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 Application (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.

Nonsignificant Risk Device (NSR IDE)

A NSR is a medical device that does not meet the definition of a Significant Risk Device.

Significant Risk Device (SR IDE)

A SR device is one that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

- Is for a use of substantial importance in diagnosing, curing, mitigating or treating disease, or other preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

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 (not a company) who both initiates and conducts an investigation and complies with all the obligations of both a sponsor and an investigator.

Contacts

The Office of Research and Innovation officially interprets this policy. The Office of Research and Innovation is responsible for obtaining approval for any revisions as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Please direct policy questions to the Office of Research and Innovation or Clinical Research Compliance Officer (CRCO).

Policy Specifics and Procedures

I. General Requirements

All university employees who file an Investigational New Drug Application (IND) or Significant Risk Investigational Device Exemption (IDE) with the Food and Drug Administration (FDA) as a sponsor must submit all documents relevant to the IND or IDE to the Clinical Research Compliance Officer (CRCO), who will track documentation and monitor compliance. Non-Significant Risk (NSR) IDEs are not submitted to the FDA but do require IRB approval. The CRCO will also track and monitor compliance of these NSR IDE studies. All communications to and from the FDA related to these INDs or IDEs must be submitted to the CRCO.

The CRCO maintains documents, including copies of the application, communications, safety reports, amendments, and annual reports; reminds sponsor-investigators of their reporting obligations to the FDA; and tracks reports and communications with the FDA. The CRCO, or designated staff, will monitor relevant FDA compliance via regular audits.

VCU employees may not serve as the authorized representative for a pharmaceutical company, governmental agency, academic institution, private organization, or other organization without prior authorization by the Vice President for Research and Innovation and approval through the Outside Professional Activity system.

II. Procedures

A VCU IND or IDE sponsor must submit required documentation for an IND or IDE according to the following procedures:

1. Consult CRCO.

- Before preparing an application, contact the CRCO (INDIDE@vcuhealth.org) to discuss the potential need for an IND or IDE and to discuss complying with this policy.

2. Submit required documents.

- Before submitting to FDA, submit all required documentation by completing the [FDA IND/IDE VCU Submission](#) survey at go.vcu.edu/submit/indide.
- The CRCO, or designee, may not review all documents prior to submission to the FDA unless the sponsor submits a specific request with enough advance notice to complete a substantive review, generally two to three weeks before desired submission date.
- After initial submission, all documents must be submitted to the CRCO within five business days of sending to or receiving from FDA with the exception of notices of clinical holds which must be submitted within 24 hours of receipt and or serious unanticipated adverse effects which should be submitted concurrent with FDA submission.

Forms

VCU and FDA forms and templates are located at go.vcu.edu/INDIDE (http://www.research.vcu.edu/IND_IDE/) and referenced in the [FDA IND/IDE VCU Submission](#) survey at go.vcu.edu/submit/indide (redcap.vcu.edu/rc/surveys/?s=Xbd3YgHxFe).

1. [Certification of IND/IDE Suitability](#)

(www.research.vcu.edu/IND_IDE/certification_IND_IDE_suitability.pdf)

This form is required for all VCU Faculty Held INDs and IDEs submitted to the FDA after August 1, 2014.

2. [Plans to Conduct a Clinical Investigation at Multi-Center, External Study Site](#)

This form is required for all VCU Faculty Held INDs and IDEs that are to be conducted at external VCU sites under this IND or IDE.

3. [Financial Interests Forms for All Clinical Investigators on a VCU Faculty Held IND or IDE](#)

To assist with completed FDA forms 3454 and 3455, these forms are to be collected by the Sponsor for all Clinical Investigators and held by the Sponsor for submission to the FDA as needed at the time of a New Drug Application, Premarket Approval or 510K. Note that this does not replace reporting in the AIRS system.

Related Documents

1. [VCU IND/IDE Procedure Handbook](#)

2. 21 CFR 312 – Investigational New Drug Applications

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?cfrpart=312>

3. 21 CFR 812 - Investigational Device Exemptions
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812>
4. 21 CFR 50 - Protection of Human Subjects
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>
5. 21 CFR 56 - Institutional Review Boards
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>
6. 21 CFR 54 - Financial Disclosure by Clinical Investigators
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54>
7. 21 CFR 58 – Good Laboratory Practice for Nonclinical Laboratory Studies
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58>
8. 21 CFR 820 - Quality System Regulation
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820>
9. [IRB WPP IX-1 – Principal Investigator Eligibility and Statement of Responsibilities](#)

Revision History

This policy supersedes the following archived policies:

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| 12/03/2015 | <i>Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE)</i> |
| 05/16/2018 | <i>Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE) [revised definitions of Investigational Device Exemption (IDE) and Investigational New Drug Application (IND)]</i> |

FAQ

There are no FAQ associated with this policy and procedure.