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

*Open the link to this form and if you see the 'Please wait' page, download and open with Adobe Acrobat to use this form

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