Submitting Investigational New Drug (IND) Applications to the FDA | 2021

Investigators who are conducting clinical investigations with human participants using FDA-regulated drugs or biologics may first need to submit an Investigational New Drug (IND) application to the FDA. An IND is commonly required when administering a drug or biologic that has not been approved by the FDA, or when using a drug outside of the FDA approved indications for research purposes. For most pharma-sponsored clinical trials, the IND application process is completed by the time the UIC investigator becomes involved in the project. In other cases, such as investigator-initiated studies, a researcher may be required to apply to the FDA for an IND, which will allow the administration of the drug within the research context or treatment use. In these cases, the investigator is considered to be the sponsor of the study ("sponsor-investigator").

Sponsors have additional requirements beyond applying for an IND. After the IND is granted, sponsors register the study on clinicaltrials.gov and have additional reporting requirements to the FDA. However, both of these activities are beyond the scope of this guidance.

This document will provide information and links that can guide you through the process of applying to the FDA for an IND.

When is an IND needed in order to conduct a study?

An IND is needed when testing or administering an investigational drug or biologic in people. This may include clinical investigations (research use), emergency use, or treatment use of unapproved drugs or biologics, or such uses of drugs or biologics that are approved for a different indication. In some cases, it may be unclear whether an investigator will require an IND. In these cases, investigators can refer to FDA guidance, or go to the website of the UIC Office for the Protection of Human Subjects (OPRS) for policies related to IRB review. In other cases, such as when the investigator has been involved in drug development and pre-clinical testing, it is unclear whether there is sufficient data to support moving on to clinical trials that would require an IND. An IND may also be required for clinical investigations involving botanical dietary supplements, if the purpose of the investigation is to assess the effects of the product on disease (i.e., to cure, treat, mitigate, prevent, or diagnose disease or symptoms). The FDA has a Pre-Clinical Consultation Program available for researchers to address these issues.

FDA guidance:
Investigational New Drug Applications (INDs) - Determining Whether Human Subjects Research Studies Can Be Conducted Without An IND
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-new-drug-applications-inds-determining-whether-human-research-studies-can-be

FDA pre-IND Consultation Program
https://www.fda.gov/drugs/investigational-new-drug-ind-application/pre-ind-consultation-program

UIC OPRS policy:
https://research.uic.edu/human-subjects-irbs/policies/research-involving-the-use-of-drugs-biologics-or-medical-devices/

Helpful tools on how to submit an IND application: ReGARDD website

The ReGARDD website has information and instructions on how to submit an IND application, using clear and straightforward language. For people new to the application process, this is a good place to start. ReGARDD, or

Regulatory Guidance for Academic Research of Drugs and Devices, was developed through a collaboration of several institutions, including the University of North Carolina at Chapel Hill, RTI International, Duke University, and Wake Forest School of Medicine, to serve as a resource for researchers.

ReGARDD website home page: http://regardd.org/
ReGARDD website, IND overview: http://regardd.org/drugs
ReGARDD website, submitting an IND application: http://regardd.org/drugs/initial-ind-submission

The ReGARDD website includes information important to the IND submission process, which might not be as apparent upon reviewing the FDA guidance (below). Therefore, it is recommended that researchers reviewing the ReGARDD website take note on instructions for formatting and consent requirements as well as links to templates for cover letters and protocol documents. Researchers can also access a sample IND application.

FDA links

The FDA website also has instructions and guidance documents regarding IND submissions. These documents in general are more detailed. These webpages often have links to related information, which researchers may find helpful when navigating the FDA website.

Overview on how to submit an IND application:
https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application

Table with helpful links to information on completing IND applications for clinical investigations, IND application reporting, IND application procedures, and IND applications for clinical treatment
https://www.fda.gov/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications

IND forms and instructions, including 1571, 1572, and others required for IND applications:
https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-forms-and-instructions

Table outlining the different parts that make up an IND application, including explanation of these components and links to helpful information
https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-applications-clinical-investigations-regulatory-and-administrative-components

Information on completing the non-clinical components of the IND application - Chemistry, Manufacturing, and Control (CMC) sections:
https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-applications-clinical-investigations-chemistry-manufacturing-and-control-cmc-information

Information on completing the clinical components of the IND application – protocol:
https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-applications-clinical-investigations-clinical-protocols