

UNITED STATES FOOD & DRUG ADMINISTRATION

Applications for FDA Approval to Market New Drug

OMB Control Number 0910-0014

Non-substantive Change Request:

I. Background:

This information collection supports FDA regulations in 21 CFR Part 312, which govern the use of investigational new drugs, including procedures and requirements for the submission of Form FDA 1571 entitled, “*Investigational New Drug Application (IND)*.” Our primary objective in reviewing an IND is to help protect the rights and safety of subjects and to help ensure that the quality of the clinical trial is adequate to evaluate a drug’s effectiveness and safety for the studied indication. To supplement the Form FDA 1571 instructions, we issued a draft guidance in May of 2015 entitled “*Investigational New Drug Applications Prepared and Submitted by Sponsor Investigators*” available at <https://www.fda.gov/files/drugs/published/Investigational-New-Drug-Applications-Prepared-and-Submitted-by-Sponsor-Investigators.pdf>. Form FDA 1571 is available as a fillable PDF document and accompanying instructions may be found on our website at <https://www.fda.gov/media/116608/download>.

II. Proposed change:

We have developed an additional collection method for data elements in Form FDA 1571 for research INDs (often/sometimes referred to as “non-commercial” INDs), however the scope of data being collected will remain unchanged. Also, the new collection method will only apply to research INDs. We generally consider a research IND to be one for which the sponsor (typically an individual investigator, academic institution or non-profit entity) does not intend to later commercialize the product. These studies are strictly for research, are usually shorter in duration than INDs for commercial development, and may result in publications in peer-reviewed journals. For sponsors (including sponsor/investigators) interested in filing or updating a research IND, a new web-based interface will be available on a mobile device or desktop to help sponsors fill out Form FDA 1571. The web-based interface will also allow sponsors to electronically submit the completed Form FDA 1571 and associated files.

The information being collected is described in 21 CFR 312.23 (a) through (f) and on Form FDA 1571, and will be submitted to FDA through a new, secure web-based interface. Use of this web-based submission is voluntary, and respondents may still elect to use a fillable PDF version of Form FDA 1571, submitted via mail, email, or fax. We believe the web-based collection method will enhance user experience with data submission to FDA and will help improve agency efficiencies. At the same time, we have made no adjustment to the currently estimated burden for the information collection at this time. Upon later evaluation we will modify our estimate as appropriate. Screenshots for the interface are included below.

Submitted: March 2021

APPLICATION BUILDER

- Application / Submission
- Company and Contact
- Product
- Nonclinical Studies
- Clinical Studies
- Upload Documents
- Review & Submit

Submit Research IND

Application/Submission Details

Submission Type

Find detailed information about the submission types on the FDA 1571 Instructions.

*This submission contains the following

IND Number

Provide the IND number if it was previously assigned. If an IND number has not been assigned, leave the field blank. For IND numbers less than six digits, the IND number should be preceded using zeros (i.e., for IND 12345 enter 012345).

*IND Number

Request IND Number

IND Serial Number

IND submission should be consecutively numbered. The Initial IND should be numbered 'Serial number: 0000'. The next submission (e.g., amendment, report, or correspondence) should be numbered 'Serial Number: 0001'. Subsequent submissions should be numbered consecutively in the order in which they are submitted.

*IND Serial Number

Select all that apply:

- Emergency Research Exception From Informed Consent Requirements
- Change Request

Expanded Access Use 21 CFR 312.300

Please visit the [Expanded Access](#) page for more information about Individual Patients.

- Individual Patient, Non-Emergency 21 CFR 312.310
- Intermediate Size Patient Population 21 CFR 312.315
- Individual Patient, Emergency 21 CFR 312.310(d)
- Treatment IND or Protocol 21 CFR 312.320

Referenced Applications

Add Application +

List Numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.420), and Biologics License Applications (21 CFR Part 601) referred to in this application.

Application Type	Application Number	Letter of Authorization
Investigational New Drug Application	333333	Authorization Letter 1.docx

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Submit Research IND

Application/Submission Details

Submission Type

Find detailed information about the submission types on the FDA 15/11 instructions.

*This submission contains the following

Protocol Amendment

*Type of Amendment

- New Protocol (Nonclinical)
- New Protocol (Clinical)
- Change in Protocol (Nonclinical)
- Change in Protocol (Clinical)
- New Investigator
- New Human Factors Protocol
- Change in Human Factors Protocol

IND Number

Provide the IND number if it was previously assigned. If an IND number has not been assigned, leave the field blank. For IND numbers less than six digits, the IND number should be preceded using zeros (i.e., for IND 12345 enter 012345).

*IND Number

121212

IND Serial Number

IND submissions should be consecutively numbered. The initial IND should be numbered 'Serial number 0000'. The next submission (e.g., amendment, report, or correspondence) should be numbered 'Serial Number: 0001'. Subsequent submissions should be numbered consecutively in the order in which they are submitted.

*IND Serial Number

0000

Select all that apply:

- Emergency Research Exception From Informed Consent Requirements
- Charge Request

Expanded Access Use 21 CFR 312.300

Please visit the Expanded Access page for more information about Individual Patients.

- Individual Patient, Non-Emergency 21 CFR 312.310
- Intermediate Size Patient Population 21 CFR 312.315
- Individual Patient, Emergency 21 CFR 312.310(d)
- Treatment IND or Protocol 21 CFR 312.320

Referenced Applications

Add Application +

List Numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.400), and Biologics License Applications (21 CFR Part 602) referred to in this application.

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Submit Research IND

Company and Contact Details

Individual Details

Enter details for the following Individuals

- + * Sponsor
- + Sponsor Representative
- + Countersigner

Person Responsible for Conduct and Progress of Clinical Investigations

Provide the Name and Title of the person responsible for monitoring the conduct and progress of the clinical Investigations (21 CFR 312.22(a)(1)(v)). For Sponsor-Investigator INDs, the Investigator has this responsibility.

Salutation	*Title
Select an Option	
*First Name	Middle Name
*Last Name	

This is the same person as entered in the previous question

Person Responsible for Review and Evaluation of Safety of the Drug Information

Provide the Name and Title of the person responsible under 21 CFR 312.22 for review and evaluation of information relevant to the safety of the drug (21 CFR 312.22(a)(1))

Salutation	*Title
Select an Option	
*First Name	Middle Name
*Last Name	

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APPLICATION BUILDER

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Company and Contact

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Nonclinical Studies

Clinical Studies

Upload Documents

Review & Submit

Submit Research IND

Product Details

Name of the Drug

For name(s) of drug (21 CFR 312.23(a)(1)(i)), list the generic name(s) and trade name, if available. Also, provide the dosage form(s), and the unique Ingredient Identifier (UNII) term and code for active substances (if applicable).

Name of Drug

Select name

Enter name of drug

+ Add Another Name

Combination Product Information

This product is a combination product (21 CFR 3.2(e))

*(Proposed) Indication for Use

Multiple Indications can be added in this section.

Add Indication +

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Submit Research IND

Nonclinical Study Details

Nonclinical Studies

Add Study +

Study ID	Study Title	Study Type
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APPLICATION BUILDER

Submit Research IND

X

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Add Clinical Study

*Study ID *Study Title

Phases of Clinical Investigation Other (specify)

*Study Type Other (specify)

*Has the study started?
 Yes No

Does this submission contain clinical study data and/or protocol information?
 Yes No

We encourage Research IND Investigators to register their study with clinicaltrials.gov.

Please provide the National Clinical Trial (NCT) number for this study, if available.

*Are any cross references associated with this study?
 Yes No

Add Study +

Save Next



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Submit Research IND

Clinical Study Details

Add Clinical Study

Add Study +

Investigator's Brochure

Investigator's Brochure -

Form FDA 3674
Certification of Compliance

Described in 21 CFR 312.23(a)(5). File uploads must be less than 45MB and one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf

Informed Consent

Upload Files Or drop files

Study Protocol

Search uploaded documents

Show All

Study Report

Dataset

Previous Human Experience

Form FDA 1572 and Investigator CVs

Other Documents

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Upload Documents

Upload contents of your IND

Document Type



Cover Letter ⓘ



Introductory Statement



General Investigational Plan



Chemistry, Manufacturing, and Control Data



Environmental Assessment or Claim for Exclusion



Nonclinical Literature Reference



Clinical Literature Reference



Additional Information

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Upload contents of your IND

Document Type



Cover Letter 0



* Form FDA 1572 and Investigator CVs

Edit



Additional Information

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We also included the screenshots of the current FDA form 1571.

Next Page	Export Data	Import Data	Reset Form
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration INVESTIGATIONAL NEW DRUG APPLICATION (IND) <i>(Title 21, Code of Federal Regulations (CFR) Part 312)</i>		Form Approved: OMB No. 0910-0014 Expiration Date: March 31, 2022 See PRA Statement on page 3. NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)	
1. Name of Sponsor		2. Date of Submission (mm/dd/yyyy)	
3. Sponsor Address		4. Telephone Number (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o)		6A. IND Number (If previously assigned)	
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City	State/Province/Region		
Country	ZIP or Postal Code	6B. Select One: <input type="checkbox"/> Commercial <input type="checkbox"/> Research	
5. Name of Drug (Include all available names: Trade, Generic, Chemical, or Code)		Continuation Page for #5	
7A. (Proposed) Indication for Use		Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
		Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	
		If yes, provide the Orphan Designation number for this indication: <input type="text"/>	
		Continuation Page for #7	
7B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)			
8. Phase of Clinical Investigation to be conducted <input type="checkbox"/> Phase 1 <input type="checkbox"/> Phase 2 <input type="checkbox"/> Phase 3 <input type="checkbox"/> Other (Specify):			
9. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.420), and Biologics License Applications (21 CFR Part 601) referred to in this application.			
10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted..		Serial Number _____	
11. This submission contains the following (Select all that apply)			
<input type="checkbox"/> Initial Investigational New Drug Application (IND) <input type="checkbox"/> Response to Clinical Hold <input type="checkbox"/> Response To FDA Request For Information <input type="checkbox"/> Request For Reactivation Or Reinstatement <input type="checkbox"/> Annual Report <input type="checkbox"/> General Correspondence <input type="checkbox"/> Development Safety Update Report (DSUR) <input type="checkbox"/> Other (Specify): _____			
Protocol Amendment		Information Amendment	
<input type="checkbox"/> New Protocol <input type="checkbox"/> PMR/PMC Protocol <input type="checkbox"/> Change in Protocol <input type="checkbox"/> New Investigator <input type="checkbox"/> Human Factors Protocol		<input type="checkbox"/> Chemistry/Microbiology <input type="checkbox"/> Pharmacology/Toxicology <input type="checkbox"/> Clinical/Safety <input type="checkbox"/> Statistics <input type="checkbox"/> Clinical Pharmacology	
		Request for	
		<input type="checkbox"/> Meeting <input type="checkbox"/> Proprietary Name Review <input type="checkbox"/> Special Protocol Assessment <input type="checkbox"/> Formal Dispute Resolution	
		IND Safety Report	
		<input type="checkbox"/> Initial Written Report <input type="checkbox"/> Follow-up to a Written Report	
12. For Originals, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> No		Combination Product Type (See instructions)	
		Request for Designation (RFD) Number	
13. Select the following only if applicable. (Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.)			
<i>Expanded Access Use, 21 CFR 312.300</i>			
<input type="checkbox"/> Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f) <input type="checkbox"/> Charge Request, 21 CFR 312.8		<input type="checkbox"/> Individual Patient, Non-Emergency 21 CFR 312.310 <input type="checkbox"/> Intermediate Size Patient Population, 21 CFR 312.315 <input type="checkbox"/> Individual Patient, Emergency 21 CFR 312.310(d) <input type="checkbox"/> Treatment IND or Protocol, 21 CFR 312.320	
For FDA Use Only			
CBER/DCC Receipt Stamp		DDR Receipt Stamp	
		Division Assignment	
		IND Number Assigned	

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14. Contents of Application – This application contains the following items (Select all that apply)

<input type="checkbox"/> 1. Form FDA 1571 (21 CFR 312.23(a)(1))	<input type="checkbox"/> 6. Protocol (Continued)
<input type="checkbox"/> 2. Table of Contents (21 CFR 312.23(a)(2))	<input type="checkbox"/> d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii) (b)) or completed Form FDA 1572
<input type="checkbox"/> 3. Introductory statement (21 CFR 312.23(a)(3))	<input type="checkbox"/> 7. Chemistry, manufacturing, and control data (21 CFR 312.23(a)(7))
<input type="checkbox"/> 4. General Investigational plan (21 CFR 312.23(a)(3))	<input type="checkbox"/> Environmental assessment or claim for exclusion (21 CFR 312.23(a)(7)(iv)(e))
<input type="checkbox"/> 5. Investigator's brochure (21 CFR 312.23(a)(5))	<input type="checkbox"/> 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8))
<input type="checkbox"/> 6. Protocol (21 CFR 312.23(a)(6))	<input type="checkbox"/> 9. Previous human experience (21 CFR 312.23(a)(9))
<input type="checkbox"/> a. Study protocol (21 CFR 312.23(a)(6))	<input type="checkbox"/> 10. Additional information (21 CFR 312.23(a)(10))
<input type="checkbox"/> b. Investigator data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572	<input type="checkbox"/> 11. Biosimilar User Fee Cover Sheet (Form FDA 3792)
<input type="checkbox"/> c. Facilities data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572	<input type="checkbox"/> 12. Clinical Trials Certification of Compliance (Form FDA 3674)

15. Is any part of the clinical study to be conducted by a contract research organization? Yes No
 If Yes, will any sponsor obligations be transferred to the contract research organization? Yes No
 If Yes, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred (use continuation page). Continuation Page for #15

16. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations

17. Name and Title of the person responsible for review and evaluation of information relevant to the safety of the drug

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold or financial hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

18. Name of Sponsor or Sponsor's Authorized Representative

19. Telephone Number (Include country code if applicable and area code) 20. Facsimile (FAX) Number (Include country code if applicable and area code)

21. Address		22. Email Address
Address 1 (Street address, P.O. box, company name c/o)		
Address 2 (Apartment, suite, unit, building, floor, etc.)		
City	State/Province/Region	23. Date of Sponsor's Signature (mm/dd/yyyy)
Country	ZIP or Postal Code	

24. Name of Countersigner

25. Address of Countersigner		26. Email Address
Address 1 (Street address, P.O. box, company name c/o)		
Address 2 (Apartment, suite, unit, building, floor, etc.)		
City	State/Province/Region	WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).
Country United States of America	ZIP or Postal Code	

27. Signature of Sponsor or Sponsor's Authorized Representative Sign

28. Signature of Countersigner Sign

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

The burden time for this collection 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 burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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