INITIAL INVESTIGATIONAL NEW DRUG APPLICATION

IND Title (if title being used)

Serial 0000

Name of Sponsor-Investigator, MD

X Professor, Department

<University of XXXX>

Date of Submission

# FDA Forms 1571 and 3674

**FDA Form 1571** – Investigational New Drug Application (IND)

* To be taken directly to the most current version of **FDA Form 1571** document PDF, please visit <https://www.fda.gov/media/123543/download>
* To read directions on how to fill out the **1571**, please visit <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM182850.pdf>

**What is the 1571 form?**

FDA Form 1571 is used for two purposes: 1) an agreement between the sponsor (or sponsor-investigator) to conduct research according to all appropriate FDA regulations; and 2) as a cover sheet for all submissions to the FDA on behalf of a particular IND.

**When is the 1571 necessary?**

1571 should be completed for every submission sent to the FDA on behalf of a particular IND.

**What information do I need to fill out the 1571?**

**Include the following information on 1571:**

* Contact information and mailing address
* IND number, if it has been issued
* Serial number (see below)
* General information about your research, the drug/biologic(s) being studied
* New information that will be provided in this particular submission
* Information regarding the individuals responsible for monitoring the study and review of safety data.

**What is the serial number in box 10?**

Each submission to the FDA regarding a particular IND is given a consecutive serial number. The initial submission will be 0000, and all subsequent correspondence will have a new serial number (0001, 0002, etc.)

**FDA Form 3674 –** Certification of Compliance

* To be taken directly to the most current version of FDA Form 3674 document PDF, please visit <https://www.fda.gov/media/134964/download>
* To read directions on how to fill out the form 3674, please visit <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm354618.pdf>

The FDA form 3674 is a document that must accompany all FDA IND initial submissions (and some types of amendments). It is a signed statement from the sponsor/investigator that they will comply with clinicaltrials.gov requirements concerning their investigation.

BOX A

Should be checked if there is not a clinical investigation covered in the IND submission.

BOX B

Should be checked if there is a clinical investigation, but the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply. This is the case for most Phase I studies.

BOX C

Should be checked if there is a clinical investigation and the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do apply. By checking this box, the investigator certifies that they will comply with those requirements.

If an investigation is funded all or in part through the NIH, it is a federal requirement that the any human clinical trial be registered on clinicaltrials.gov.

<https://grants.nih.gov/ClinicalTrials_fdaaa/index.htm>

Please see the link below for more information

<https://clinicaltrials.gov/ct2/manage-recs/fdaaa>

*Rather than insert the FDA Form 1571 and Form FDA 3674 within this Word document, we recommend that you assemble the IND after separately printing this IND document and forms (if submitting in paper) or after converting this IND document to a PDF (if submitting electronically). To ensure that the TOC reflects the true number of pages in the IND, format the page number on the following page to reflect the additional pages in the forms.*

*To format the page number, highlight the page number in the footer, right click and choose “Format Page Numbers”. Then click “Start numbering at” and put the new number accounting for the number of inserted pages. Also note, to be able reformat page numbers, you need to insert a “section break (next page)” rather than a simple page break.*

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*Immediately following the Cover Letter and FDA 1571, the IND submission should contain a table of contents. Both Word and Acrobat have the capability of formatting a document to automatically create and update a table of contents. Linking the headers in the table of contents to the actual section in the submission can be very useful. The entire submission should have a continuous page numbering system. The table of contents and page numbering will facilitate a reviewer’s ability to navigate throughout the document.*

*The topics for the table of contents are listed below (note that the page numbers will change with each submission). These sections should be left as-is. If a particular section does not apply to your specific investigation, note that in the section, but do not delete it.*

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# Introduction

## Introductory Statement

*Briefly describe the research plan submitted in this IND. This section should be 2-3 pages long. This should include a brief discussion of the disease state to be assessed. The intent of this section is to place the use of the drugs with this indication into perspective for the FDA.*

*Refer to 21 CFR 312.23(a)(3) (*[*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.23*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.23)*)*

***Maintain all of the headings*** *in this document and if not applicable to your IND, simply state this.*

### Name of the Drug and All Active Ingredients

*Include all known names of the drug: generic and marketed names, chemical name.*

### Pharmacological Class of the Drug

*Include the pharmacological class of the drug.*

### Structural Formula of the Drug

*Both the structural and chemical formulas should be here.*

*This section may not be applicable to biologics. You could describe the protein or complex of proteins instead (e.g. 341 amino acids with a molecular weight of 150 g/mol)*

### Formulation of the Dosage Form(s) to be Used

*Include a brief description of the formulation and dosage. Describe formulations/dosages of every active component of a combination therapy.*

*Include placebo information, if applicable.*

### Route of Administration

*Briefly describe the route of administration and the planned exposure (ie duration of study drug administration).*

### Objectives and Duration of the Proposed Clinical Investigation(s)

*If more than one protocol is being submitted under this IND, detail each separately, and clearly indicate that there is more than one planned investigation.*

## Summary of Previous Human Experience

*This is a brief summary of previous human experience with the drug(s), with reference to the relevant literature or other INDs, if pertinent. Also, investigational or marketing experience in other countries may be relevant to the safety of the proposed clinical investigation(s). This topic will be written up in detail in Section 9; however, for many sponsor-investigator INDs that use commercially available drugs, Section 3.2 and 9 are often identical.*

*If an IND application or other document previously submitted to the FDA is to be referenced, then the sponsor must identify the file/document by:*

* *Name*
* *Reference number*
* *Volume*
* *Page number where the information may be found*

*In order to reference an IND application previously submitted by others (i.e. other sponsor’s INDs), such a reference is required to contain a written statement that authorizes the reference and that is signed by the person who submitted the referenced information.*

## Status of Drug in Other Countries

*This section is likely not applicable to a standard Sponsor-Investigator IND submission. If the drug has been withdrawn from investigation or marketing in any country for any reason related to safety or effectiveness, identification of the country(ies) where the drug was withdrawn and the reasons for the withdrawal are stated here. For a Sponsor-Investigator IND, you may simply state you are not aware of any withdrawals.*

## References

*List any references for Section 3*

# General Investigational Plan

*As the studies contained in this IND progress from phase 1 to phases 2 and 3, the contents of this section will change. For the purpose of the initial submission, provide information that will be relevant for the first year of investigation. Changes to the plan and additional protocols can be included in future annual reports and amendments.*

## Rationale

*The rationale for the drug and/or research study. Provide enough background information on the topic for the FDA to understand the scientific justification for the investigation.*

## Indication to be Studied

*Identify the indication to be studied in this investigation. Describe sub-sets of a more general study population if needed.*

## General Approach for Evaluation of Treatment

*Provide a high-level description of data to be collected and its use in evaluation of the efficacy of the intervention being studied.*

## Description of First Year Trial(s)

*The FDA understands that study plans may change over time. In this section provide a high-level description of the plan for the first 12 months of clinical investigation.*

## Number of Subjects to be Evaluated

*Provide the planned number of subjects to be enrolled in the first year of IND activity.*

## Drug Related Risks

*Any risks of particular severity or seriousness anticipated on the basis of the toxicological data in animals or prior studies in humans with the drug(s) or related drugs. Include any study procedures that carry risks of more than minimal severity.*

## References

*List any references for Section 4*

# Investigator Brochure

*For sponsor-investigator initiated INDs, there is no requirement to produce an Investigator Brochure (IB) if you have a single site study. You may incorporate the following statement:*

“In accordance with 21 CFR Part 312.55(a), an Investigator’s Brochure is not required for a sponsor-investigator IND.”

*If an approved drug is being investigated, then it is appropriate to refer to the labeling and provide a URL link to the most current product label. You may find these links useful for finding current product labeling:*

* <http://dailymed.nlm.nih.gov/dailymed/about.cfm>
* <http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/>

*You may also reference Letters of Authorization in this section.*

**Multi-Site Investigations:**

*If there will be a multi-center (external site) clinical investigation under a University-based, sponsor-investigator IND application, an Investigator’s Brochure should be developed for dissemination to each of the involved study sites and should address the following information:*

* *A brief description of the active drug substance and the drug product formulation, including the structural formula of the active drug substance, if known.*
* *A summary of the pharmacological and toxicological effects of the drug in animals and, to the extent known, in humans.*
* *A summary of the pharmacokinetics and biological distribution of the drug in animals and, if known, in humans.*
* *A summary of information relating to the safety and effectiveness of the drug in humans obtained from prior clinical studies. (Reprints of published articles describing such studies may be appended to the Brochure if they are anticipated to be useful.)*
* *A description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or related drugs, and of precautions or special monitoring to be done as part of the investigational use of the drug.*

*Rather than insert the IB within this document, we recommend that you assemble the IND after separately printing this IND document and the IB (if submitting in paper) or after separately converting this IND document and IB to PDFs (if submitting electronically). To ensure that the Table of Contents (TOC) reflects the true number of pages in the IND, format the page number on the Protocol page to reflect the additional pages in the IB.*

*To format the page number, highlight the page number in the footer, right click and choose “Format Page Numbers”. Then click “Start numbering at” and put the new number accounting for the number of inserted pages. Also note, to be able reformat page numbers, you need to insert a “section break (next page)” rather than a simple page break.*

# Proposed clinical research

Provide a protocol and informed consent document for each planned study.

## Study Protocol

*Refer to 21 CFR 312.23(6) for complete protocol requirements. The general summary of the overall research plan should be followed by the “Executive Summary” section(s) of the protocol template (or some similar brief protocol summary) for each protocol to be included in this IND application. The actual full protocol(s) is/are to be included in this section. Rather than insert the protocol within this Word document, we recommend that you assemble the IND after separately printing this IND document and the protocol (if submitting in paper) or after separately converting this IND document and the protocol to PDFs (if submitting electronically). To ensure that the TOC reflects the true number of pages in the IND, format the page number on the Informed Consent page to reflect the additional pages in the protocol.*

*To format the page number, highlight the page number in the footer, right click and choose “Format Page Numbers”. Then click “Start numbering at” and put the new number accounting for the number of inserted pages. Also note, to be able reformat page numbers, you need to insert a “section break (next page)” rather than a simple page break.*

*Due to the unpredictable nature of Phase 1 studies, Phase 1 protocols can be flexible and more focused on providing a general outline of the clinical investigation (dosing plan, safety precautions). Additionally, following IND approval, changes to Phase 1 protocols that do not affect the safety of subjects need only be included in IND annual reports, not more frequent amendments.*

*The main components of a clinical protocol are described in* [*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf)*. Some of the information listed in this guidance document may be contained in other protocol referenced documents, such as the IB.*

##

## Informed Consent

*Informed consent documents (ICD) do not need to be included in the IND submission, but it is recommended that they be included. If a sponsor does not submit an ICD as part of its IND submission, the review division may request and review the ICD at any time. The request will reference 21 CFR 312.23(a)(11), which states that if requested by the FDA, the sponsor must submit “any other relevant information needed for review of the application.”*

*Include a statement here that informed consent will be obtained by all study participants in accordance with 21 CFR Part 50 Protection of Human Subjects.*

*If the investigation involves an exception from informed consent requirements, this should be stated in this section and the reasoning explained.*

*Some guidelines are listed below to assist in drafting an informed consent document:*

*Informed consent documents are institution-specific but all forms will address the same topics listed below:*

* *A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;*
* *A description of any reasonably foreseeable risks or discomforts to the subject;*
* *A description of any benefits to the subject or to others that may be reasonably expected from the research;*
* *A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;*
* *A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained;*
* *For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;*
* *An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.*
* *A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.*

*Informed Consent documents should be written in such a way that they can be understood by the general public. Language should be targeted at a 5th grade reading level. It is advisable to keep the document concise for the benefit of the reader.*

*Rather than insert the informed consent document within this Word document, we recommend that you assemble the IND after separately printing this IND document and the informed consent document (if submitting in paper) or after separately converting this IND document and the informed consent document to PDFs (if submitting electronically). To ensure that the TOC reflects the true number of pages in the IND, format the page number on the Investigator and Facilities Data page to reflect the additional pages in the informed consent document.*

*To format the page number, highlight the page number in the footer, right click and choose “Format Page Numbers”. Then click “Start numbering at” and put the new number accounting for the number of inserted pages. Also note, to be able reformat page numbers, you need to insert a “section break (next page)” rather than a simple page break.*

##

## Investigator and Facilities Data

*Provide the name, address, and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator as well as the name of each sub-investigator (i.e., research fellow, resident) working under the supervision of the investigator. Also needed are the name(s) and address(es) of the research facility(ies) to be used as well as the name and address of each reviewing Institutional Review Board (IRB).*

*The information needed for this section is provided to the FDA on the FDA Form 1572 (see below for additional guidance) along with copies of the Sponsor-Investigator’s CV. While not required, the Sponsor-Investigator may also provide copies of the CVs for all sub-investigators listed in Box 6 of the 1572. If the Sponsor-Investigator chooses not provide the sub-investigators’ information in the application, the applicant MUST maintain copies of this documentation in an IND regulatory binder. Additional guidance on the completion of the FDA forms for this section as well the website where fillable PDF forms can be found are provided below.*

*Insert completed FDA Form 1572 and a copy of the Sponsor-Investigator’s CV (does not need to be a signed copy).*

*Rather than insert the FDA Form 1572 and CV within this Word document, we recommend that you assemble the IND after separately printing this IND document, FDA Form 1572, and CV (if submitting in paper) or after converting this IND document to a PDF (if submitting electronically). To ensure that the TOC reflects the true number of pages in the IND, format the page number on the following CMC page to reflect the additional pages in the FDA Form 1572 and CV.*

*To format the page number, highlight the page number in the footer, right click and choose “Format Page Numbers”. Then click “Start numbering at” and put the new number accounting for the number of inserted pages. Also note, to be able reformat page numbers, you need to insert a “section break (next page)” rather than a simple page break.*

*• For FDA information regarding FDA Form 1572, please visit* [*http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf*](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf)

*• To be taken directly to the most current version of FDA Form 1572 document PDF, please visit* [*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf*](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf)

*• To read directions on how to fill out the 1572, please visit* [*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM223432.pdf*](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM223432.pdf)

*The intent of the 1572 form is two-fold. It is a signed agreement from the Investigator that he/she will conduct the research in compliance with FDA regulations. Additionally, it collects all the clinical site and investigator information needed by the sponsor (or sponsor-investigator) to assure the FDA that all investigators have the experience and background needed to conduct the trial. As the sponsor of a study, you are responsible for ensuring that updated 1572 forms are submitted to the FDA. If you are a site investigator, you are responsible for updating your site’s 1572 form and providing it to the sponsor in a timely manner (so they can send the information to the FDA).*

**When is the 1572 necessary?**

* + *When filing an Initial IND Submission, a completed 1572 form must be sent from each site.*
	+ *When adding a new investigator (or new site), or replacing an investigator at an existing site. Note: a 1572 must be submitted to the FDA within 30 days of enrolling the first subject.*
	+ *When changing any site information: IRB, laboratory, or clinical site.*
	+ *When filing a new protocol amendment, a completed 1572 form must be sent from each site that will be conducting the new protocol.*

**What information do I need to fill out the 1572?**

* + *A current CV of the investigator listed on the 1572. It does not need to be signed.*
	+ *Name and address of the location where the clinical investigation will be conducted, the clinical laboratories that will be used, and the IRB reviewing the study.*
	+ *Names of the sub-investigators at the site*
	+ *Name of the protocol to be studied at the site.*

# Chemistry, Manufacturing and Control Information

## Chemistry, Manufacturing and Control

*If the investigational drug has been marketed, this section may be covered by referring to the product labeling. You may refer back to the URL identified in Section 5. Alternatively, it might be appropriate to refer to a ‘Letter of Authorization’ if using a drug provided by a commercial company.*

*This section describes the composition, manufacture, and control of the drug substance and the drug product according to 21 CFR 312.23(7).* *NOTE: Reference to the current edition of the United States Pharmacopoeia – National Formulary may satisfy relevant requirements in this section.*

### Drug Substance

* *Description of drug; include physical, chemical, or biological characteristics and evidence supporting structure and identity of the active pharmaceutical ingredient(s)*
* *Name and address of manufacturer of drug product*
* *Description of the general method of preparation of the drug substance, including a list of the reagents, solvents, and catalysts used. A detailed flow diagram is suggested as the most effective presentation. More information may be needed to assess the safety of biotechnology-derived drugs or drugs extracted from human or animal or plant sources*
* *The acceptable limits and analytical methods used to ensure the identity, strength, quality, and purity of the drug substance, with a brief description of the test methods used (i.e., Nuclear Magnetic Resonance, Infrared, UV spectra to prove the identity, and High Performance Liquid chromatograms to support the purity level and impurities, etc.). Submission of certificates of analysis is also suggested.*
* *Information to support stability of the drug substance during storage in the intended container closure and during the toxicological and clinical studies*

### Drug Product

* *List all components used in the manufacture of the investigational drug product, including both those components intended to appear in the drug product and those which may not appear but which are used in the manufacturing process*
* *Where possible, the quantitative composition of the investigational drug product, including any reasonable variations that may be expected during the investigational stage*
* *Brief general description of the manufacturing process (in the form of a flow diagram is suggested) and packaging procedure, as well as other relevant tests, as appropriate for the product.*
* *Final specifications for the drug product intended to be used in toxicological and clinical studies should be included. For injectable products, sterility and pyrogenicity tests, endotoxin levels and particulate matter should be included. Submitting a copy of the certificate of analysis of the clinical batch is also suggested.*
* *Information sufficient to assure the product’s stability during the planned clinical studies.*
* *The acceptable limits and analytical methods used to ensure the identity, strength, quality, and purity of the drug product*
* *Information to support stability of the drug product during the planned clinical studies*

### Placebo Product

***NOTE****: Delete this section if not applicable*

*Include a brief general description of the composition, manufacture, and control of any placebo used in the controlled clinical trial.*

### Labeling

*Include copies of the label constructed for the study drug and any associated package. Note: Labels must contain the phrase: “Caution: New Drug – Limited by Federal law to investigational use”*.

Dose Level

Lot Number

## Environmental Assessment

*Insert the statement below, unless there is a reason to believe the distribution and use of the drug could have an environmental impact. The FDA may require an environmental analysis to ensure the study agent does not impose an undue environmental hazard {21 CFR 312.23(7)(e)}. For products already marketed, it may be possible to request and exemption from the requirement to conduct an environmental analysis. Details around the expectation of the FDA for this section should be discussed in the pre-IND meeting held between the sponsor-investigator and the FDA to discuss the IND application.*

*“We request a claim for categorical exclusion for this proposed clinical trial as provided for in 21 CFR Part 312.31(e) in that the drug shipped under this notice is intended to be used in clinical trials in which the amount of waste expected to enter the environment may reasonably be expected to be non-toxic.”*

# Pharmacology and Toxicology Information

*As was true for Section 7, you may use an authorization letter(s) or cite the drug label to satisfy this section.*

*Per 21 CFR 312.23(8), this section is expected to include information about pharmacological and toxicological (laboratory animals or in vitro) studies on the basis of which the sponsor of the IND application has concluded that it is reasonably safe to conduct the proposed clinical investigations. The kind, duration, and scope of animal and other studies required in the application will depend on the duration and nature of the proposed clinical investigations. For recommendations regarding study types and duration, refer to the FDA Guidance for Industry: M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorizations for Pharmaceuticals* [*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073246.pdf*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073246.pdf)

*Compliance with Good Laboratory Practice (GLP) is generally expected for pivotal in vitro and in vivo studies submitted in support of an IND application. For each non-clinical laboratory study subject to the GLP regulations, investigators are expected to state in the study report that the study was conducted in compliance with the GLP regulations. If the study was not conducted in compliance with the GLP regulations, investigators should submit a brief statement of the reason for noncompliance. FDA Guidance documents relevant to Pharmacology and Toxicology information are available at the FDA website* [*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065014.htm*](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065014.htm)

*The IND sponsor should also provide a statement describing where the non-clinical investigations were conducted and the location of all records available for inspection.*

## Pharmacology and Drug Distribution

* *Description of the pharmacologic effects and mechanism(s) of actions of the drug in animals*
* *Information on the absorption, distribution, metabolism, and excretions of the drug*

*NOTE: The regulations do not further describe the presentation of these data, in contrast to the more detailed description of how to submit toxicological data. A summary report, without individual animal records or individual study results, usually suffices. In most circumstances, five pages or less should suffice for this summary. If this information is not known, it should simply be so stated.*

### Pharmacology Summary and Conclusions

*Provide high-level summary and general conclusions to be drawn from the pharmacology data.*

## Toxicology: Integrated Summary

*This section should include an integrated summary of the toxicological effects of the drug in animals an in vitro {21 CFR 312.23(8)(ii)(a)}. For this section, refer to discussions in the FDA Pre-IND meeting, where the FDA will clarify guidance and requirements for your submission.*

*Expected content elements for describing specific toxicology studies for this section typically include:*

* *Study title*
* *Study drug formulation/vehicle*
* *Brief description of the design of the trials*
* *Dosing*
* *Systematic presentation of the findings from the animal toxicology and toxicokenetic studies. The format of this part of the summary may be approached from a “systems review” perspective: i.e. CNS, cardiovascular, gastrointestinal, renal, hepatic, genitourinary, hematopoietic and immunologic, and dermal.*
* *Provide high-level summary and general conclusions of the preceding toxicology findings.*
* *Identification and qualifications of the individual(s) who evaluated the animal safety data and concluded that it is reasonably safe to begin the proposed human study. This person(s) should sign the summary attesting that the summary accurately reflects the animal toxicology data from the completed studies.*
* *A statement of where the animal studies were conducted and where the records of the studies are available for inspection, should an inspection occur.*
* *According to 21 CFR 321.23(8)(iii), a statement that the study was conducted in compliance with the good laboratory practices (GLP) in 21 CFR 58, or, if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance and the sponsor's view on how such noncompliance might affect the interpretations of the findings.*

## Toxicology: Full Data Tabulation

*The sponsor should submit, for each animal toxicology study that is intended to support the safety of the proposed clinical investigation, a full tabulation of data suitable for detailed review. This should consist of line listings of the individual data points, including laboratory data points, for each animal in these trials along with summary tabulations of these data points. To allow interpretation of the line listings, accompanying the line listings should be either: 1) a brief description (i.e., a technical report or abstract including a methods description section) of the study, or 2) a copy of the study protocol and amendments.*

# Previous Human Experience

*A summary of previous human experience with the drug known to the applicant. If the drug(s) is already marketed in the US, then you may be able to simply refer to the product labeling.*

*There is no specific format for describing previous human experience with an investigational drug in an IND application; however, the FDA website provides helpful points to consider when writing a summary of previous human experience* [*http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm362446.htm*](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm362446.htm)

*If the drug is a combination of drugs previously investigated or marketed, the information should be provided for each active drug component. However, if any component in such combination is subject to an approved marketing application or is otherwise lawfully marketed in the United States, the sponsor is not required to submit published material concerning that active drug component unless such material relates directly to the proposed investigational use (including publications relevant to component- component interaction).*

*If there is no data on previous human experience for this drug, insert a statement reflecting that under each subheading.*

## Marketed Experience

Overview any FDA-approved marketed indications for the study drug. Reference to the FDA drug labeling for approved indications should be noted here.

If the drug was withdrawn from the market for any reason related to safety or effectiveness, identify the country(ies) where the drug was withdrawn and the reasons for withdrawal.

## Prior Clinical Research Experience

*If the drug has been the subject of controlled trials, detailed information on trials that are relevant to an assessment of the drug’s effectiveness for the proposed investigational use(s) should also be provided. Any published material that is relevant to the safety of the proposed investigation or to an assessment of the drug’s effectiveness for its proposed investigational use should be provided in full. Published material that is less directly relevant may be supplied by a bibliography.*

*If there has been no previous human experience, the submission should so state.*

## Clinical Care Experience

***Note****: Delete this sub-section if not applicable.*

It is not uncommon for marketed drugs to be used in clinical care settings to treat patients for indications that do not have an FDA approval. This is often termed “off-label” use. Any published literature on the safety of the drug in that setting, and if available, published practice guidelines of the use of the drug for standard-of-care and the associated safety information could be referenced here. This is particularly relevant if the patient population treated with this off-label use of the drug is similar to the proposed study population for this IND application.

## References

*List any references for Section 9. Complete PDFs (reprints) of 2-3 selected references can be included in section 10. Do not assume that FDA can access all references.*

# Additional Information

*In certain applications, as described below, information on special topics may be needed. Such information shall be submitted in this section as outlined below. Otherwise you may simply state ‘not applicable’.*

## Drug Dependence and Abuse Potential

*If the drug is a psychotropic substance or otherwise has abuse potential, a section describing relevant clinical studies and experience and studies in test animals.*

*If this section is relevant to your investigation, please see the guidance below:* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf>

## Radioactive Drugs

*If the drug is a radioactive drug, sufficient data from animal or human studies should be provided, to allow a reasonable calculation of radiation-absorbed dose to the whole body and critical organs upon administration to a human subject. Phase 1 studies of radioactive drugs must include studies which will obtain sufficient data for dosimetry calculations.*

*If this section is relevant to your investigation, please see the guidance below:*

[*http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm092895.htm*](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm092895.htm)

## Pediatric Studies

*If the investigational drug will be studied in pediatric setting, plans for assessing pediatric safety and effectiveness should be provided.*

*If this section is relevant to your investigation, please see the guidance below:*

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm>

## Other Information

*A brief statement of any other information that would aid evaluation of the proposed clinical investigations with respect to their safety or their design and potential as controlled clinical trials to support marketing of the drug.*

## Selected References

*If you are including reprints with your submission, list them in this section.*

# Relevant Information

*If requested by FDA, any other relevant information needed for review of the application.*