VCU
Office of the Vice President
for Research and Innovation

# Step by Step Process for IND Sponsor/Sponsor Investigator

This list includes major steps to obtaining an IND but does not include important steps like scientific rigor, feasibility, cost coverage analysis, logistics, preparing CRFs, and required steps after starting an IND.

1. After you decide on your research idea and have the basic details of the protocol, determine whether an IND is required.
    - 21 CFR 312
    - The FDA Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs)- Determining Whether Human Research Studies Can Be Conducted Without an IND (SEPTEMBER 2013)
    - IND determination algorithm: ReGARDD's "Is My Study Exempt"

2. Contact Lauren Kanigher, MD, FDA Program Manager to discuss either your need for an IND or the process and responsibilities of obtaining an IND. She can be reached at kanigherl@vcu.edu or indide@vcu.edu

3. If you do not think you need an IND but you need documentation of agreement from the FDA submit a Form 1571. For item 11, choose "Other" and specify "Request for Concurrence of Exempt Status," Cover Letter (see template) and clinical protocol to:

    **For a Drug:**

    Food and Drug Administration
    Center for Drug Evaluation and Research
    Central Document Room
    5901-B Ammendale Rd
    Beltsville, MD 20705-1266

**For a Therapeutic Biological Product:**

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave
WO71, G112
Silver Spring, MD 20993-0002

4. See the FDA website for Investigator Initiated INDs https://www.fda.gov/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications

5. See VCU IND Website for resources, handbook, policies, and templates at https://research.vcu.edu/IND_IDE/ or go.vcu.edu/indide

6. Consider whether you need to consult with VCU Innovation Gateway regarding patents, intellectual property, commercialization, and/or VCU Startups. innovationgateway.vcu.edu

7. Read the Sponsor/Investigator Responsibilities for Faculty Held INDs. This will give you an overview of the responsibilities that you will have as the sponsor and/or an investigator on an IND.

8. Look at the VCU Handbook for Faculty Sponsor/Investigators of INDs and IDEs. This can be searched topically to answer questions about preparation as well as conduct and reporting for an IND.

9. Choose your investigator(s) and determine if it will be a multisite study. Begin collecting necessary documents from investigators. Obtain 1572, CV and Financial Interest Forms from all Investigators at all sites. If multisite you will need to complete the VCU Multisite Certification Form and submit to the FDA Program Manager.

10. If this is a multisite study, determine how you will obtain IRB approval for all sites.

11. Prepare your IRB protocol for the study. If more than one protocol will be under an IND you will need to submit all protocols to the IRB and FDA. You do not have to submit all protocols at the same time. The IRB protocol and the FDA protocol must match at submission. If changes are made to one the other will need to be amended. See https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-reporting-protocol-amendments for criteria for submitting amendments to a protocol already submitted to the FDA.

12. Prepare the application: The FDA does not provide templates for submission of the IND application. FDA Guidance can be found in the document *Guidance for Industry: Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well Characterized, Therapeutic Biotechnology-*

*derived Products* (NOVEMBER 1995)

13. The FDA IND checklist is located at https://www.fda.gov/media/86911/download

14. Required Forms and Documents for Submission to FDA with the IND
    a. Cover Letter (see the VCU Template)
    b. Investigational New Drug Application (IND) form: FDA Form 1571 completed and signed
    c. Statement of Investigator form(s) Form 1572 and CV of the respective investigator(s)
    d. IND Application (See Content and Format of an IND Application)
        i. Table of contents
        ii. Introductory Statement and General Investigational Plan
        iii. Chemistry, Manufacturing, and Control Information
        iv. Pharmacology Toxicology Information
        v. Investigator's Brochure
        vi. Clinical Protocol(s)
        vii. Summary of Previous Human Experience with the Investigational New Drug
        viii. Additional Information, if applicable (e.g. drug dependence and abuse potential, pediatric studies, etc.)
        ix. Other Relevant Information, if applicable or if requested by FDA
    e. Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank: FDA Form 3674

**NOTE:** This must be submitted for the clinical protocol that accompanies the initial IND application as well as for new protocols submitted under an IND. It is advised that submission to ClinicalTrials.gov occurred after the study has been finalized based on input from the FDA and the IRB. On the Form 3674 choose the appropriate statement regarding registration. If this is a new submission of an IND which contains a clinical trial but no participants have been enrolled then choose answer B (I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies). The clinical trial must be registered *within 21 days of the first participant enrollment*. The updated form noting the registration is then submitted to the FDA as an information Amendment to the IND application. Not submitted with IND but FDA recommends collecting at the beginning of a study is the COI information. See VCU policy and forms.

15. Complete the IND/IDE Sponsor Certification

16. If this study will be conducted at sites external to VCU domestic facilities then complete the IND/IDE external to VCU (domestic facilities) Multisite Certification.

17. Per VCU policy, all documents being submitted to the FDA in the initial IND application must first be submitted to the VCU FDA Regulatory Resource Manager via the REDCap survey at https://redcap.vcu.edu/surveys/?s=NR7K7LR4JW. Also submit the IND/IDE Sponsor Certification and Multisite Certification as applicable.

18. Once submitted to the FDA Program Manager you may submit to the FDA. If you want a review of your documents prior to submission please allow time and notify the FDA Program Manager at kanigherl@vcu.edu or indide@vcu.ede.

Submit all application documents in triplicate (original and 2 copies) to:

**For a Drug:**
**Product:**

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, Md. 20705-1266

**For a Therapeutic Biological**

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
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Silver Spring, MD 20993-0002

NOTE: Documents sent via mail should be bound for submission per FDA guidelines. See https://www.fda.gov/media/89820/download

19. Documents may be submitted electronically with CDER's NextGen Portal (for submissions not required in eCTD). More information on this Electronic Regulatory Submission and Review can be found here:

20. Receipt of documents by the FDA. When the FDA receives your application an IND number will be assigned, and it will be forwarded to the appropriate reviewing division. The Sponsor- Investigator will receive a letter which will contain the IND assigned number, the date of receipt of the original application, address where future submissions to the IND should be sent, and the name and contact information for the FDA person to who questions should be directed. This document should be submitted to the IRB of record and submitted through the VCU FDA Submission Portal.

21. REMINDER: Studies cannot be initiated prior to IRB approval. Also, studies under the IND cannot be initiated until 30 days after the date of receipt of the IND by the FDA unless you receive earlier notification from the FDA that the studies may begin or an FDA Clinical Hold has been lifted.

22. View the essential documents and begin the regulatory binder and checklist.

Version 1: July 13, 2014
Version 2: August 27, 2015
Version 3: September 22, 2017
Version 4: August 25, 2020
Version 5: July 29, 2021