

Step by Step Process for IND Sponsor/Sponsor Investigator

This list includes major steps to obtaining an IND/IDE it 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. See 21 CFR 312, FDA Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs)- Determining Whether Human Research Studies Can Be Conducted Without an IND
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf> and IND determination algorithm.
2. Contact Betsy Ripley, MD, MS VCU Clinical Research Compliance Officer to discuss either your need for an IND or the process and responsibilities of obtaining an IND. She can be reached at eripley@mcvh-vcu.edu or 804-828-1955.
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 Drug Evaluation and Research
 Therapeutic Biological Products Document Room
 5901-B Ammendale Road
 Beltsville, MD 20705-1266

4. See the FDA website for Investigator Initiated IND's
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343349.htm>
5. See VCU CRCO IND Website for resources, handbook, policies, and templates. xxxx
6. Consider whether you need to consult with VCU Innovation Gateway regarding patents, intellectual property, commercialization, and/or VCU Startups.
<http://www.research.vcu.edu/ott/index.htm>
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 CRCO.
10. If this is multisite 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 <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm360054.htm> for criteria for submitting amendments to a protocol already submitted to the FDA.
12. Preparing the application: The FDA does not provide templates for submission of the IND application. Guidance can be found in Guidance for Industry content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well Characterized, Therapeutic Biotechnology-derived at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM074980.pdf>
13. The FDA IND checklist is located here <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/UCM368873.pdf>
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: 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

Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank: Form 3674 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 is study will be conducted at sites external to VCU domestic facilities then complete the IND/IDE external to VCU (domestic facilities) Multisite Certification.
17. All documents being submitted to the FDA must first be submitted to the VCU Clinical Research Compliance Officer via the REDCap survey. Also submit the IND/IDE Sponsor Certification and Multisite Certification as applicable.
18. Once submitted to the CRCO you may submit to the FDA. If you want a review of your documents prior to submission please allow time and notify the CRCO at eripley@mcvh-vcu.edu. Submit all application documents in triplicate (original and 2 copies) to:

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Central Document Room
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Therapeutic Biological Products Document Room
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Beltsville, MD 20705-1266

19. Documents should be bound for submission. See <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm> .
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.
21. Studies cannot be initiated prior to IRB approval and 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.