IND Templates, Education and Useful Links

IND Templates, Education & Useful Links

- 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 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 Cover Letter (CDER)
- IND Annual Report Cover Letter (CBER)
- IND Annual Report Template
- IND Final Report Cover Letter
- IND Final Report Template

Safety Reports
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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