

# Investigational New Drug (IND) Application

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## Introduction

Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.

FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer), having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

There are three IND types:

- An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.23 (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>) or Sec. 312.20 (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.2>). It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories:

- Commercial
- Research (non-commercial)

The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use).
- Manufacturing Information - Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product.

This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.

- Clinical Protocols and Investigator Information - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators--professionals (generally physicians) who oversee the administration of the experimental compound--to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

*This web site is designed for individuals from pharmaceutical companies, government agencies, academic institutions, private organizations, or other organizations interested in bringing a new drug to market. Each of the sections below contains information from CDER to assist you in the IND application process. For specific information, click on a link to go directly to a section or web page.*

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## Resources for IND Applications

The following resources include the legal requirements of an IND application, assistance from CDER to help you meet those requirements, and internal IND review principles, policies and procedures.

## Pre-IND Consultation Program

CDER's [Pre-Investigational New Drug Application \(IND\) Consultation Program \(/pre-ind-consultation-program\)](#) fosters early communications between sponsors and new drug review divisions to provide guidance on the data necessary to warrant IND submission. The review divisions are organized generally along therapeutic class.

## Guidance Documents for INDs

Guidance documents represent the Agency's current thinking on a particular subject. These documents provide FDA review staff and applicants/sponsors with guidelines to the processing, content, and evaluation/approval of applications and also to the design, production,

manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and establish inspection and enforcement procedures.

Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the courts. An alternative approach may be used if it satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office.

To find guidance documents to help prepare INDs, go to [Guidances \(Drugs\) \(/drugs/guidance-compliance-regulatory-information/guidances-drugs\)](#) and use "investigational" in the search box.

## Laws, Regulations, Policies and Procedures

The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. *The Federal Food, Drug, and Cosmetic Act (/federal-food-drug-and-cosmetic-act-fdc-act)* is the basic food and drug law of the U.S. The law is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

### *Code of Federal Regulations (CFR)*

The final regulations published in the *Federal Register* (<https://www.federalregister.gov/public-inspection>) (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the *Code Of Federal Regulations (CFR)* (<http://www.ecfr.gov/cgi-bin/ECFR?page=browse>). The *CFR* is divided into 50 titles that represent broad areas subject to Federal regulations. The FDA's portion of the *CFR* interprets the *The Federal Food, Drug, and Cosmetic Act (/federal-food-drug-and-cosmetic-act-fdc-act)* and related statutes. *Section 21 of the CFR* (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>) contains most regulations pertaining to food and drugs. The regulations document all actions of all drug sponsors that are required under Federal law.

The following regulations apply to the IND application process:

Search:

| Number         | Regulation                                                                                                                                                                                                                                                                                                                                                                              |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 21CFR Part 201 | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=201&amp;showFR=1">Drug Labeling</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=201&amp;showFR=1">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=201&amp;showFR=1</a> )                                              |
| 21CFR Part 312 | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312">Investigational New Drug Application</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312</a> )                                                              |
| 21CFR Part 314 | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314">INDA and NDA Applications for FDA Approval to Market a New Drug (New Drug Approval)</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314</a> )               |
| 21CFR Part 316 | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=316">Orphan Drugs</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=316">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=316</a> )                                                                                      |
| 21CFR Part 50  | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&amp;showFR=1">Protection of Human Subjects</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&amp;showFR=1">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&amp;showFR=1</a> )                                  |
| 21CFR Part 54  | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&amp;showFR=1">Financial Disclosure by Clinical Investigators</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&amp;showFR=1">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&amp;showFR=1</a> )                |
| 21CFR Part 56  | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56&amp;showFR=1">Institutional Review Boards</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56&amp;showFR=1">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56&amp;showFR=1</a> )                                   |
| 21CFR Part 58  | <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58&amp;showFR=1">Good Lab Practice for Nonclinical Laboratory [Animal] Studies</a> ( <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58&amp;showFR=1">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58&amp;showFR=1</a> ) |

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- [Final Rule: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans \(/drugs/investigational-new-drug-ind-application/final-rule-investigational-new-drug-safety-reporting-requirements-human-drug-and-biological-products\)](#) (issued 9/28/2010)

## Manual of Policies and Procedures (MaPPs)

CDER's [Manual of Policies and Procedures \(MaPPs\) \(/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp\)](#) are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities. All MAPPs are available for the public to review for a better understanding of office policies, definitions, staff responsibilities and procedures. To find MaPPs

of particular interest to IND sponsors, go to [CDER Manual of Policies and Procedures \(/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp\)](#) and use "INDs" in the search box.

## Emergency Use of an Investigational Drug or Biologic

- [Emergency Use of an Investigational Drug or Biologic - Information Sheet \(/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic-information-sheet\)](#)
- The [Guidance for Institutional Review Boards and Clinical Investigators \(/regulatory-information/search-fda-guidance-documents/non-local-irb-review-information-sheet\)](#) contains information on: Obtaining an Emergency IND, Emergency Exemption from Prospective IRB, Approval Exception from Informed Consent, and Requirement Planned Emergency Research, Informed Consent Exception.
- [Physician Request for a Single Patient IND for Compassionate or Emergency Use \(/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use\)](#)
- [Instructions for Sponsors of Emergency Investigational New Drug \(EIND\) Applications for Antimicrobial Products \(/drugs/investigational-new-drug-ind-application/emergency-investigational-new-drug-eind-applications-antiviral-products\)](#). From the Office of Antimicrobial Products, Division of Antiviral Products

### Emergency use requests:

- For investigational biological products regulated by CBER, call 800-835-4709 or 240-402-8020.
- For all other investigational drugs, call 301-796-3400.
- After working hours, call FDA's Office of Emergency Operations at 1-866-300-4374 or 301-796-8240.

## CDER Learn Courses

- [Chemistry, Manufacturing, and Controls \(CMC\) Perspective of the IND course \(http://www.accessdata.fda.gov/cder/cmc/index.htm\)](#)
- [Courses for Industry on drug development \(/drugs/cder-small-business-industry-assistance-sbia/cder-small-business-and-industry-assistance-sbia-learn\)](#)

## Guidance documents to help prepare INDs include:

Search: 

| Title                                                                                                                                                                                                                                                                                                                                                                                                                              | Issued<br>Date |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <u>Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations (PDF - 805KB) (http://wcms-internet.fda.gov/files/drugs/published/Bioavailability-and-Bioequivalence-Studies-Submitted-in-NDAs-or-INDs—General-Considerations.pdf)</u>                                                                                                                                                            | 3/17/2014      |
| <u>Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products. Questions and Answers (PDF - 14KB) (http://wcms-internet.fda.gov/files/drugs/published/Content-and-Format-of-INDs-for-Phase-1-Studies-of-Drugs--Including-Well-Characterized--Therapeutic--Biotechnology-Derived-Products--Questions-and-Answers.pdf)</u>                                   | 10/1/2000      |
| <u>Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products (PDF - 42KB) (http://wcms-internet.fda.gov/files/drugs/published/Content-and-Format-of-Investigational-New-Drug-Applications-(INDs)-for-Phase-1-Studies-of-Drugs--Including-Well-Characterized--Therapeutic--Biotechnology-derived-Products.pdf)</u> | 11/1/1995      |
| <u>Current Good Manufacturing Practice for Phase 1 Investigational Drugs (PDF - 92KB) (http://wcms-internet.fda.gov/files/drugs/published/Current-Good-Manufacturing-Practice-for-Phase-1-Investigational-Drugs.pdf)</u>                                                                                                                                                                                                           | 7/14/2008      |
| <u>Drug Master Files: Guidelines (http://wcms-internet.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines)</u>                                                                                                                                                                                                                                                                                                             | 9/1/1989       |
| <u>Exploratory IND Studies (PDF - 220KB) (http://wcms-internet.fda.gov/files/drugs/published/Exploratory-IND-Studies.pdf)</u>                                                                                                                                                                                                                                                                                                      | 1/12/2006      |
| <u>FDA IND, NDA, ANDA, or Drug Master File Binders (http://wcms-internet.fda.gov/drugs/drug-master-files-dmfs/fda-ind-nda-anda-or-drug-master-file-binders)</u>                                                                                                                                                                                                                                                                    |                |
| <u>Immunotoxicology Evaluation of Investigational New Drugs (PDF - 100KB) (http://wcms-internet.fda.gov/files/drugs/published/Immunotoxicology-Evaluation-of-Investigational-New-Drugs.pdf)</u>                                                                                                                                                                                                                                    | 10/1/2002      |
| <u>IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (PDF - 172KB) (http://wcms-internet.fda.gov/files/drugs/published/IND-Exemptions-for-Studies-of-Lawfully-Marketed-Drug-or-Biological-Products-for-the-Treatment-of-Cancer.pdf)</u>                                                                                                                                      | 1/15/2004      |
| <u>Safety Assessment for IND Safety Reporting Guidance for Industry (PDF - 411KB) (http://wcms-internet.fda.gov/files/drugs/published/Safety-Assessment-for-IND-Safety-Reporting-Guidance-for-Industry.pdf)</u>                                                                                                                                                                                                                    |                |

| Title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Issued<br>Date |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <a href="http://wcms-internet.fda.gov/files/drugs/published/Safety-Reporting-Requirements-for-INDs-(Investigational-New-Drug-Applications)-and-BA-BE-(Bioavailability-Bioequivalence)-Studies.pdf">Safety Reporting Requirements for INDs (Investigational New Drug Applications) and BA/BE (Bioavailability/Bioequivalence) Studies (PDF - 227KB)</a> ( <a href="http://wcms-internet.fda.gov/files/drugs/published/Safety-Reporting-Requirements-for-INDs-(Investigational-New-Drug-Applications)-and-BA-BE-(Bioavailability-Bioequivalence)-Studies.pdf">http://wcms-internet.fda.gov/files/drugs/published/Safety-Reporting-Requirements-for-INDs-(Investigational-New-Drug-Applications)-and-BA-BE-(Bioavailability-Bioequivalence)-Studies.pdf</a> ). | 12/19/2012     |

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## Manuals of Policies and Procedures (MAPP)

Search:

| Title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Issued<br>Date |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <a href="/media/71646/download?attachment">Consulting the Controlled Substance Staff on INDs and Protocols That Use Schedule I Controlled Substances and Drugs (PDF - 89KB)</a> ( <a href="/media/71646/download?attachment">/media/71646/download?attachment</a> )                                                                                                                                                                                                                                                                          | 5/14/2003      |
| <a href="/media/71646/download?attachment">Consulting the Controlled Substance Staff on INDs and Protocols That Use Schedule I Controlled Substances and Drugs (PDF - 89KB)</a> ( <a href="/media/71646/download?attachment">/media/71646/download?attachment</a> )                                                                                                                                                                                                                                                                          | 5/14/2003      |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/IND-Clinical-Holds.pdf">IND Clinical Holds (PDF - 94KB)</a> ( <a href="http://wcms-internet.fda.gov/files/about%20fda/published/IND-Clinical-Holds.pdf">http://wcms-internet.fda.gov/files/about%20fda/published/IND-Clinical-Holds.pdf</a> )                                                                                                                                                                                                                              | 2/20/2018      |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/IND-Clinical-Holds.pdf">IND Clinical Holds (PDF - 94KB)</a> ( <a href="http://wcms-internet.fda.gov/files/about%20fda/published/IND-Clinical-Holds.pdf">http://wcms-internet.fda.gov/files/about%20fda/published/IND-Clinical-Holds.pdf</a> )                                                                                                                                                                                                                              | 2/20/2018      |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Exception-from-Informed-Consent-Requirements-for-Emergency-Research.pdf">INDs: Exception from Informed Consent Requirements for Emergency Research (PDF - 283KB)</a> ( <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Exception-from-Informed-Consent-Requirements-for-Emergency-Research.pdf">http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Exception-from-Informed-Consent-Requirements-for-Emergency-Research.pdf</a> ) | 11/17/2014     |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Exception-from-Informed-Consent-Requirements-for-Emergency-Research.pdf">INDs: Exception from Informed Consent Requirements for Emergency Research (PDF - 283KB)</a> ( <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Exception-from-Informed-Consent-Requirements-for-Emergency-Research.pdf">http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Exception-from-Informed-Consent-Requirements-for-Emergency-Research.pdf</a> ) | 11/17/2014     |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Processing-Treatment-INDs-and-Treatment-Protocols.pdf">INDs: Processing Treatment INDs and Treatment Protocols (PDF - 164KB)</a> ( <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Processing-Treatment-INDs-and-Treatment-Protocols.pdf">http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Processing-Treatment-INDs-and-Treatment-Protocols.pdf</a> )                                                                         | 12/9/2011      |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Processing-Treatment-INDs-and-Treatment-Protocols.pdf">INDs: Processing Treatment INDs and Treatment Protocols (PDF - 164KB)</a> ( <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Processing-Treatment-INDs-and-Treatment-Protocols.pdf">http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Processing-Treatment-INDs-and-Treatment-Protocols.pdf</a> )                                                                         | 12/9/2011      |

| Title                                                                                                                                                                                                                                                                                                                                                                                                                                 | Issued<br>Date |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Review-of-Informed-Consent-Documents.pdf">INDs: Review of Informed Consent Documents (PDF - 183KB) (http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Review-of-Informed-Consent-Documents.pdf)</a>                                                                                                                                              | 5/2/2014       |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Review-of-Informed-Consent-Documents.pdf">INDs: Review of Informed Consent Documents (PDF - 183KB) (http://wcms-internet.fda.gov/files/about%20fda/published/INDs--Review-of-Informed-Consent-Documents.pdf)</a>                                                                                                                                              | 5/2/2014       |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/Review-of-Investigational-New-Drug-Applications-(Bio-INDs)-by-the-Office-of-Generic-Drugs.pdf">Review of Investigational New Drug Applications (Bio-INDs) by the Office of Generic Drugs (PDF - 126KB) (http://wcms-internet.fda.gov/files/about%20fda/published/Review-of-Investigational-New-Drug-Applications-(Bio-INDs)-by-the-Office-of-Generic-Drugs.pdf)</a> | 10/25/2016     |
| <a href="http://wcms-internet.fda.gov/files/about%20fda/published/Review-of-Investigational-New-Drug-Applications-(Bio-INDs)-by-the-Office-of-Generic-Drugs.pdf">Review of Investigational New Drug Applications (Bio-INDs) by the Office of Generic Drugs (PDF - 126KB) (http://wcms-internet.fda.gov/files/about%20fda/published/Review-of-Investigational-New-Drug-Applications-(Bio-INDs)-by-the-Office-of-Generic-Drugs.pdf)</a> | 10/25/2016     |

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## Related Resources

- [CDER Investigational New Drug \(IND\) Renumbering \(/drugs/investigational-new-drug-ind-application/investigational-new-drug-ind-renumbering\)](/drugs/investigational-new-drug-ind-application/investigational-new-drug-ind-renumbering)
- [Drug Applications and Current Good Manufacturing Practice \(CGMP\) Regulations \(/drugs/manufacturing/current-good-manufacturing-practice-cgmp-regulations\)](/drugs/manufacturing/current-good-manufacturing-practice-cgmp-regulations)
- [Drug Development and Review Definitions \(/drugs/investigational-new-drug-ind-application/drug-development-and-review-definitions\)](/drugs/investigational-new-drug-ind-application/drug-development-and-review-definitions)
- [Electronic Regulatory Submissions and Review Helpful Links \(/drugs/electronic-submissions-cder/electronic-regulatory-submissions-and-review-helpful-links\)](/drugs/electronic-submissions-cder/electronic-regulatory-submissions-and-review-helpful-links)
- [FDAAA Certification to Accompany Drug, Biological Product, and Device Applications or Submissions \(/regulatory-information/food-and-drug-administration-amendments-act-fdaaa-2007/fdaaa-certification-accompany-drug-biological-product-and-device-applications-or-submissions\)](/regulatory-information/food-and-drug-administration-amendments-act-fdaaa-2007/fdaaa-certification-accompany-drug-biological-product-and-device-applications-or-submissions)
- [Federal Regulations for Clinical Investigators \(/drugs/investigational-new-drug-ind-application/federal-regulations-clinical-investigators\)](/drugs/investigational-new-drug-ind-application/federal-regulations-clinical-investigators)
- [Information for Clinical Investigators \(INDs\) \(/drugs/investigational-new-drug-ind-application/information-clinical-investigators-ind\)](/drugs/investigational-new-drug-ind-application/information-clinical-investigators-ind)
- [Institutional Review Boards \(IRBs\) and Protection of Human Subjects in Clinical Trials \(/about-fda/about-center-drug-evaluation-and-research/institutional-review-boards-irbs\)](/about-fda/about-center-drug-evaluation-and-research/institutional-review-boards-irbs)

and-protection-human-subjects-clinical-trials)

- CDER Small Business & Industry Assistance (SBIA) ([/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia](#))
- Small Business Assistance: FAQs on Drug Development and IND Applications ([/drugs/cder-small-business-and-industry-assistance/small-business-assistance-frequently-asked-questions-drug-development-and-investigational-new-drug](#))
- Small Business Assistance: FAQs on the Pre-Investigational New Drug (IND) Meeting ([/drugs/cder-small-business-and-industry-assistance/small-business-and-industry-assistance-frequently-asked-questions-pre-investigational-new-drug-ind](#))
- New Drug Application (NDA) ([/drugs/types-applications/new-drug-application-nda](#))
- Therapeutic Biologics Applications (BLA) ([/drugs/types-applications/therapeutic-biologics-applications-bla](#))
- Abbreviated New Drug Application (ANDA) ([/drugs/types-applications/abbreviated-new-drug-application-anda](#))
- Investigator-Initiated IND Applications ([/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications](#))
- Final Rule: IND Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans ([/drugs/investigational-new-drug-ind-application/final-rule-investigational-new-drug-safety-reporting-requirements-human-drug-and-biological-products](#))
- Reorganization of the Office of New Drugs with Corresponding Changes to the Office of Translational Sciences and the Office of Pharmaceutical Quality (<http://wcms-internet.fda.gov/drugs/regulatory-science-research-and-education/reorganization-office-new-drugs-corresponding-changes-office-translational-sciences-and-office>)