IND Development Overview

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Confused about the need to file an IND? Think your study may be exempt? Not sure where to start? You are not alone. ResearchGo provides information, templates and resources to guide you through the IND process.

An academic researcher may be required to submit an IND application to the FDA in order to study a marketed medical product in a new (i.e. unapproved) clinical indication. An investigator is always required to hold an IND to study an unmarketed (i.e. unapproved) medical product. In both cases, the products are considered "investigational" by FDA. The vast majority of INDs on file with the FDA are for noncommercial research.

This toolkit (adapted from The Institute of Translational Health Sciences) helps you navigate each step of the IND process by providing guidance and templates relevant to each step. The information provided focuses on INDs for studies of marketed medical products for new indications.

Please review the latest FDA guidance for determining the need for an IND. For additional information on submitting INDs for unmarketed medical products, review of your IND application submission, or need assistance, please contact ResearchGo.

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