CDER NextGen

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Research IND

Getting Started

Welcome to the Research IND Application Builder! To compile your application, please complete the following sections in your preferred order. After having completed all sections, you can proceed to Review & Submit section to formally send your Research IND to the FDA for review.

IND SUBMISSION ASSISTANT

Application / Submission Details

For this section, you will identify the contents of your submission, the type of application, IND identifiers, and related applications that you would like to reference in your submission.

Company and Contact Details

In order to effectively track the responsible stakeholders in your submission, you will provide the contact information for the organization or individuals that are involved in the submission of the Research IND in this section.

Product Details

Use this section to describe the drug and indication of your Research IND. If applicable, you can also include Combination Product and Orphan Drug information.

Nonclinical Study Details

In this section, you can provide planned, in progress, or completed nonclinical studies referenced to your Research IND submission.

Clinical Study Details

In this section, you can provide planned, in progress, or completed clinical studies referenced to your Research IND submission.

Upload Documents

Some additional supporting documentation is also required for your submission. You can also use this section to provide any supplementary documents.

The information below applies only to requirements of the Paperwork Reduction Act of 1995

The burden time for this colletion of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this buden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

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Department of Health and Human Services
Food and Drug Administration
Office of Operations Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hh.gov.

Please do NOT send your completed form to this PRA Staff email address.

Form Approved: OMB No. 0910-0014 Expiration Date: March 31, 2022

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