Sponsor Investigator (SI) Support

FDA Miniseries

Part 1 “Preparing for an IND/IDE”

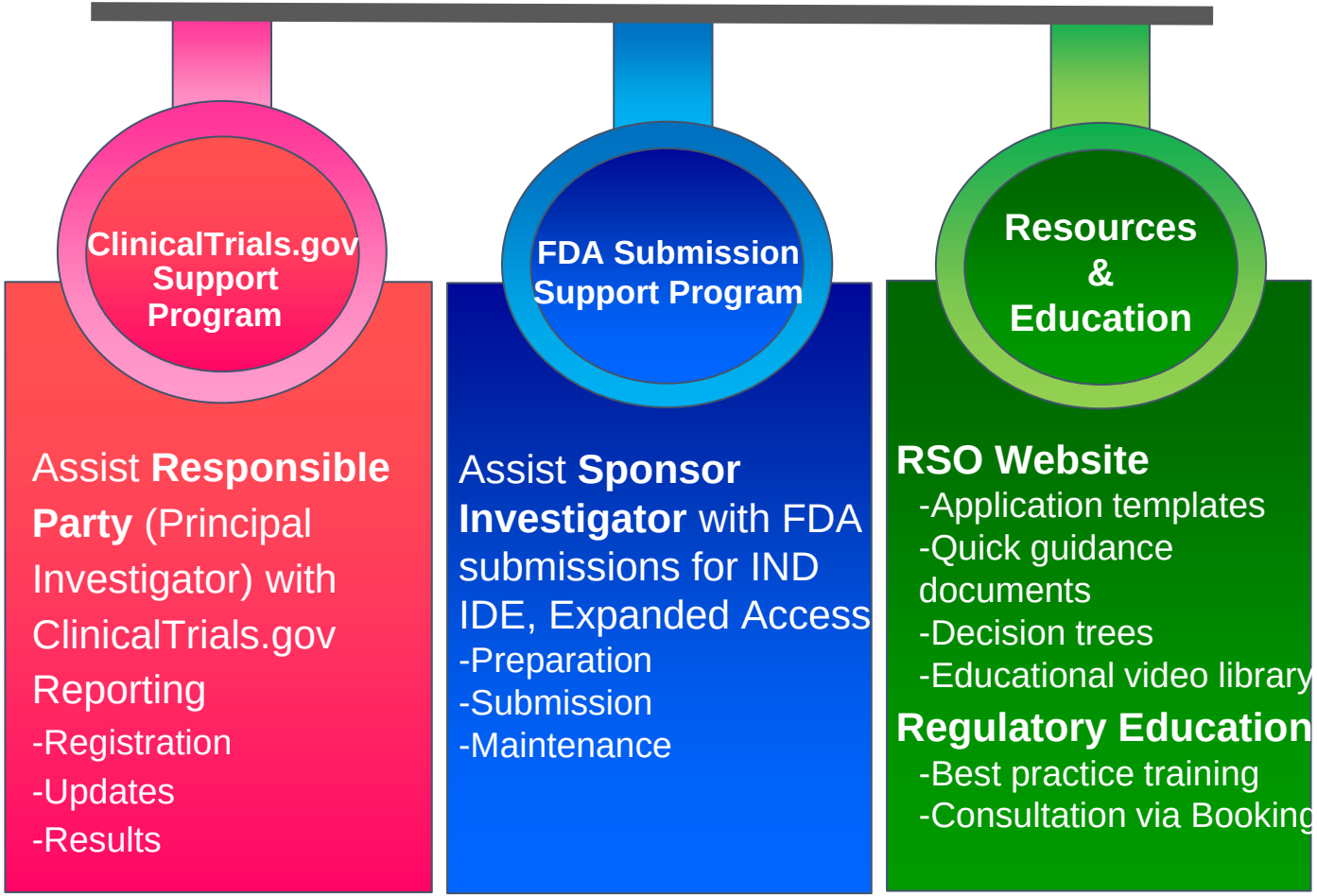
By

HRPP Regulatory Support Office (RSO)

Raj Varadarajan, Rasija Nambiar, Eriko Iwatate

3/21/2023

Regulatory Support Office (RSO)



Sponsor Investigator (SI) Support FDA Miniseries

Part 1
Preparing for an IND/IDE

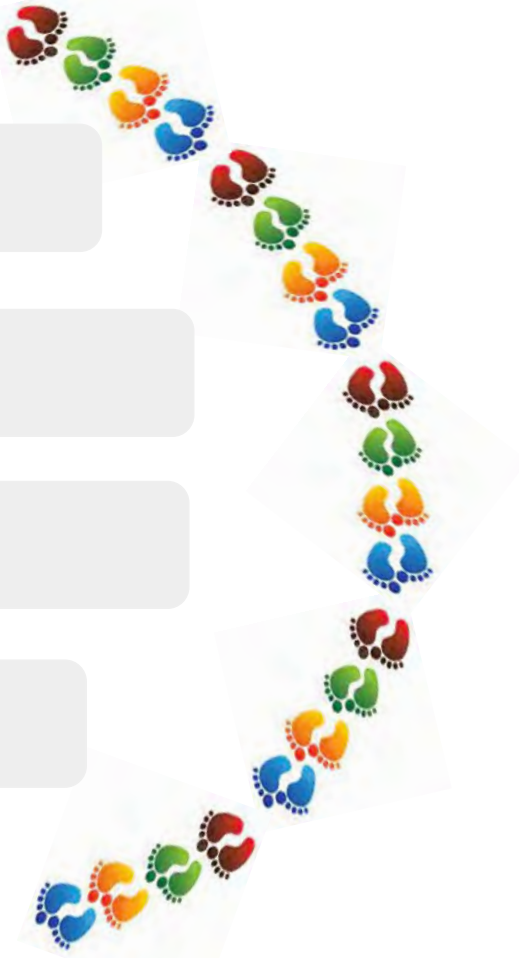
Part 2
Initial IND/IDE submissions

Part 3
Modifications to IND/IDE

Part 4
Safety (Incident) Reports

Part 5
Annual Reports

Part 6
Ending IND/IDE

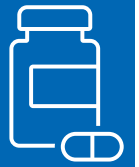


IND Overview

FDA U.S. FOOD & DRUG ADMINISTRATION

What is an IND

Request to FDA for authorization to administer an investigational articles to human



What are the Main Types of IND

Commercial IND: Goal is to obtain marketing approval

Research IND: Investigator Initiated IND, research driven

What are the content of IND Application

1. Manufacturing Information
2. Animal pharmacology/toxicology data
3. Clinical protocols and investigator information

Who must Submit IND

Sponsor and Sponsor Investigator

Product	Agency Center	Regulatory Pathways	Ways to Submit
Drug E.g., prescription/non-prescription drugs, toothpaste, antiperspirants, shampoos, sunscreens	**CDER** (Center for Drug Evaluation and Research)	**IND** • Investigator IND • Emergency Use IND • Treatment IND	CDER NextGen Portal* CBERDCC_eMailSub@fda.hhs.gov
Biologic E.g., blood products vaccines, allergenic, gene/cellular therapy, tissue products	**CBER** (Center for Biologics Evaluation and Research)	**IND** • Investigator IND • Emergency Use IND • Treatment IND	CBERDCC_eMailSub@fda.hhs.gov

3 Steps to Prepare IND

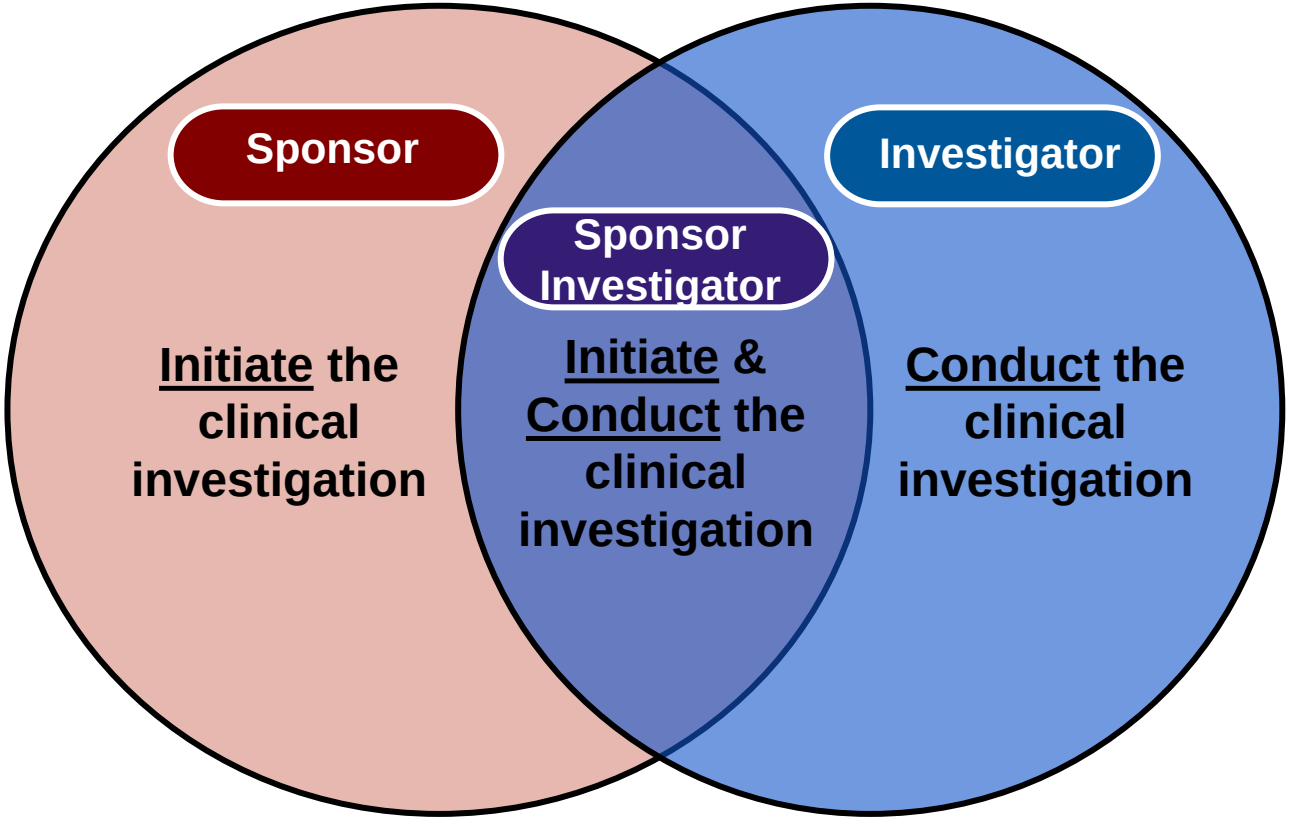
Step 1 Book a Free Consultation with RSO

Step 2 Fill out IND Application Template

Step 3 Contact RSO for review/submission

Sisupport@utsouthwestern.edu

Definitions



Sponsor Responsibilities	Investigator Responsibilities
• **Select qualified Investigators, monitors**	• **Protect the rights, safety, and welfare of subjects under the investigator's care**
• **Obtain information from the Investigator** (e.g., signed Investigator's statement, Investigator's CV etc.)	• **Ensure that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations**
• **Inform investigators** (through IB, a current version of the IRB approved protocol, inform about the new observations/ SAEs, safe use of drug)	• **Provide assurance of IRB review by a qualified IRB for initial and continuing review and approval of the investigation**
• **Assure the compliance of investigators** (as per obligations addressed under the signed Statement of Investigator (i.e., FDA Form 1572), the general investigational plan, or applicable FDA regulations)	• **Investigator record keeping** (To accurately document the case histories and disposition of the drug including dates, quantity and use by subjects)
• **Ensure proper monitoring of the progress and conduct of the clinical investigation(s) at each of the involved study sites**	• **Investigator record retention** (To retain all correspondence relating to the use of human Subjects in research, as well as copies of the IRB application forms, approval notices, and signed Informed Consent Documents (ICD)
• **Maintain an effective (i.e., up-to-date) IND** (i.e, will review & evaluate evidence relating to safety and effectiveness of the drug, submit Safety reports, Annual Reports, Protocol amendments to FDA)	• **Control of the investigational drug** (Ensures the investigational drug not given to any person not under the investigator's care)
• **Ensure that the FDA and all participating Investigators are promptly informed of SUSARs and/or other newly identified, significant risks related to the investigational drug.**	• **Inspection of investigator's records and reports** (Must allow FDA's authorized officer access to all records to verify the information)
• **Record-keeping and record retention requirements** (Maintain adequate & accurate records of the receipt, shipment/ disposal of the drug and Retain records for up to 2 yrs)	• **Delegate authority to qualified individuals**
• **Disposition of unused supplies of the investigational drug** (Assure safe return and disposal of unused investigational drug from each investigator who discontinued/ has been terminated)	• **Furnish all reports i.e, Progress reports, Safety reports and Final report to sponsor**
• **Inspection of the sponsor's records and reports** (Must allow FDA's authorized officer access to all records to verify the information)	• **Must take adequate precautions to ensure the safe and secure handling of the investigational drug if it is a controlled substance.**
• **Update ClinicalTrials.gov records (if a responsible party)** (when there is a change in recruitment status, protocol amendments, and results for an applicable clinical trial as per CT.gov's reporting requirements.)	• **Provide adequate medical care to trial subjects** (in case of AEs/ abnormal lab results related to trial)
• **May transfer of full/ partial obligations to CRO in writing** (shall be subject to same regulatory action as a Sponsor)	• **Promptly update the financial disclosure to sponsor as needed and for 1 year following study completion**

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Watch on YouTube

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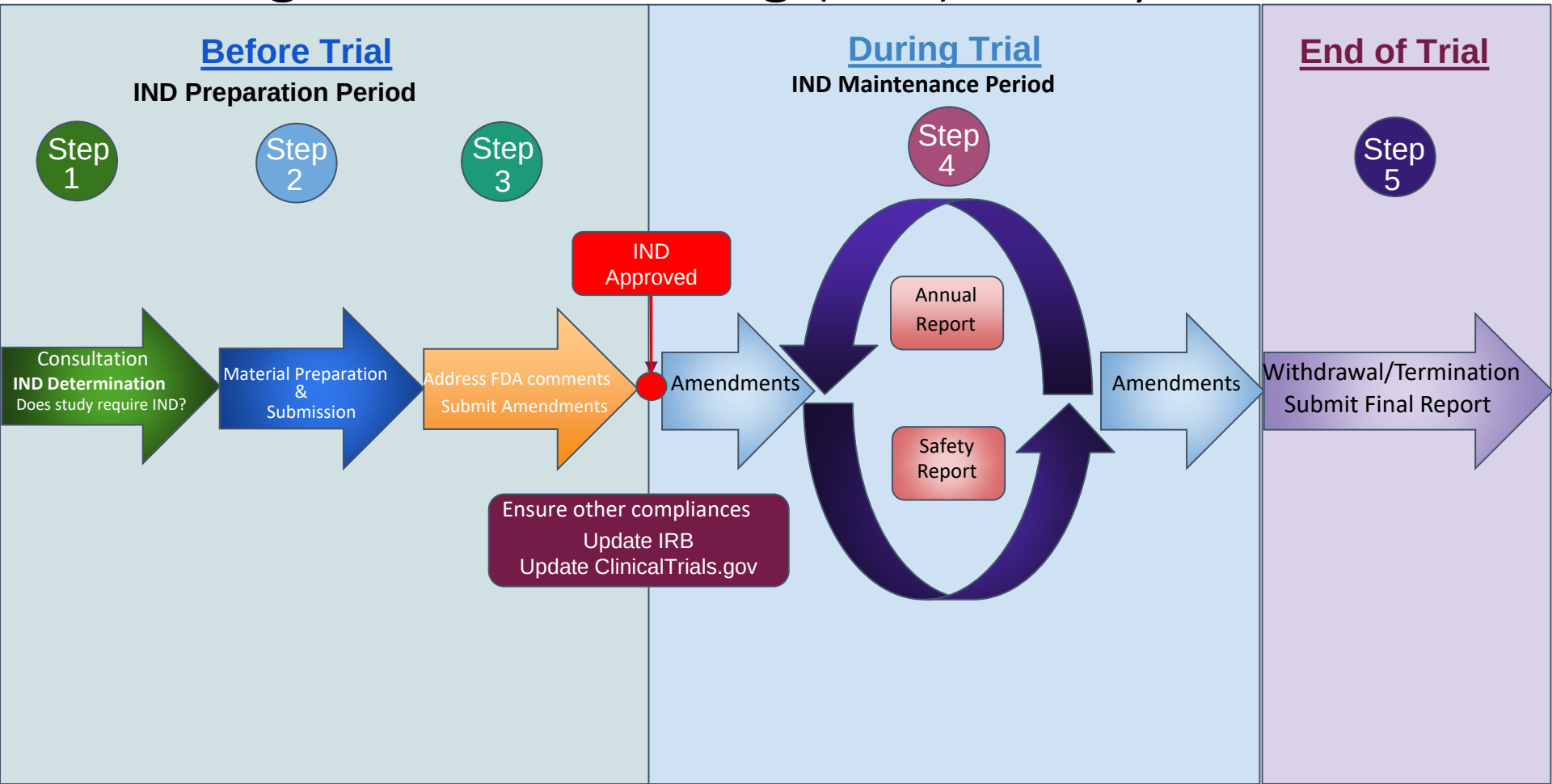
Investigational New Drug (IND) Life Cycle



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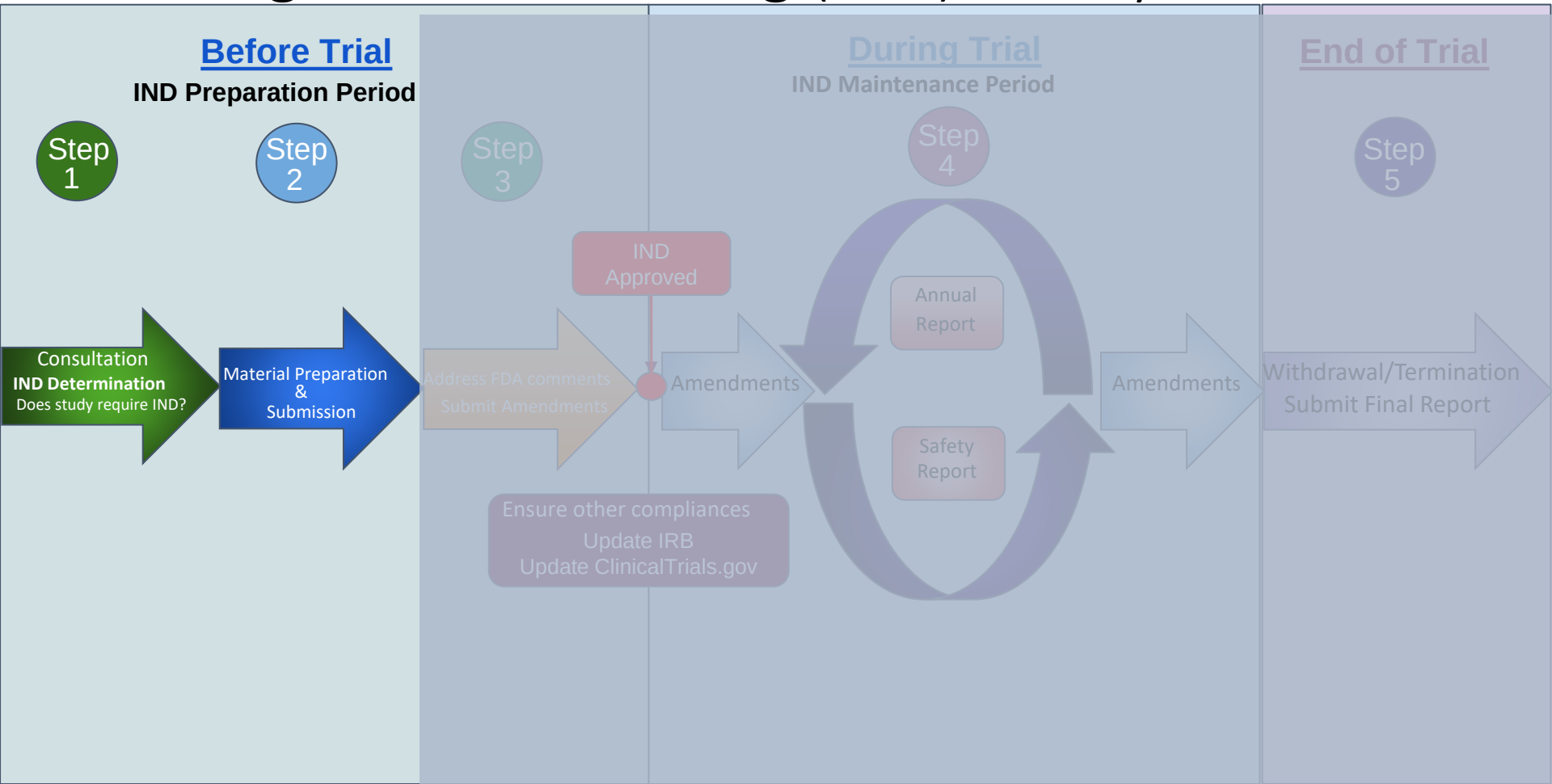


Step 1

Book one-on-one Consultation

Contact Us

Assigned SI-Support staff help with:

1. Determination of regulatory passway based on:
   - Types of drug and agent
   - Types of IND
     - -Research Intent
     - -Commercial intent

2. Determination of the division based on the indication studies in the IND

3. Initial IND application preparation by providing
   - Templates
   - IND Submission Guidance

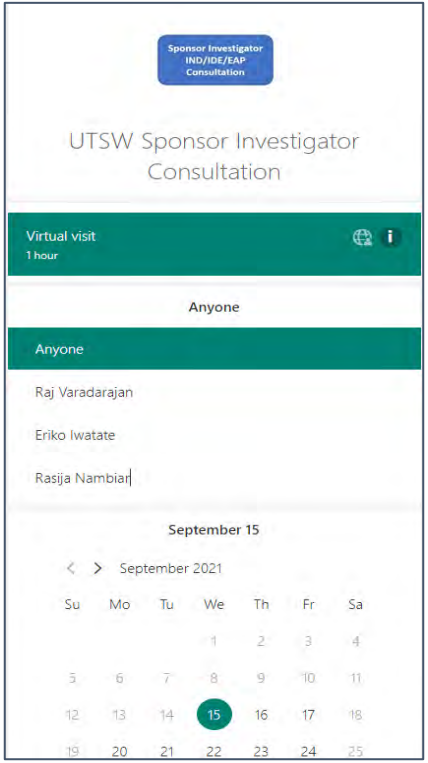
5. Preparation of other parallel requirements
   - IRB submission
   - ClincialTrials.gov registration

A

Visit SI-Support Website

B

Book a free consultation with RSO team



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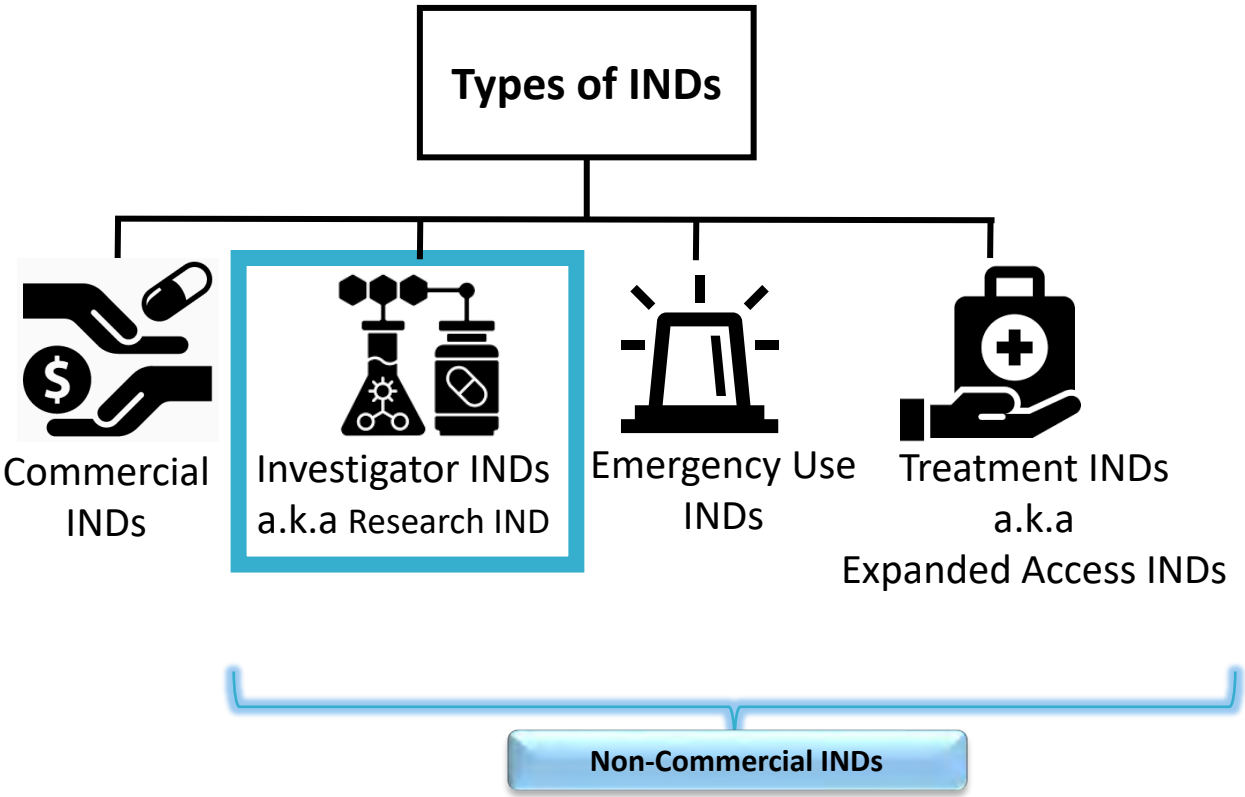
Meet with RSO team: Determination of appropriate regulatory pathways



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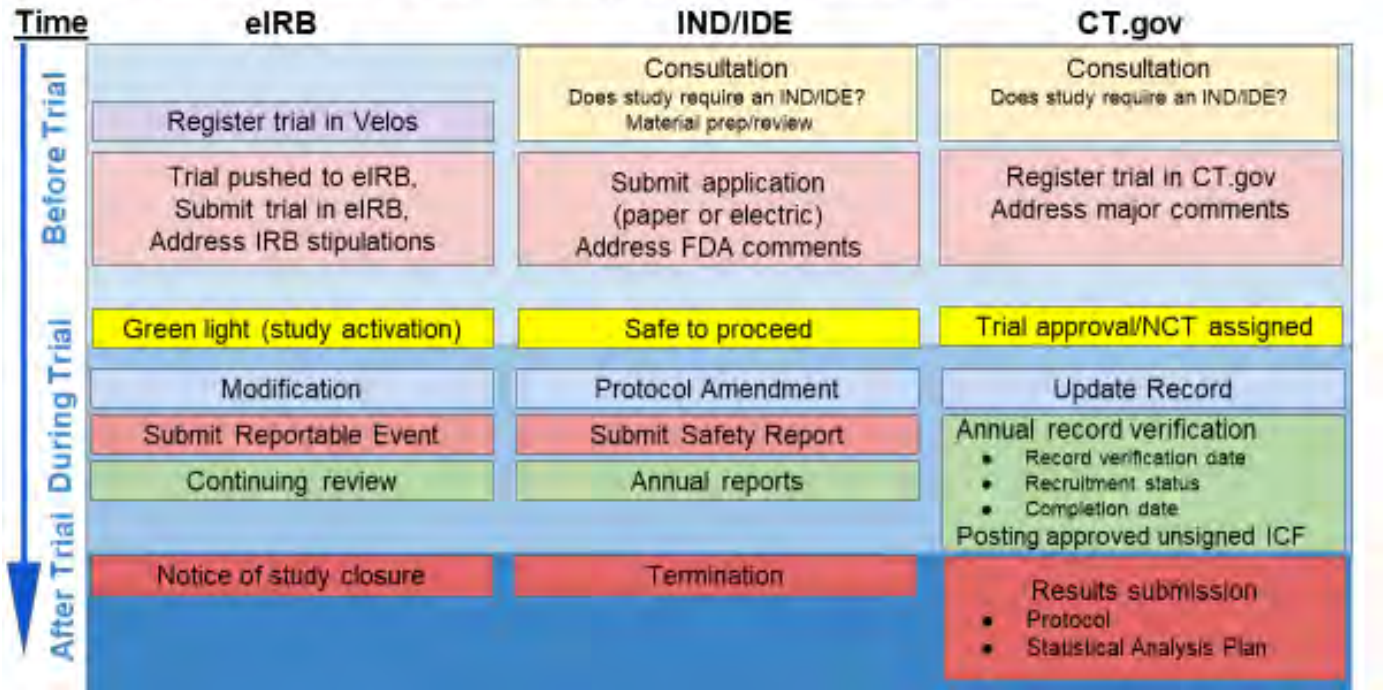
D

Meet with RSO team: Provide guidance on other parallel requirements (IRB submission & Clinical Trials.gov registration)

IND/IDE, eIRB and CT.gov clinical trial timeline



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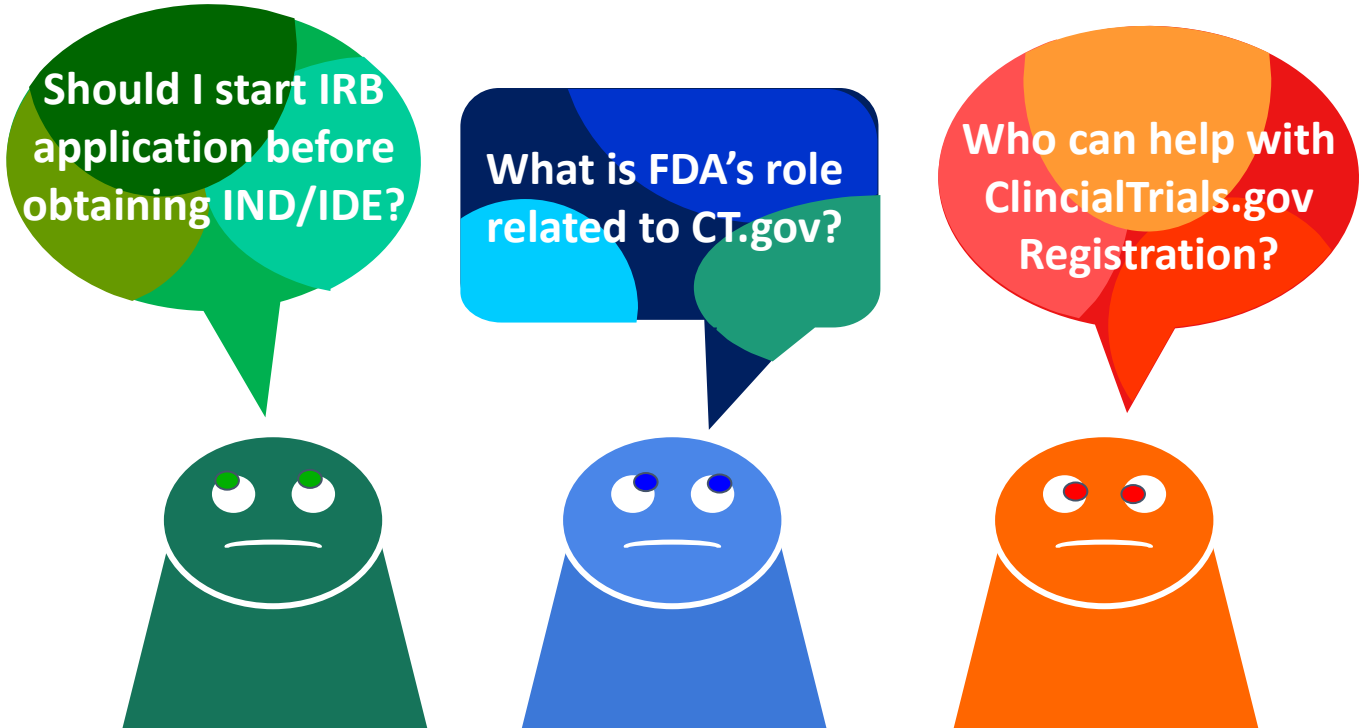

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F

Meet with RSO team: Needs assessment for pre-IND consultation/meeting with FDA

CENTER FOR DRUG EVALUATION AND RESEARCH
PRE-IND Consultation Contacts

Office of Drug Evaluation I

Division of Cardiovascular and Renal Products
Edward Fromm
301-796-2240
FAX 301-796-9841

Division of Neurology Products Jacqueline Ware
301-796-1160
FAX 301-796-9842

Division of Psychiatry Products
Steve Hardeman
301-796-1081
FAX 301-796-9838

Office of Drug Evaluation II

Division of Anesthesia, Analgesia, and Addiction Products
Parinda Jani
301-796-1232
Matt Sullivan
301-796-1245
FAX 301-796-9722

Division of Metabolism and Endocrinology Products
Julie Van der Waag
301-796-1290
Pamela Lucarelli
301-796-3961
FAX 301-796-9712

Division of Pulmonary, Allergy, and Rheumatology Products
Sandy Barnes
301-796-1174
FAX 301-796-9728

Office of Drug Evaluation III

Division of Gastroenterology and Inborn Error Products
Richard (Wes) Ishihara
Brian Strongin
301-796-2120
FAX 301-796-9906

Division of Dermatology and Dental Products Barbara Gould
301-796-4224
FAX 301-796-9895

Division of Reproductive and Urologic Products
Jennifer Mercier
301-796-0934
Margie Kober
301-796-0937
FAX 301-796-9897

Office of Drug Evaluation IV

Division of Nonprescription Clinical Evaluation
Dan Brum
301-796-0578
FAX 301-796-9899

Division of Medical Imaging Products
Kyong Kang
301-796-2050
FAX 301-796-9849

Division of Non Prescription Regulation Development
Dan Brum
301-796-0578
FAX 301-796-9899

Botanical Review Team
Jagit Grewal
301-796-0846
FAX 301-595-7865

Office of Antimicrobial Products: Pre-IND Consultation Program

Division of Anti-Infective Products
Carrmen DeBellas
301-796-1203
Maureen Dillon-Parker
301-796-0706
FAX 301-796-9881

Division of Transplant and Ophthalmology Products Products
Dianna Willard
301-796-1600
FAX 301-796-9880

Division of Anti-Viral Products
Nina Mani
Karen Winestock
301-796-1500
FAX 301-796-9883

Office of Hematology and Oncology Drug Products

Division of Oncology Products (1)
Christy Cottrell
301-796-4256
Alice Kacuba
301-796-1381
FAX 301-796-9845

Division of Oncology Products (2)
Monica Hughes
301-796-9225
Melanie Pierce
301-796-1273
FAX 301-796-9849

Division of Hematology Products
Theresa A. Carioti
301-796-2848
Amy Baird
301-796-4969
FAX 301-796-9848

Division of Hematology, Oncology, Toxicology

(Please reference any of the point of contacts listed above.)

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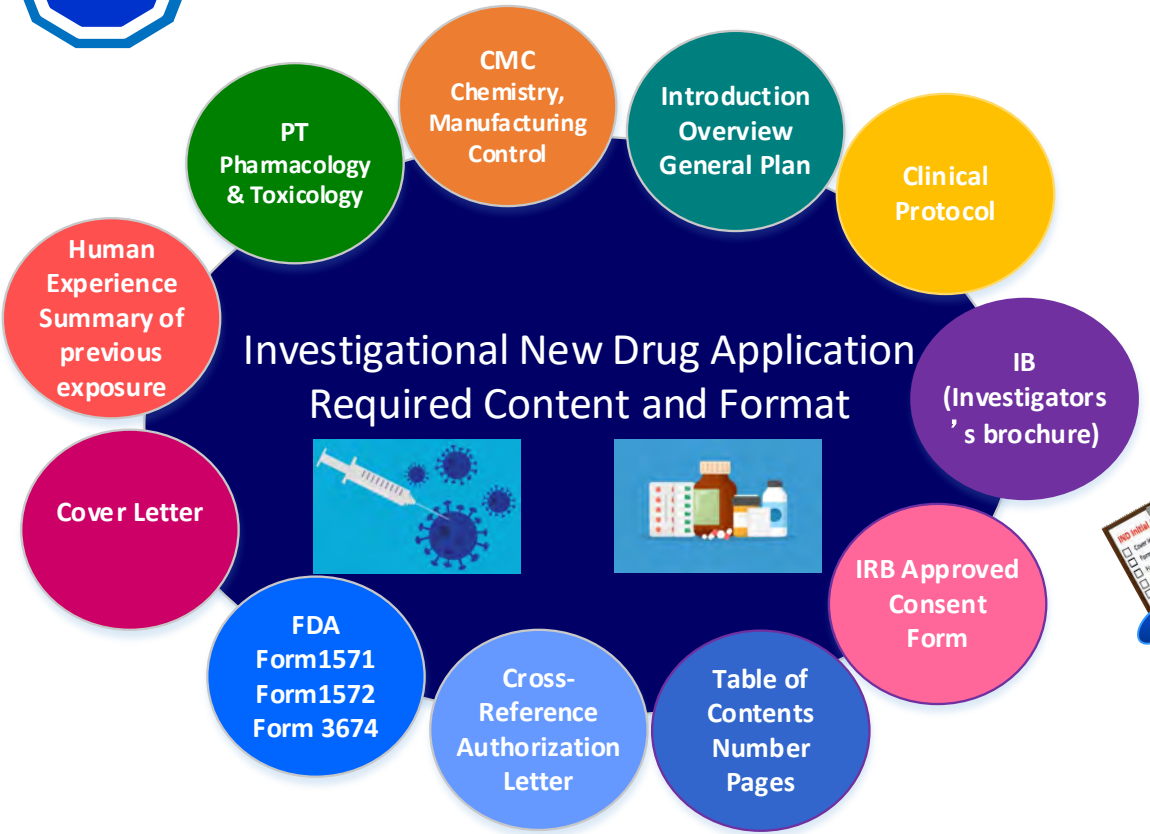
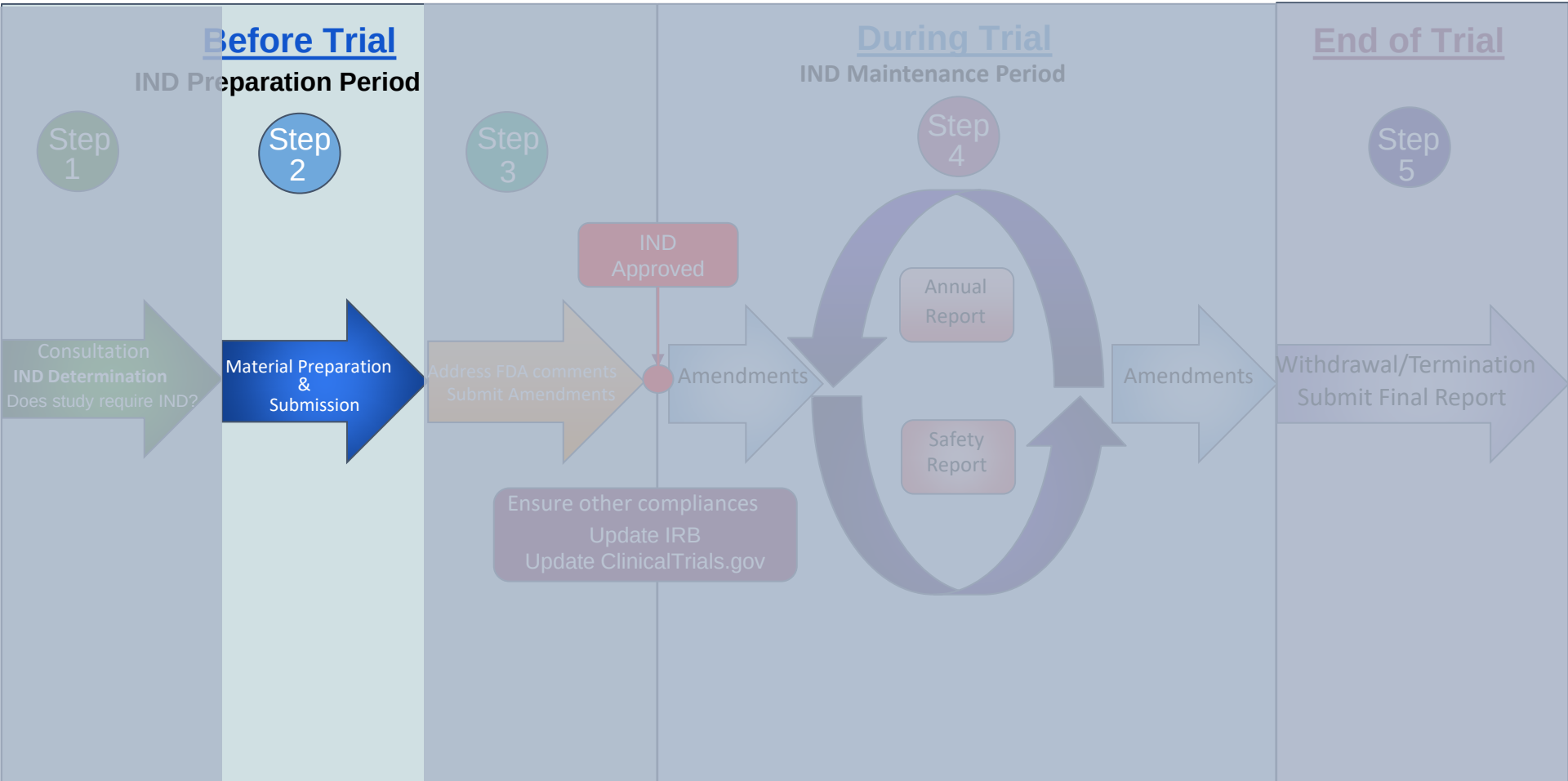
G

Meet with RSO team: Review IND initial application package together



UTSouthwestern Medical Center

Investigational New Drug (IND) Life Cycle



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H

Meet with RSO team: Review IND Content and Format

21 CFR 312 – IND content and format

- ☐ **Regulatory and Administrative Components**
  312.23 (a)(1-5)
- ☐ **Clinical Components**
  312.23(a)(6) and (9)
- ☐ **Nonclinical Components (CMC and Pharm/Tox)**
  312.23(a)(7-8)
- ☐ **Additional Information**
  312.23(a)(10-11)

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Meet with RSO team: Review IND initial application package

IND Initial Application Package

- ☐ Cover letter
- ☐ Form FDA 1571
- ☐ Form FDA 1572
- ☐ Form FDA 3674
- ☐ Form FDA 3454 or Form FDA 3455
- ☐ Letter of Authorization (Cross reference letter for IND)
- ☐ Initial IND Application
- ☐ Protocol
- ☐ Informed Consent Document
- ☐ Investigator Brochure or package insert
- ☐ Investigator's CV

Step 2

Material Preparation & Submission

1. Prepare IND contents using
   - Initial application template
   - Cover Letter template

Contact Us

2. Once completed, contact SI office for review

3. Submit initial IND applications to FDA either:
   - via CDER NextGen Portal for research IND involving small molecule drug
   - via emailing CBERDCC_eMailSub@fda.hhs.gov for research IND involving biologics, antibody, gene therapy agent

* Send IND to the correct FDA division or Document Control Center
Choose the division based on the indication studies in the IND
Descriptions of specific indications can be found
CDER Offices & Divisions
CBER Key Staff Directory

H

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Cover Letter

Form 1571
Contractual agreement between Sponsor & FDA

Form 1572
Contractual agreement between Investigator & Sponsor

Form 3674
Certification of registration at CT.gov

Form 3454
Financial Certification

Form 3455
Disclosure Statement

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Letter of Authorization (LOA)

A permission letter from sponsor (manufacture of investigational products) allowing the FDA to cross-reference confidential information of sponsor's existing IND on file to support your new IND application. Such confidential information may include:

- Description of the facility where the drug is manufactured
- Chemistry, Manufacturing, and Controls
- Pharmacology, Toxicology information
- Labeling
- Previous Human Experience

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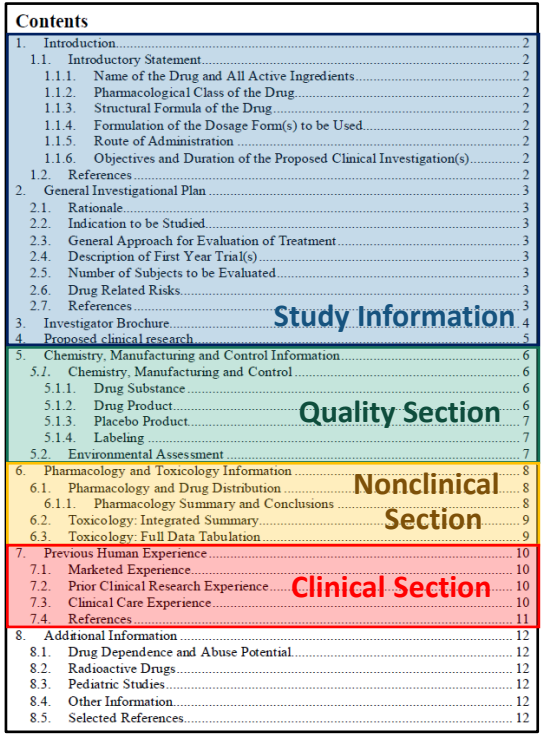

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1. INTRODUCTION

1.1. 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)

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

1.1.1. Name of the Drug and All Active Ingredients

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

1.1.2. Pharmacological Class of the Drug

Include the pharmacological class of the drug.

1.1.3. 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)

1.1.4. 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.

1.1.5. Route of Administration

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

1.1.6. 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.

1.2. References

List any references for Section 1

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2. 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.

2.1. 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.

2.2. Indication to be Studied

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

2.3. 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.

2.4. 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.

2.5. Number of Subjects to be Evaluated

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

2.6. 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.

2.7. References

List any references for Section 2

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CBER Key Staff Directory

Good News!

You can refer to drug labeling or to Letter of Authorization (LOA) for the following section of IND application:

- Investigator Brochure
- Chemistry, Manufacturing, and Controls
- Pharmacology, Toxicology information
- Previous Human Experience

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3. 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. Cross-reference Letters for IBs and INDs are provided as separate attachments as a part of the Appendix item.

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.*

IB is provided as a separate document as an Appendix Item. If multiple drugs are involved in the IND, IBs for of the drugs are to be included in the application.

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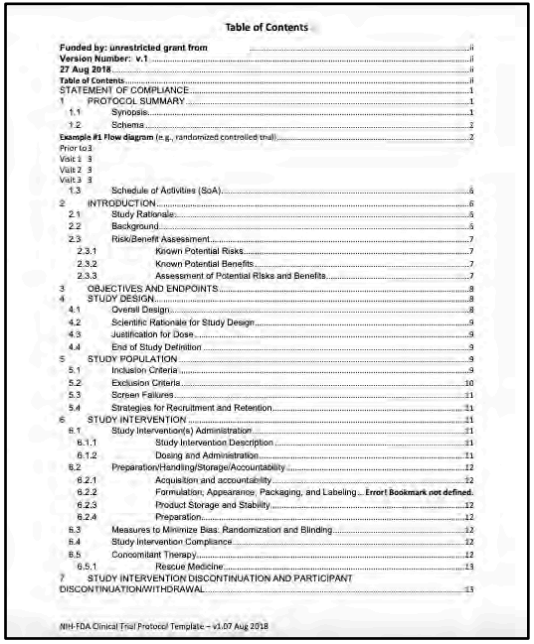
4. PROPOSED CLINICAL RESEARCH

Provide a brief summary of clinical protocol and informed consent for each study planned under the IND.

Indicate that the Protocol and Consent are provided in separate documents (Appendix Items) to accompany this IND application.



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5. CHEMISTRY, MANUFACTURING AND CONTROL INFORMATION

5.1. 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.

5.1.1. 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*

5.1.2. 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.*

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Quality Section

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6. PHARMACOLOGY AND TOXICOLOGY INFORMATION

As was true for Section 5, 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

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

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.

6.1. 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.

6.1.1. Pharmacology Summary and Conclusions

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

6.2. 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)(iii)(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:

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Nonclinical Section

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7. 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

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.

7.1. 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.

7.2. 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.

7.3. 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.

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Clinical Section

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8. 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'.

8.1. 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

8.2. 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

8.3. 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

8.4. 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.

8.5. Selected References

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

9. APPENDIX

List the applicable items from the following which will accompany this Application Document-

9.1. FDA Form 1571
9.2. FDA Form 1572
9.3. FDA Form 3674
9.4. Protocol
9.5. Informed Consent Document
9.6. Investigator Brochure
9.7. Letter of Agreement for Drug Supply
9.8. Letter of Cross-reference for IND
9.9. Investigators CV (and Medical License, as applicable)
9.10. Previous FDA Communications
9.11. Other Documents (e.g., Package Inserts, Literature References, Certificate of Approval [for Drug Product])

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Prepare IND Contents

IND Initial Application Package

- [x] Cover letter
- [x] Form FDA 1571
- [x] Form FDA 1572
- [x] Form FDA 3674
- [x] Form FDA 3454 or Form FDA 3455
- [x] Letter of Authorization (Cross reference letter for IND)
- [x] Initial IND Application
- [x] Protocol
- [ ] Informed Consent Document
- [ ] Investigator Brochure or package insert
- [ ] Investigator's CV

SCCC Protocol Template

NIH-FDA Protocol Template

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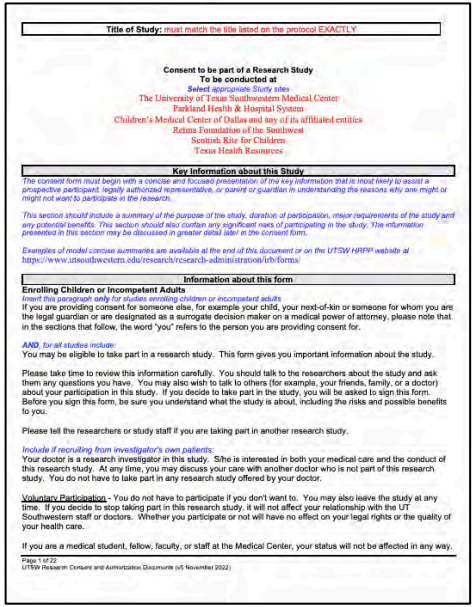

Title of Study: must match the title listed on the protocol EXACTLY

Consent to be part of a Research Study
To be conducted at
Select appropriate Study sites
The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center of Dallas and any of its affiliated entities
Retina Foundation of the Southwest
Scottish Rite for Children
Texas Health Resources

Key Information about this Study

The consent form must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant, legally authorized representative, or parent or guardian in understanding the reasons why one might or might not want to participate in the research.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.

Examples of model concise summaries are available at the end of this document or on the UTSW HRPP website at https://www.utsouthwestern.edu/research/research-administration/irb/forms/

Information about this form

Enrolling Children or Incompetent Adults
Insert this paragraph only for studies enrolling children or incompetent adults
If you are providing consent for someone else, for example your child, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow, the word "you" refers to the person you are providing consent for.

AND, for all studies include:
You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Include if recruiting from investigator's own patients:
Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

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ICF Template

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Package Insert is a quick-reference brochure

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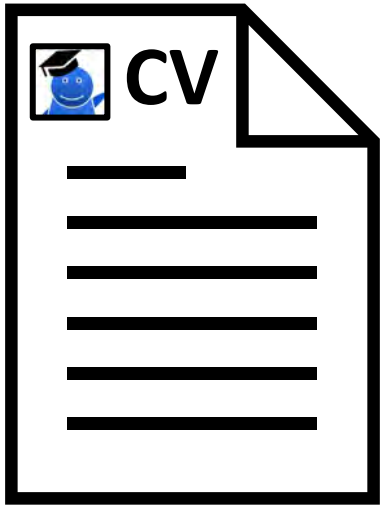


Device Overview & IDE

FDA U.S. FOOD & DRUG ADMINISTRATION

What is a Medical Device

Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, other meets the definition of medical device per the FD&C Act

What are Classes of Medical Device

Class I: e.g., toothbrush, mask, bandage, beds
Class II: e.g., catheters, blood pressure cuffs
Class III: e.g., pacemakers, breast implants, ventilators

What is a Significant Risk Device

Devices presents a potential for serious risk to health, safety, or welfare of a subject per 21 CFR 812.3(m) Need IDE before begin clinical investigations of device

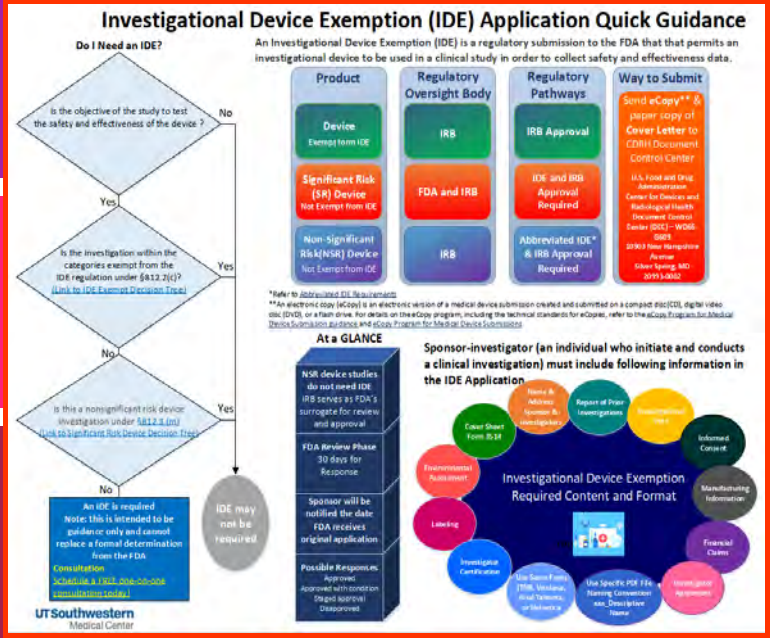
What is Non-Significant Risk Device

Devices do not pose a significant risk to the human subjects. Does not need IDE but must comply with abbreviated IDE requirements under 21 CFR 812.2 (b)

What is IDE?

Request to FDA for authorization to use investigational significant risk device in human. Exemption may apply

Do I Need an IDE?



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Watch on YouTube

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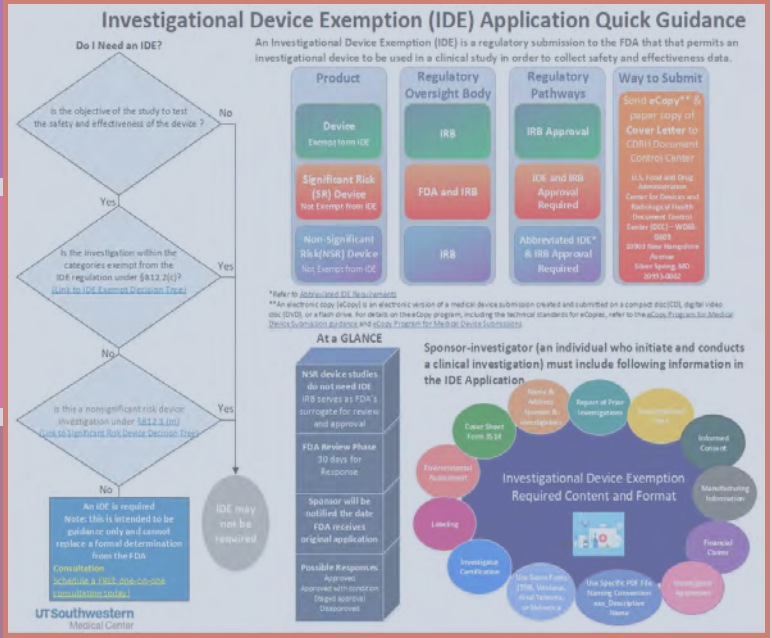
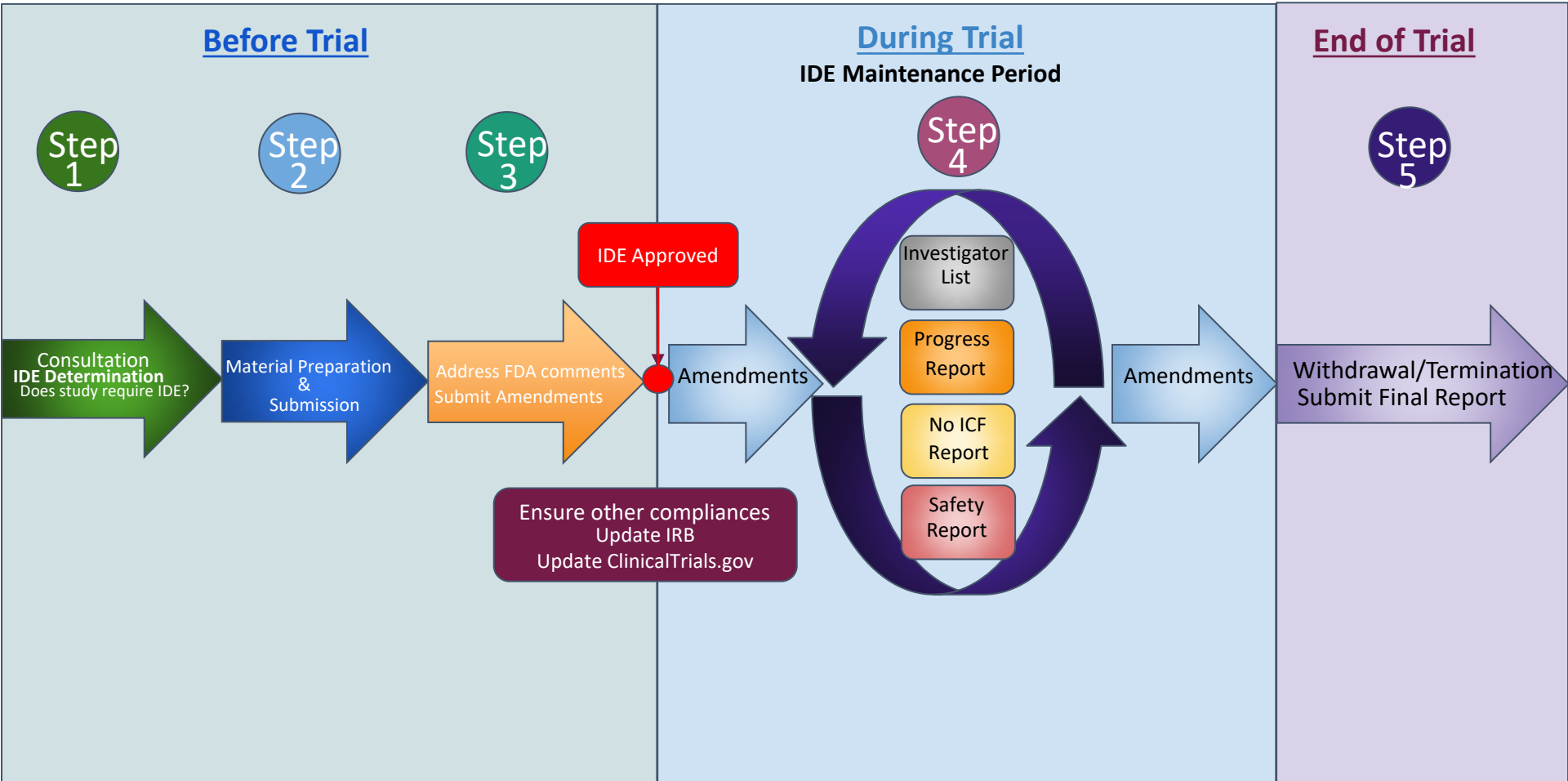
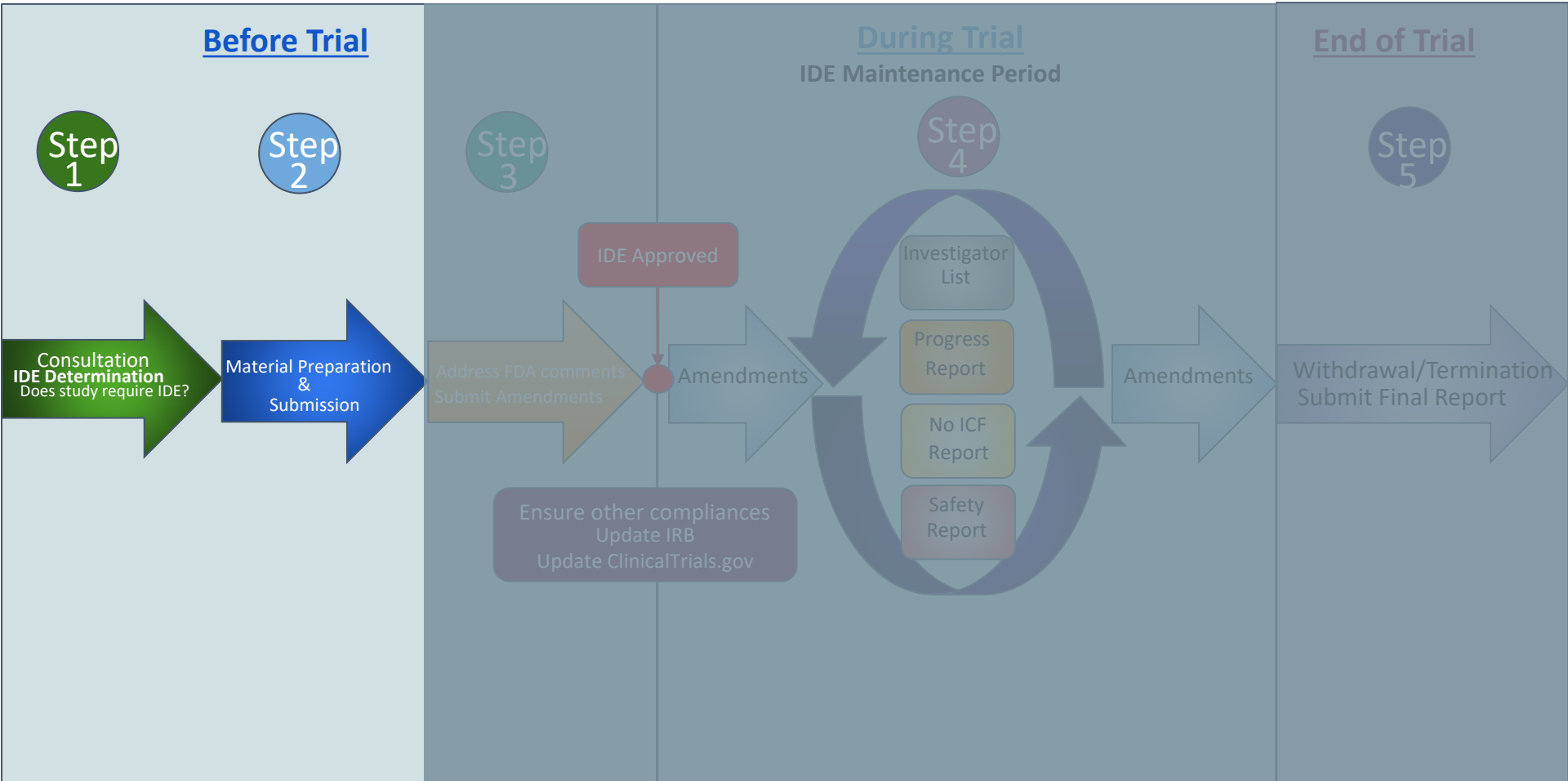


Investigational Device Exemption (IDE) Life Cycle



Investigational Device Exemption (IDE) Life Cycle



Step 1

Book one-on-one Consultation

Contact Us

Assigned SI-Support staff help with:

1. Determination of regulatory passway based on the product classification
   - IDE Exempt Device
   - Significant Device (IDE)
   - Non-Significant Device (Abb IDE)

2. Determination of the Document Control Center (CDRH vs CBER)

3. IDE application preparation by providing
   - Templates
   - IDE Submission Guidance

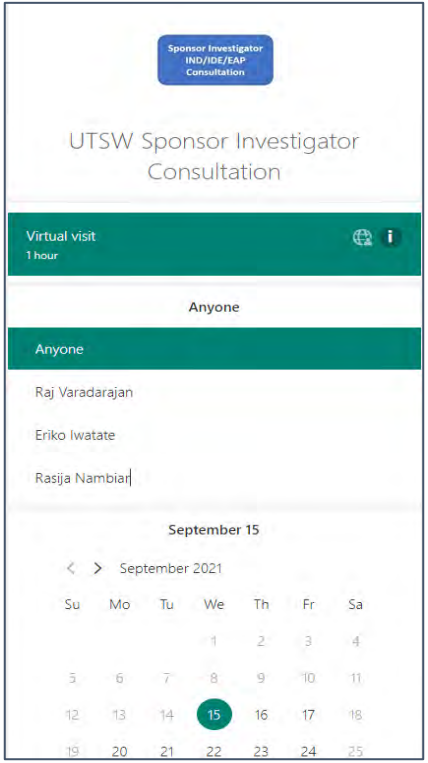
4. Preparation of other parallel requirements
   - IRB submission
   - ClincialTrials.gov registration

A

Visit SI-Support Website

B

Book a free consultation with RSO team



Step 1

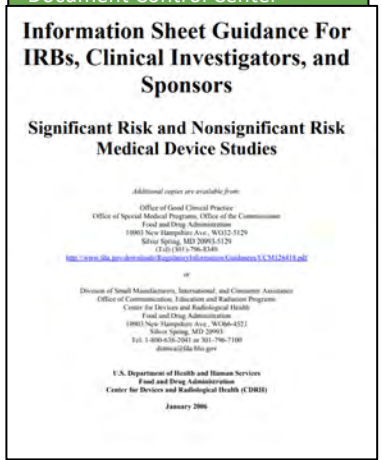
Book one-on-one Consultation

Contact Us

Assigned SI-Support staff help with:

1. Determination of regulatory passway based on the product classification
   - IDE Exempt Device
   - Significant Device (IDE)
   - Non-Significant Device (Abb IDE)

2. Determination of the Document Control Center



Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors

Significant Risk and Nonsignificant Risk Medical Device Studies

Additional copies are available from:

Office of Good Clinical Practice
Office of Special Medical Programs, Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Ave., WO32-5129
Silver Spring, MD 20993-5129
(Tel) (301) 796-8349
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

or

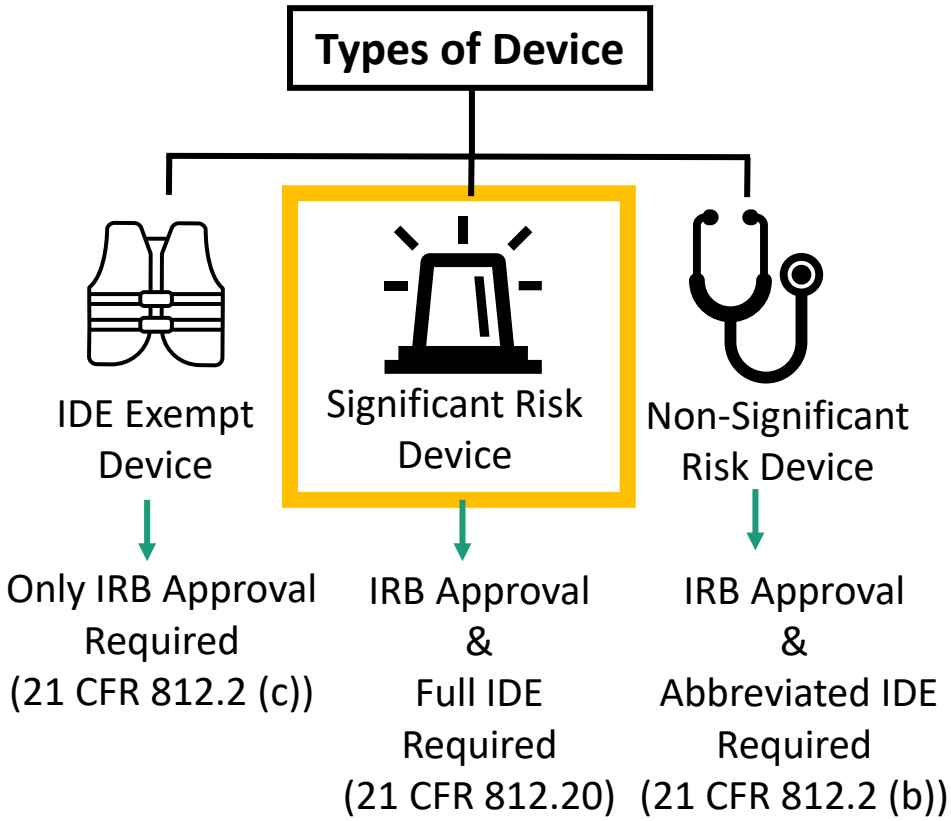
Division of Small Manufacturers, International, and Consumer Assistance
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., WO66-4521
Silver Spring, MD 20993
Tel. 1-800-638-2041 or 301-796-7100
dsmica@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)

January 2006

C

Meet with RSO team: Determination of appropriate regulatory pathway



Step 1

Book one-on-one Consultation

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Assigned SI-Support staff help with:

1. Determination of regulatory passway based on the product classification
   - IDE Exempt Device
   - Significant Device (IDE)
   - Non-Significant Device (Abb IDE)

2. Determination of the Document Control Center (CDRH vs CBER)

3. IDE application preparation by providing
   - Templates
   - IDE Submission Guidance

4. Preparation of other parallel requirements
   - IRB submission
   - ClincialTrials.gov registration

D

Meet with RSO team: Ask your device questions !

Step 1

Book one-on-one Consultation

Contact Us

Assigned SI-Support staff help with:

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Meet with RSO team: Needs assessment for Q-submission/meeting with FDA

Q-Submission Type	Meeting as Method of Feedback	Timeframe for Meeting/Teleconference (from receipt of submission)
Pre-Submission	Upon Request	60-75 days
Informational Meeting	Yes	90 days
Study Risk Determination	No	90 days
Agreement Meeting	Yes	30 days or within time frame agreed to do with sponsor
Determination Meeting	Yes	Date for meeting agreed upon within 30 days of request
Submission issue request	Yes	21 days 70 days
Day 100 Meeting	Yes	100 days (from PMA filling date)

Step 1

Book one-on-one Consultation

Contact Us

Assigned SI-Support staff help with:

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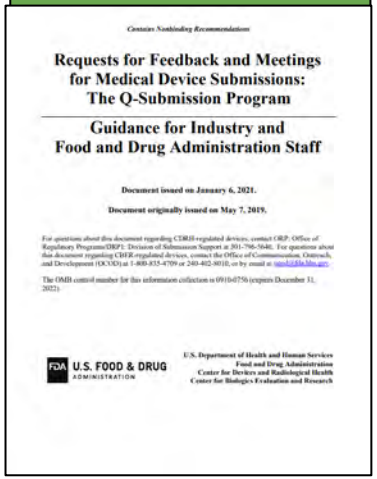
2. Determination of the



Contains Nonbinding Recommendations

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on January 6, 2021.

Document originally issued on May 7, 2019.

For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs/DRP1: Division of Submission Support at 301-796-5640. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

The OMB control number for this information collection is 0910-0756 (expires December 31, 2022).

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Meet with RSO team: Needs assessment for Q-submission/meeting with FDA

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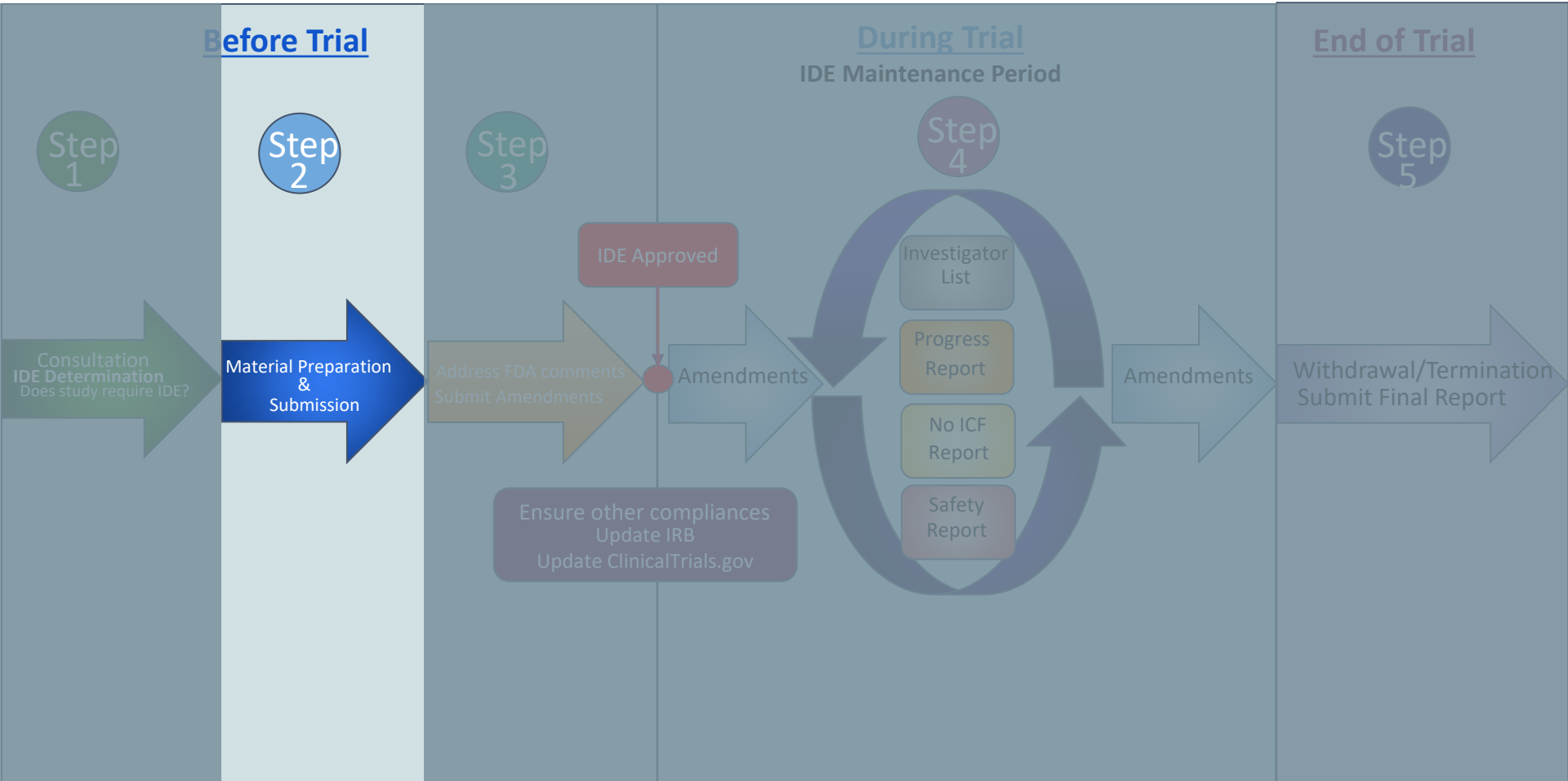
Meet with RSO team: Review IDE initial application package together

UTSouthwestern Medical Center

Investigational Device Exemption (IDE) Life Cycle



Step 2

Material Preparation & Submission

1. Prepare IDE contents using
   - Initial application template
   - Cover Letter template

2. Once completed, contact SI office for review

Contact Us

H

Prepare IDE Contents

IDE Initial Application Package

- ☐ Cover Sheet Form FDA 3514
- ☐ Name and Address of the Sponsor
- ☐ Report of Prior Investigations
- ☐ Investigational Plan
- ☐ Manufacturing Information
- ☐ Investigator Agreement
- ☐ Investigator Certification
- ☐ IRB Information
- ☐ Name & Address of Investigator's Institution
- ☐ Financial Claims
- ☐ Environmental Assessment
- ☐ Labeling
- ☐ Informed Consent
- ☐ Additional Information

UTSouthwestern Medical Center

Step 2

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Prepare IDE Contents

IDE Initial Application Package

- [x] Cover Sheet Form FDA 3514
- [ ] Name and Address of the Sponsor
- [ ] Report of Prior Investigations
- [ ] Investigational Plan
- [ ] Manufacturing Information
- [ ] Investigator Agreement
- [ ] Investigator Certification
- [ ] IRB Information
- [ ] Name & Address of Investigator's Institution
- [ ] Financial Claims
- [ ] Environmental Assessment
- [ ] Labeling
- [ ] Informed Consent
- [ ] Additional Information

Form 3514

IDE cover sheet

IDE Cover Letter

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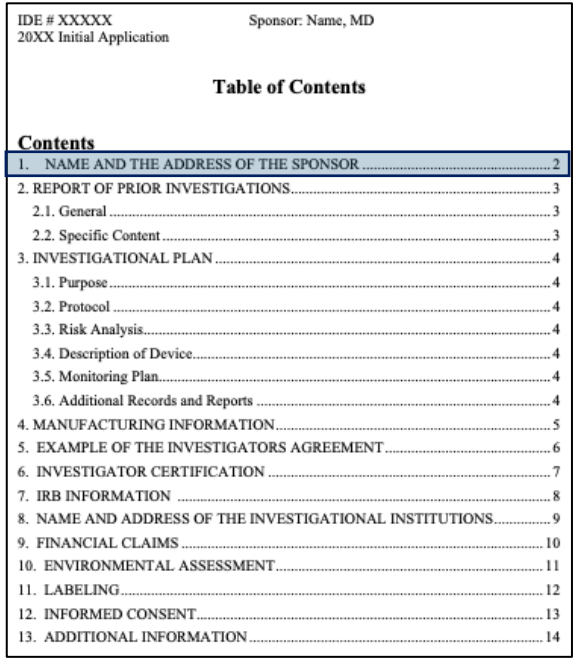
1. NAME AND THE ADDRESS OF THE SPONSOR

Name
Address
Phone number
Fax
Email address

Name and contact information of alternate contact (if applicable)



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2. REPORT OF PRIOR INVESTIGATIONS

In this section, sponsor should provide a complete report of prior investigations of the device.

2.1. General

The report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation.

2.2. Specific Content

a) A bibliography of all publications, whether adverse of supportive, that are relevant to an evaluation of the safety or effectiveness of the device, copies of all published and unpublished adverse information, and, if requested by an IRB or FDA, copies of other significant publications.

b) A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of safety or effectiveness of the device.

c) If information on nonclinical laboratory studies is provided a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice (GLP) regulation in 21 CRF part 58. If the study was not conducted in compliance with such regulations, a brief statement of the reason for the non-compliance.

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3. INVESTIGATIONAL PLAN

At the beginning of this section, sponsor can give a brief overview of the investigation plan, logic and need for this trial, is it a single-site study, what are the end points etc.

3.1. Purpose

The name and intended use of the device and the objectives and duration of the investigations.

3.2. Protocol

A written protocol should describe the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound. Protocol should include objectives and the hypothesis of the trial. Also describe the type of trial (i.e., controlled/open, double-blind/single/blind, etc.) Describe in details how the trial will be conducted and analytical methods that will be used to evaluate the study. If case report forms (CFR) will be used, please attach it to the protocol.

3.3. Risk Analysis

A description and analysis of all increased risks to which subject will be exposed by the investigation; the manner in which these risk will be minimized; a justification for the investigation; and a description of the patient population including the number, age, sex, and condition.

3.4. Description of Device

A description of each important component, ingredient, property and principle of operation of the device and of each anticipated change in the device during the course of investigation

3.5. Monitoring Plan

The sponsor's written procedures for monitoring the investigation and the name and address of any monitor.

3.6. Additional Records and Reports

The sponsor's written procedures for monitoring the investigation and the name and address of any monitor.

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4. MANUFACTURING INFORMATION

If you are using a marketed device, then it is appropriate to refer to the product label and provide copy or a URL to the most current product label. If any modifications have been made, provide details on all changes.

If you have a Letter of Authorization (LoA) from another sponsor referencing their FDA submission (IND, NDA, BLA, IDE, DMF, etc), include the LoA in this section. The LoA serves the purpose to allow the FDA reviewer to review their submission on file in relation to your IDE application.

A description of the methods, facilities, and controls used for the manufacture, processing, storage, and, where appropriate, installation of the device, in sufficient details so that a person generally familiar with good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.

Source of Manufacturing information

FDA Approved Device-Off Label and/or Modified

Refer to approved product label & describe any changes

Non-FDA Approved Device

Manufactured by Company -> insert manufacturing information provided by the company & LOA

Manufactured by You ->methods, facilities, controls for manufacturing, packaging, storage, installation of device

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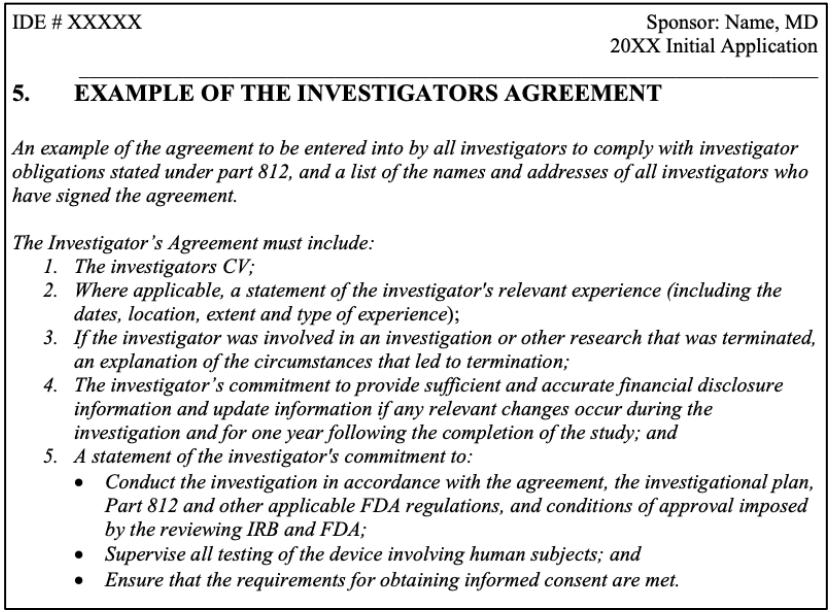

IDE # XXXXX

Sponsor: Name, MD
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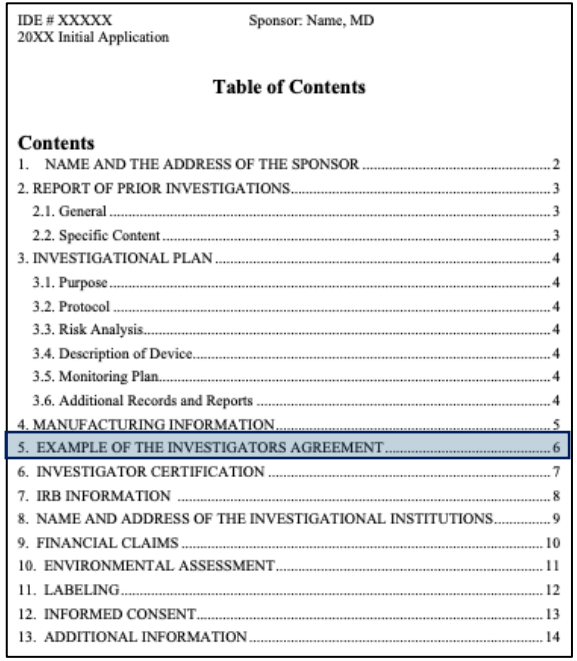
5. EXAMPLE OF THE INVESTIGATORS AGREEMENT

An example of the agreement to be entered into by all investigators to comply with investigator obligations stated under part 812, and a list of the names and addresses of all investigators who have signed the agreement.

The Investigator's Agreement must include:

1. *The investigators CV;*
2. *Where applicable, a statement of the investigator's relevant experience (including the dates, location, extent and type of experience);*
3. *If the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination;*
4. *The investigator's commitment to provide sufficient and accurate financial disclosure information and update information if any relevant changes occur during the investigation and for one year following the completion of the study; and*
5. *A statement of the investigator's commitment to:*
   - *Conduct the investigation in accordance with the agreement, the investigational plan, Part 812 and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB and FDA;*
   - *Supervise all testing of the device involving human subjects; and*
   - *Ensure that the requirements for obtaining informed consent are met.*



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6. INVESTIGATOR CERTIFICATION

A certification that all investigators who will participate in the investigation have signed the agreement, that the list of investigators includes all the investigators participating in the investigation, and that no investigator will be added to the investigation until they have signed the agreement.

The following statement can be used to satisfy this requirement: "As required for an IDE study, we commit to obtain a signed investigator agreement from all current investigators who are participating in the investigation. Additionally, no future investigators will be added until they have signed the agreement."

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7. IRB INFORMATION

A list of the name, address, and chairperson of each IRB that has been or will be asked to review the investigation and a certification of the action concerning the investigation taken by such IRB.

The University of Texas Southwestern Medical Center (UT Southwestern) (IORG0000638) has obtained a Federal wide Assurance (FWA) from the Department of Health and Human Services (DHHS) (FWA00005087). This FWA assures that all UT Southwestern activities related to human subject research, will be guided by the ethical principles in the Belmont Report and will be reviewed and implemented in compliance with DHHS human subjects regulations, 45 CFR 46, Subparts A-D. All UT Southwestern IRBs are also in compliance with Title 21 CFR Parts 50 and 56, all other Parts governing the use of investigational devices, drugs, and biologics as well as with good clinical practice (GCP) as adopted by the FDA. The FWA expires on October 16, 2023.

There is one overarching IRB with 4 separate IRB committees that operate at UTSW, and any of these IRB committees could review aspects of this IDE. Please find below the address and details for all 4 UTSW IRB committees:

IRB committee numbers, names and Chairpersons are below:
- IRB00000974 (IRB1 – David Karp, MD, PhD).
- IRB00000975, (IRB2 – Scott Roberts, MD)
- IRB00000976 (IRB3 – John Sadler, MD) and
- IRB00003142 (IRB4 – Victor Aquino, MD).

The address for UTSW IRBs is:
- UT Southwestern Medical Center

5323 Harry Hines Boulevard
Dallas, Texas 75390-8843

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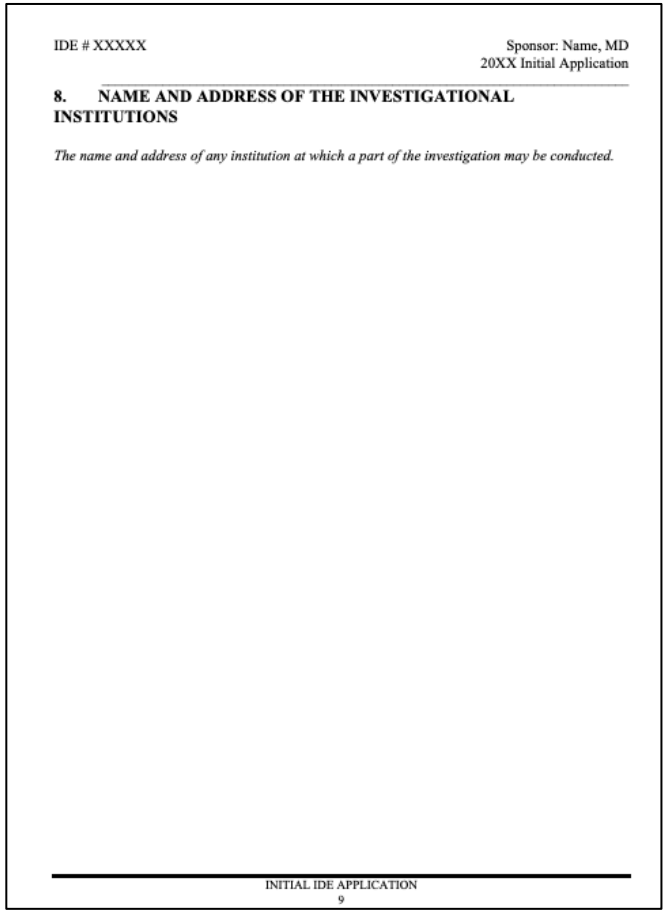

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8. NAME AND ADDRESS OF THE INVESTIGATIONAL INSTITUTIONS

The name and address of any institution at which a part of the investigation may be conducted.

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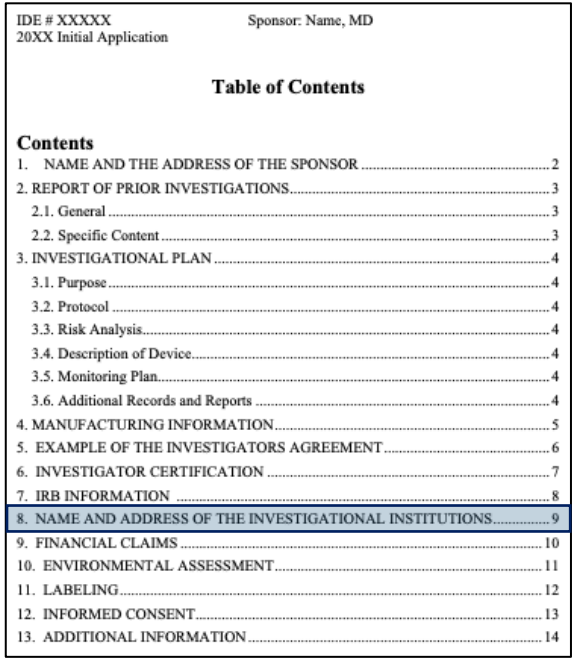

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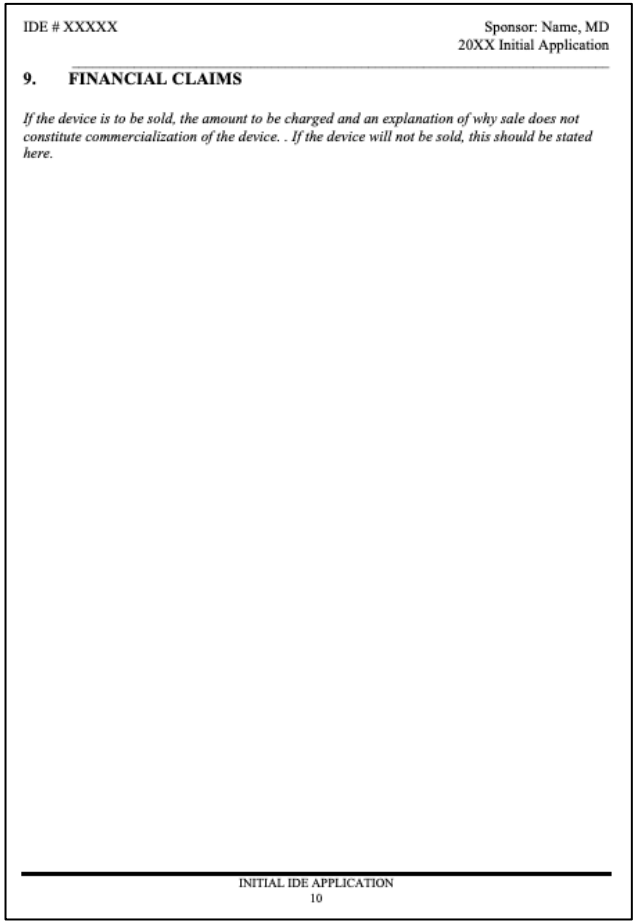

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Sponsor: Name, MD
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9. FINANCIAL CLAIMS

If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device. . If the device will not be sold, this should be stated here.

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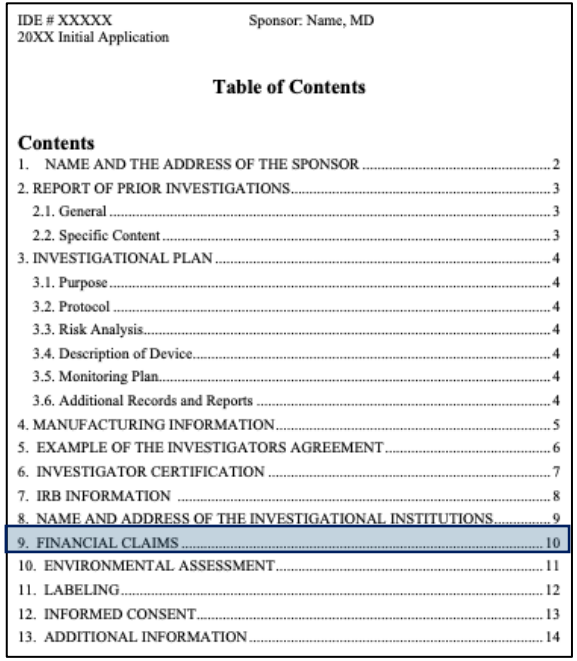

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20XX Initial Application

10. ENVIRONMENTAL ASSESSMENT

Per the CDRH Web site, https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-application, an environmental assessment as required under 21 CFR 25.40 or a claim for categorical exclusion under 21 CFR 25.30 or 25.34 is no longer required.

Please maintain this header and include the following statement: Please note that an environmental assessment as required under 21 CFR 25.40 or a claim for categorical exclusion under 21 CFR 25.30 or 25.34 is no longer required [§25.34(g)].

INITIAL IDE APPLICATION
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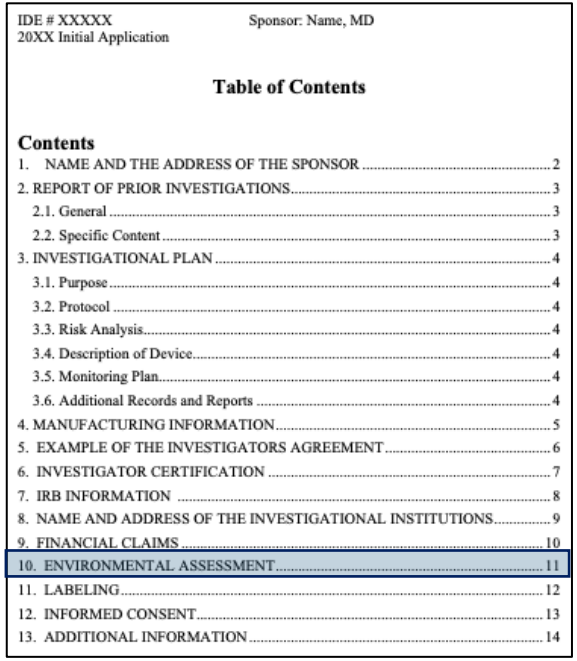

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11. LABELING

Copies of all labeling for the device. (If you are using a marketed device, then it is appropriate to refer to the most current product labeling and provide a copy or a URL link to the most current labeling here.)

Labeling is defined as 'all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce."

An investigational device or its immediate package must bear a label with the following information:

- *the name and place of business of the manufacturer, packer, or distributor;*
- *the quantity of contents, if appropriate; and*
- *the statement, "CAUTION -- Investigational device. Limited by Federal (or United States) law to investigational use."*

The label must also describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

The labeling of an investigational device must not contain any false or misleading statements nor imply that the device is safe or effective for the purposes being investigated.

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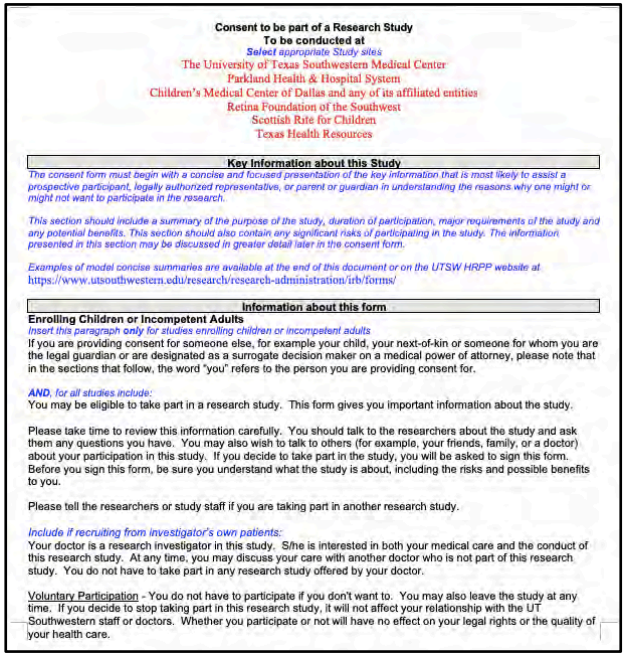


Consent to be part of a Research Study
To be conducted at
Select appropriate Study sites
The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center of Dallas and any of its affiliated entities
Retina Foundation of the Southwest
Scottish Rite for Children
Texas Health Resources

Key Information about this Study

The consent form must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant, legally authorized representative, or parent or guardian in understanding the reasons why one might or might not want to participate in the research.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.

Examples of model concise summaries are available at the end of this document or on the UTSW HRPP website at
https://www.utsouthwestern.edu/research/research-administration/irb/forms/

Information about this form

Enrolling Children or Incompetent Adults
*Insert this paragraph **only** for studies enrolling children or incompetent adults*
If you are providing consent for someone else, for example your child, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow, the word "you" refers to the person you are providing consent for.

***AND**, for all studies include:*
You may be eligible to take part in a research study. This form gives you important information about the study.

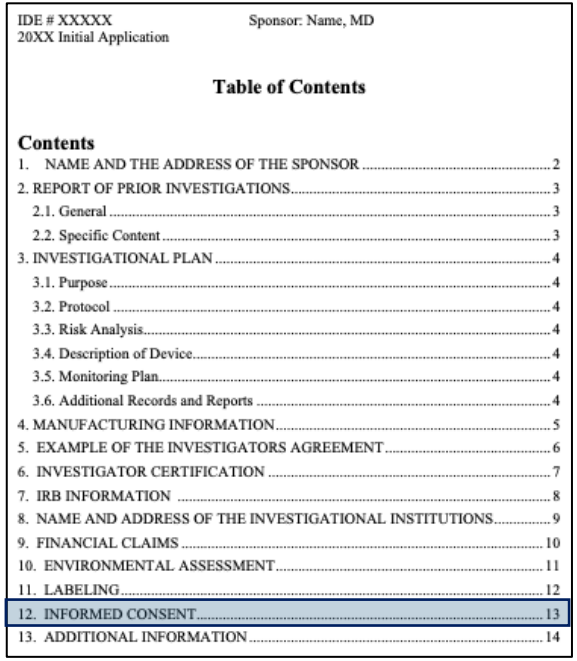
Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Include if recruiting from investigator's own patients:
Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

ICF Template



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13. ADDITIONAL INFORMATION

Any other relevant information FDA requests for review of the application.
This is a good place to include the list any references you are attaching to the application.

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   - Initial application template
   - Cover Letter template

2. Once completed, contact SI office for review

Contact Us

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Prepare IDE Contents

IDE Initial Application Package

- [x] Cover Sheet Form FDA 3514
- [x] Name and Address of the Sponsor
- [x] Report of Prior Investigations
- [x] Investigational Plan
- [x] Manufacturing Information
- [x] Investigator Agreement
- [x] Investigator Certification
- [x] IRB Information
- [x] Name & Address of Investigator's Institution
- [x] Financial Claims
- [x] Environmental Assessment
- [x] Labeling
- [x] Informed Consent
- [x] Additional Information

UT Southwestern Medical Center

Sponsor Investigator (SI) Support FDA Miniseries

Part 1
Preparing for an IND/IDE

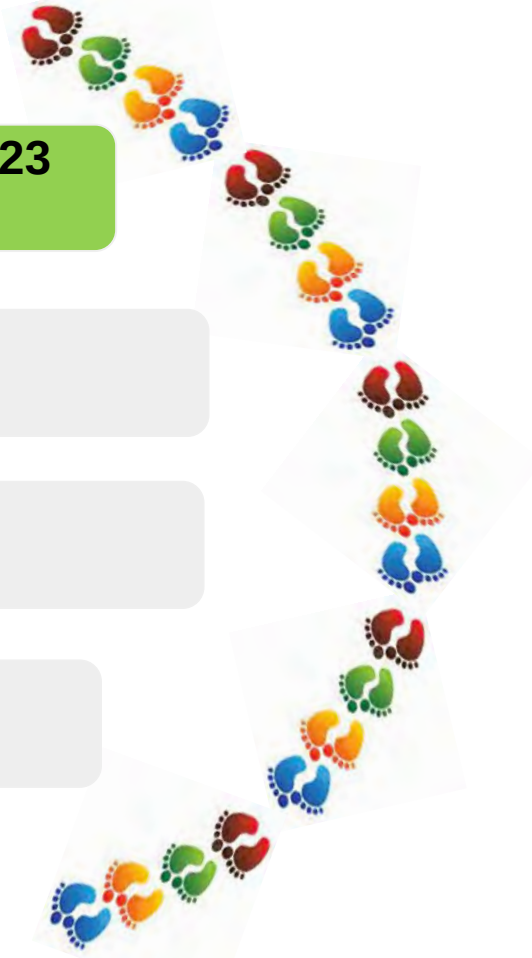
Part 2 Research Matter April 18, 2023
Initial IND/IDE submissions

Part 3
Modifications to IND/IDE

Part 4
Safety (Incident) Reports

Part 5
Annual Reports

Part 6
Ending IND/IDE



We are here to help

Contact Regulatory Support Office Today

Selected Resources for ClincialTrials.gov Support


CT.gov Video Library

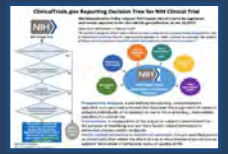

CT.gov Decision Tree

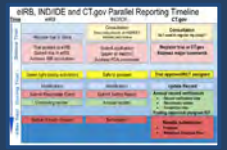

Quick CT.gov Guide


Step-by-step Registration


Step-by-step Results

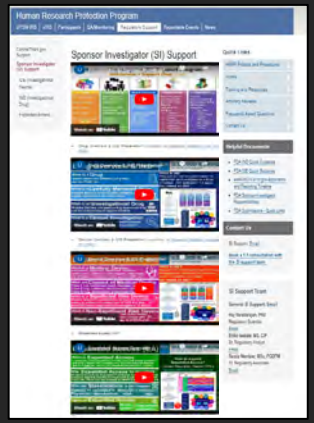

Website


CT.gov Guide for NIH Funded Trial


Reporting Timeline


ClinicalTrials.gov Consultation Booking

Selected Resources for Sponsor Investigator FDA Support


SI-Educational Video Library


EA Quick Guide


IND Quick Guide


IDE Quick Guide


Timeline


Website


EA Step-by-Step


SI Responsibilities


Templates


SI-Consultation Booking