IND Templates, Education and Useful Links

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- IND Decision Tool
- IND Exemption Letter (example 1)
- IND Exemption Letter (example 2)
- Pre-IND Briefing Packet
- Pre-IND Meeting Request

IND Submissions

- FDA IND Checklist
- 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

IND Amendments

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

Annual and Final Reports

- 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 the CTSI Office of FDA Affairs.

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