Submitting the IND

Submit the Initial IND and Receive an IND Number

Research IND applications are strongly encouraged to be submitted electronically for efficiency, although paper submissions are still accepted. Electronic submission remains optional for sponsor-investigators at academic institutions.

If submitting electronically, follow the FDA's Center-specific standards and guidance for CDER or CBER. Additionally, please refer to the following contacts and guidance:

- Questions and general information regarding the preparation of submissions in electronic format may be directed to CDER at esub@fda.hhs.gov or CBER at esubprep@cber.fda.gov. Questions regarding submission of datasets to CDER may be sent to edata@fda.hhs.gov.
- Please visit the Electronic Common Technical Document (eCTD) web page to access a wide variety of resources and support regarding eCTD submissions.

For paper submissions, send the IND application in triplicate (one original and two copies) to the appropriate FDA center.

For CDER-Regulated Products:
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

For CBER-Regulated Products:
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

The FDA responds to the initial submission of a new IND application with a letter, acknowledging receipt of the submission and assigning the IND number. The sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND application for safety to assure that research subjects will not be subjected to unreasonable risk. If there are no issues, the IND generally goes into effect 30 days after the Date of Receipt shown in this letter. It is advised that you obtain written confirmation (email or fax) that the FDA review has been completed and that the Study May Proceed. Please upload FDA Study May Proceed confirmation in BruinIRB.

The IND Acknowledgement letter also provides instructions for submission methods and contact information for all subsequent submissions to the IND.

Need assistance or have regulatory questions? Please contact ResearchGo.

Last updated: 7 Mar 2025

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