

[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 Package](#)
- [Pre-IND Meeting Request](#)
- [INTERACT Meeting Briefing Package](#)
- [INTERACT Meeting Request - CBER](#)
- [INTERACT Meeting Request - CDER](#)

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 Submission Checklist](#)
- [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](#)

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