Selected List of Resources for IND

Before Trial

Pre-IND

FDA Guidance

- IND Exemption- FDA Guidance
- IND Exemptions - Lawfully Marketed Drug / Biological Products (Treatment of Cancer)
- IND Applications- Sponsor Investigator
- Request for Designation (RFD)

Other useful Links

- Pre-IND Consultation Program (FDA)
- Pre-IND Consultation CDER

IND Preparation & Submission

Research INDs and subsequent amendments (CDER) (Drugs/ Small Molecules)

- CDER NextGen Portal
- CDER NextGen Portal FAQs
- CDER NextGen Portal Reference guide
- Electronic Submission Gateway (ESG) (for < 10 Gb or less)

Research INDs and subsequent amendments (CBER) (Biologics/ Large Molecules)

- eCTD Specifications Guidance (for >10 Gb)
- Sample submission- eCTD
- IND Submission - CBER Guidance
- Electronic Submission Gateway (ESG) (for < 10 Gb or less)

Forms & Other Guidance documents

- Requesting a Pre-Assigned application Number
- List of Regulatory and Administrative Components- IND
- **Form 1571** (Instructions for completion)
- **Form 1572** (Information sheet guidance for Sponsors, Clinical Investigators and IRBs)
- **Form 3674***(Instructions for

During Trial

Maintenance Activities

Amendments

- Protocol Amendments
- Information Amendments (new toxicology, CMC info etc.)

Safety Reports

- **Form 3500A***(Instructions for completion)
- Form 1571 (Instructions for completion)
- Guidance: Safety Reporting Requirements for INDs and BA/BE studies
- Final Rule: IND Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans
- Sponsor Responsibilities- Safety Reporting requirements for IND and BA/ BE studies guidance for Industry
- Investigator Responsibilities- Safety Reporting for Investigational Drugs
- Guidance for Clinical Investigators, Sponsors- AE Reporting
- Where to Send Completed Form FDA 3500A MANDATORY Reporting Form

Annual Reports

- **Form 1571** (Instructions for completion)
- Information list- to be included in Annual Report
- Guidance for Clinical Investigators, Industry and FDA Staff: Financial disclosure by Clinical Investigators

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End of Trial

Withdraw/Termination

- Withdrawal of IND
- Termination of IND
- **Form 1571** (Instructions for completion)
- Final Report *

*Template on our Regulatory Support Office webpage

Selected List of Resources for IDE

Before Trial

Pre-IDE (Consultation)

FDA Guidance

- Q-Submission Program: Requests for Feedback and Meetings (Medical Device)
- Significant Risk and Nonsignificant Risk Medical Device Studies
- IDEs for Early Feasibility medical device Clinical Studies & First in Human (FIH) Studies
- FDA Decisions for IDEs

Other Useful Links

- IDE Exempt Investigations
- In Vitro Diagnostic (IVD) Device Studies -Frequently Asked

IDE Material Preparation & Submission

IDE Submission to CDRH

- eCopy Program- FDA guidance
- eCopy Program Instructions
- eSubmitter-eCopies Tool
- eSubmitter Quick Guide
- IDE Application

Other useful links

- Combination Product Contacts
- CDRH Contact
- Sponsor Responsibilities for Significant Risk Device Studies
- Sponsor Responsibilities for Nonsignificant Risk Device Studies
- Investigator Responsibilities for Significant Risk Device Studies
- Investigator Responsibilities for

During Trial

Maintenance Activities

Amendments

- FDA Guidance: Changes or Modifications During the Conduct of a Clinical Investigation
- IDE Modifications

IDE Reports

- Sponsor Reports
- Suggested Format for IDE Progress Report
- Suggested Format for IDE Final Report
- Investigator Reports
- Investigator Annual Progress Reports

Other useful links:

- Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices

End of Trial

Withdraw/Termination

- Suggested Format for IDE Final Report
- Investigator Final Reports

Selected List of Resources for EAP

Before Trial

EAP (Consultation)

FDA Guidance

- Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers Guidance for Industry (fda.gov)

Other useful links

- Expanded Access | Information for Physicians
- Expanded Access Categories for Drugs (Including Biologics)
- Expanded Access for Medical Devices

Material Preparation & Submission

Single/ Individual/ Non-Emergency, Emergency patient use IND

- **Form 3926** (Instructions to complete) by mail
- Non-Emergency Individual Patient IND Process Step by Step Instructions
- Emergency Individual Patient IND Process Step by Step
- 21 CFR 312.310 Individual patients, including emergency use

Intermediate Access, Treatment INDs

- **Form 1571** and
- **Form 1572**
- Quick Guide to Forms 1571 and 1572
- Intermediate-Size Population IND Step-by-step instructions
- 21 CFR 312.315 Intermediate-size patient populations
- 21 CFR 312.320 Treatment IND or treatment protocol
- Expanded Access IND Application: Contents and Format

During Trial

Maintenance Activities

Follow-up Expanded Access Reports

- Amendments
- Safety Reports
  - **Form 3500A***(Instructions for completion)
  - Form 1571 (Instructions for completion)
  - Where to Send Completed Form FDA 3500A MANDATORY Reporting Form
- Annual Reports
  - **Form 1571** (Instructions for completion)

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End of Trial

Withdraw/Termination

Expanded Access IND

- **Form 1571** (Instructions for completion)
- Final Report *

Expanded Access IDE

- Suggested Format for IDE Final Report
- Investigator Final Reports

*Template on our Regulatory Support Office webpage