IND Development Process

- IND Development Overview
- The Pre-IND Process
- The IND Clinical Study Protocol
- Preparing the Initial IND Application Submission
- Submitting the IND
- Maintaining the IND
- IND Templates, Education and Useful Links

IND Development Overview

Confused about the need to file an IND? Think your study may be exempt? Not sure where to start? You are not alone. ResearchGo provides information, templates and resources to guide you through the IND process.

An academic researcher may be required to submit an IND application to the FDA in order to study a marketed medical product in a new (i.e. unapproved) clinical indication. An investigator is always required to hold an IND to study an unmarketed (i.e. unapproved) medical product. In both cases, the products are considered "investigational" by FDA. The vast majority of INDs on file with the FDA are for noncommercial research.

This toolkit (adapted from The Institute of Translational Health Sciences) helps you navigate each step of the IND process by providing guidance and templates relevant to each step. The information provided focuses on INDs for studies of marketed medical products for new indications.

Please review the latest FDA guidance for determining the need for an IND. For additional information on submitting INDs for unmarketed medical products, review of your IND application submission, or need assistance, please contact ResearchGo.

Last updated: 7 Mar 2025

The Pre-IND Process

Review the five requirements in the IND Exemptions below to determine if your study qualifies for exemption from an IND (21 CFR 312.2).

Still not sure? Start with the IND Decision Tool. Pay particular attention to requirement #3. The FDA Draft Guidance Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted without an IND provides more detail on a range of topics, including the process for consulting with FDA. In addition, please consult with the IRB to determine whether a formal letter from FDA is required to document the IND Exemption.

If you think an INTERACT meeting or pre-IND meeting with the FDA is warranted, please contact ResearchGo for

assistance. Templates for a meeting request letter and meeting briefing packages are provided below.

- IND Exemption Letter
- Pre-IND Consultation Contact List
- Request for Pre-IND Meeting
- Pre-IND Briefing Package
- INTERACT Meeting Briefing Package
- INTERACT Meeting Request - CBER
- INTERACT Meeting Request - CDER
- Types of Meetings with the FDA

IND Exemptions

A drug that is lawfully marketed in the United States is exempt from the requirements for an IND if all of the following apply:

- The investigation is not intended to be reported to the FDA in support of a new indication for use or any other significant change in the labeling for the drug.
- The investigation is not intended to support a significant change in the advertising for a prescription drug product.
- The investigation does not involve a change in route of administration, dosage level, or patient population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with use of the drug product.
- The investigation is conducted in compliance with the requirements for IRB review (21 CFR 56) and informed consent (21 CFR 50).
- The drug may not be represented as safe or effective for the purposes for which it is under investigation, nor may it be commercially distributed or sold.

For additional information about whether or not an IND is required for a cancer therapy drug, contact the NCI Regulatory Affairs Branch.

Need assistance or have regulatory questions? Please contact ResearchGo.

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The IND Study Protocol

A fully developed GCP compliant clinical protocol is the basis for both the IRB application and the initial IND application submission.

Review the IND Protocol Template for required content. A completed clinical protocol must be included in the IND application.

Start with a protocol synopsis (pages 9 to 11 of the protocol template). The protocol synopsis will be valuable if you are planning a pre-IND meeting. Compile a reference list - include all published articles and unpublished reports or manuscripts cited.

Collect a copy of each article or report listed. For approved medications, review the Prescribing Information.

Product information should be integrated into the clinical protocol. In addition, your safety plan should acknowledge

known safety risks from the prescribing information and incorporate relevant safety monitoring into the clinical protocol - or show why it is not relevant to the disease under study.

Need assistance or have regulatory questions? Please contact ResearchGo.

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Prepare the Initial IND Application Submission

The IND Sponsor-Investigator compiles information in three broad areas:

1. **Nonclinical Components - Animal Pharmacology and Toxicology Studies:** Preclinical data used to assess whether the product is reasonably safe for studies in humans. For studies of marketed drugs in new indications, this section might contain data from animal models supporting the utility of the drug in the new indication.

2. **Chemistry, Manufacturing, and Controls (CMC):** The composition, stability, and controls used for manufacturing the drug substance and the drug product.

    - For marketed drugs, the FDA already has this information on file in the manufacturer's Drug Master File (DMF). For unmarketed drugs, the Investigator-Sponsor can request a Letter of Authorization (LOA) from the manufacturer to cross-reference the Drug Master File or existing IND if there is one. Although it is not required, the LOA is recommended.

    - For legally marketed drugs, the information in the product label or package insert might suffice for the manufacturing information.

3. **Clinical Components:** A detailed clinical study protocol, summary of previous human experience with the investigational drug, and Investigator Brochure (IB) are required sections of an IND application. The IB is primarily needed for multi-center studies and is a summary of information needed by participating investigators to assess the safety of the investigational product. For approved medications, a copy of the Prescribing Information may be used in place of an IB.

The IND Sponsor-Investigator prepares the IND using the IND Application Template format. The initial IND submission should be accompanied by a cover letter, an IND Application Form - FDA 1571 (see instructions) and a ClinicalTrials.Gov Certification of Compliance - FDA 3674.

The IND Sponsor-Investigator must also submit a Statement of Investigator - FDA Form FDA 1572 (see instructions). This form is a formal contract with FDA to adhere to Informed Consent, IRB review, and general IND regulations.

Need assistance or have regulatory questions? Please contact ResearchGo.

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Submit the Initial IND and Receive an IND Number

Research IND applications are strongly encouraged to be submitted electronically for efficiency, although paper submissions are still accepted. Electronic submission remains optional for sponsor-investigators at academic institutions.

If submitting electronically, follow the FDA's Center-specific standards and guidance for CDER or CBER. Additionally, please refer to the following contacts and guidance:

- Questions and general information regarding the preparation of submissions in electronic format may be directed to CDER at esub@fda.hhs.gov or CBER at esubprep@cber.fda.gov. Questions regarding submission of datasets to CDER may be sent to edata@fda.hhs.gov.
- Please visit the Electronic Common Technical Document (eCTD) web page to access a wide variety of resources and support regarding eCTD submissions.

For paper submissions, send the IND application in triplicate (one original and two copies) to the appropriate FDA center.

For CDER-Regulated Products:
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

For CBER-Regulated Products:
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

The FDA responds to the initial submission of a new IND application with a letter, acknowledging receipt of the submission and assigning the IND number. The sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND application for safety to assure that research subjects will not be subjected to unreasonable risk. If there are no issues, the IND generally goes into effect 30 days after the Date of Receipt shown in this letter. It is advised that you obtain written confirmation (email or fax) that the FDA review has been completed and that the Study May Proceed. Please upload FDA Study May Proceed confirmation in BruinIRB.

The IND Acknowledgement letter also provides instructions for submission methods and contact information for all subsequent submissions to the IND.

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Maintain the IND

To maintain an IND, the Sponsor-Investigator has three reporting responsibilities. Each type of report is time-sensitive and has a specific structure. The first two, Protocol Amendments and Safety Reports, are submitted when needed to

report updated or unforeseen circumstances. The third type, the Annual Report, is submitted every year, even when no studies are in progress under the IND. Send all submissions following the instructions provided in the IND Acknowledgement letter received in response to the initial submission.

IND Protocol Amendments
Once an IND is in effect, the IND Sponsor-Investigator is responsible to amend it as needed to ensure that the clinical investigations are conducted according to protocols included in the application. An IND Protocol Amendment should have a IND Amendment Cover Letter and is a submission to an existing IND notifying the FDA of one or more of the following:

- New study protocol
- Change in an existing study protocol
- New investigator
- Transfer of IND Obligations

IND Annual Reports
An IND Annual Report requires a cover letter to CDER or CBER and is a brief report of the progress of studies conducted under an IND, due annually to the FDA within 60 days of the anniversary of the date that the IND went into effect.

IND Safety Reports
An IND Safety Report is expedited, written notification to the FDA of an adverse experience associated with the use of a study drug that is both serious and unexpected. “Associated with the use of the drug” is a Code of Federal Regulations term meaning “There is a reasonable possibility that the experience may have been caused by the drug.” An IND Safety Report consists of a MedWatch Form and a cover letter. It is due to the FDA within 15 calendar days of initial receipt of the SAE Report.

Need assistance or have regulatory questions? Please contact ResearchGo.

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IND Templates, Education & Useful Links

- IND Decision Tool
- IND Exemption Letter (example 1)
- IND Exemption Letter (example 2)
- Pre-IND Briefing Package
- Pre-IND Meeting Request
- INTERACT Meeting Briefing Package
- INTERACT Meeting Request - CBER
- INTERACT Meeting Request - CDER

IND Submissions

- FDA IND Application
- FDA Form 1571 - IND Application and Instructions (not optimized for chrome)
- FDA Form 1572 - IND Investigator Statement and Instructions
- FDA Form 1572 (Box 8) - Protocol Summary Template
- UCLA Form FDA 1572 SOP
- FDA Form 3454 - Financial Interest and Arrangement
- FDA Form 3455 - Investigator Financial Interest Disclosure

- FDA Form 3674 - IND Certification of Compliance
- IND Application Template (approved drugs)
- IND Application Template (expanded)
- IND Cover Letter
- UCLA Protocol Template
- Request for Orphan Drug Determination

Expanded Access/Compassionate Use

- Single Patient IND
- Expanded Access IND Submission
- Form 3926 (Individual Patient Expanded Access IND)
- Form 3926 Instructions
- UCLA OHRPP Guidance - Emergency Use of a Test Article

IND Amendments

- IND Amendment Cover Letter
- IND Protocol Amendment Template
- IND Transfer of Obligations

Annual and Final Reports

- IND Annual Report Submission Checklist
- IND Annual Report Cover Letter - CDER
- IND Annual Report Cover Letter - CBER
- IND Annual Report Template
- IND Final Report Cover Letter
- IND Final Report Template

Safety Reports

- IND Safety Report Cover Letter
- IND Safety Report and Instructions (not optimized for chrome)
- Safety Reporting Guidance

Useful Links

- 21 CFR 312
- Biological IND Submissions
- Center for Drug Evaluation & Research Guidance Documents (CDER)
- Center for Biologics Evaluation and Research Guidance Documents (CBER)
- Content and Format of IND Applications
- Exploratory INDs (aka Phase 0)
- FAQs about the IND Application
- FAQs about the Pre-IND Meeting
- FDA Form 1571
- FDA Form 1572
- FDA Form 3454
- FDA Form 3455
- FDA Form 3674
- Investigational New Drug Applications
- Mobile Medical Apps
- UCLA Guidance for IND

Need assistance or have regulatory questions? Please contact ResearchGo.

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Source URL:https://www.researchgo.ucla.edu/ind-development-process

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