

# Sponsor Investigator (SI) Support 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)**

FDA Submission

Support Program

ClinicalTrials.gov Support Program

Assist **Responsible Party** (Principal Investigator) with ClinicalTrials.gov Reporting -Registration -Updates -Results

Assist **Sponsor Investigator** with FDA submissions for IND IDE, Expanded Access -Preparation -Submission -Maintenance Resources & Education

## **RSO Website**

- -Application templates
- -Quick guidance documents
- -Decision trees
- Educational video library

## **Regulatory Education**

-Best practice training -Consultation via Booking

# Sponsor Investigator (SI) Support FDA Miniseries



Part 2 Initial IND/IDE submissions

> Part 3 Modifications to IND/IDE

Part 4 Safety (Incident) Reports

Part 5 Annual Reports



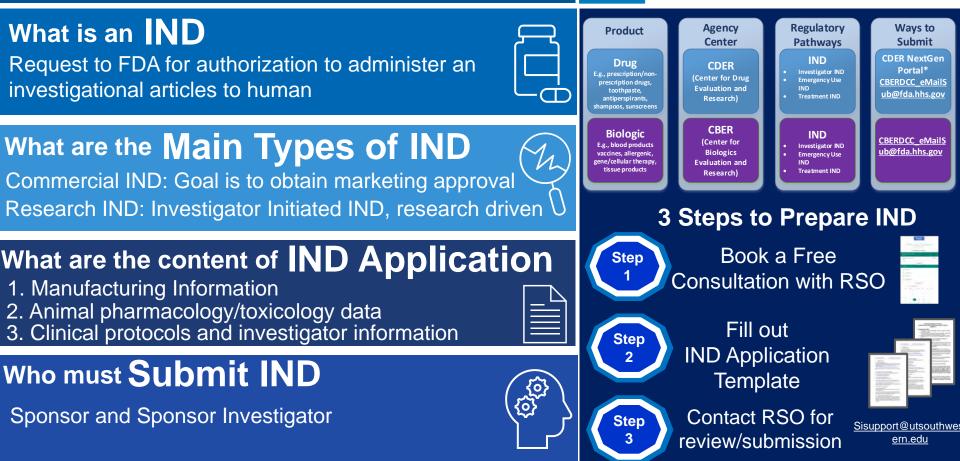
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Part 6 Ending IND/IDE

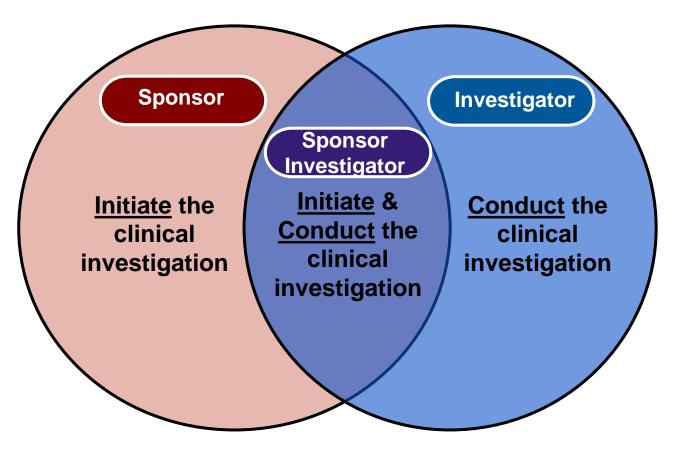
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# **IND Overview**

# FDA U.S. FOOD & DRUG



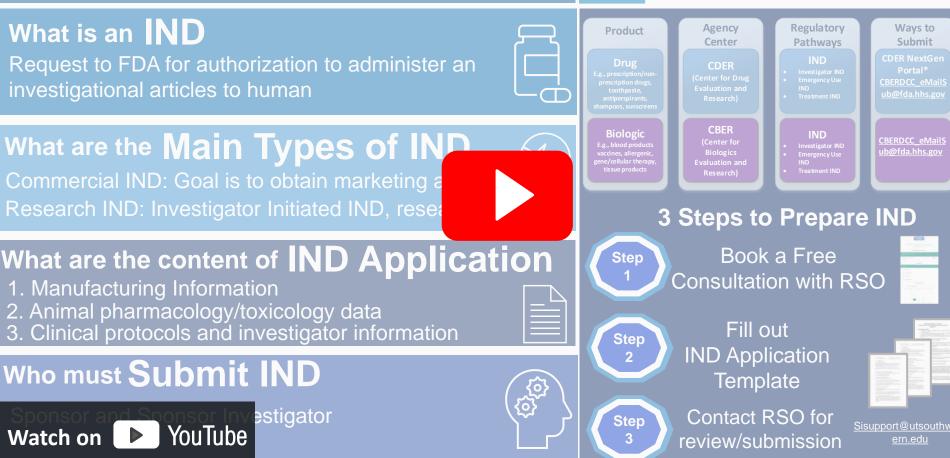
# **Definitions**



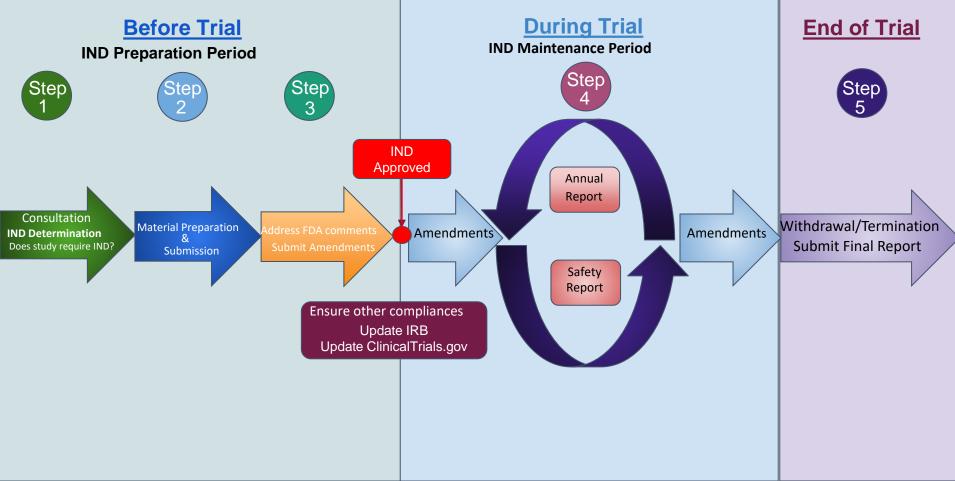
Sponsor Responsibilities	Investigator Responsibilities
Select qualified Investigators, monitors	Protect the rights, safety, and welfare of subjects under the investigator's care
Obtain information from the Investigator (e.g., signed Investigator's statement, Investigator's CV etc.)	• Ensure that an investigation 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)
<ul> <li>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.</li> </ul>	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

# **IND Overview**

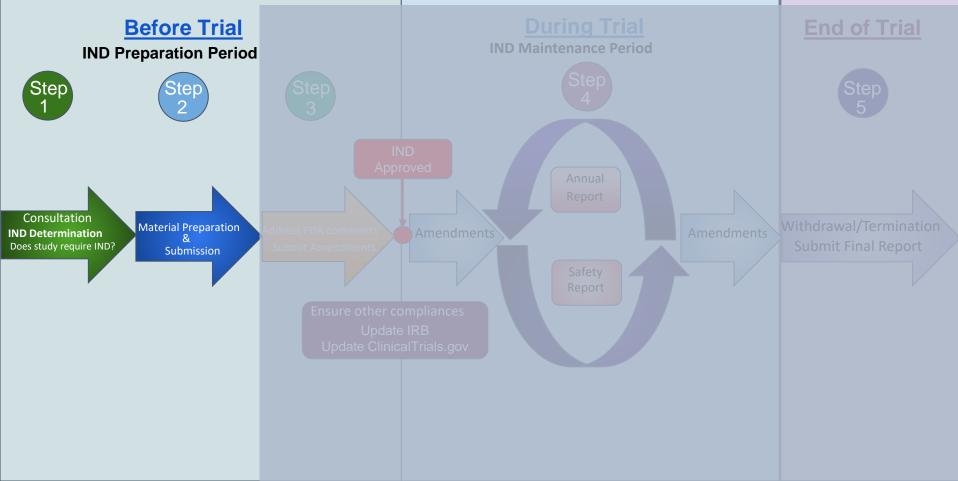
# FDA U.S. FOOD & DRUG



# Investigational New Drug (IND) Life Cycle



# Investigational New Drug (IND) Life Cycle



Step



Assigned SI-Support staff help with:

1. Determination of regulatory passway based on:

- Types of drug and agent
- Types of IND
  - 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 0



Sponsor Investigator (SI) Support IDE (Investigational Device) IND (Investigational Drug) Expanded Access

regulated research. Our goal is to provide the UTSW community with oversight, tools, training and support needed to navigate the complex regulatory pathways that accompany FDA regulated clinical investigation.

support and oversight the HRPP requires that all IND/IDE submissions to the FDA also be reported to the HRPP Regulatory Support Office's SI Support Team. The SI Support Team will maintain a shadow file of all IND and IDE. investigations held by all UTSW faculty, students, or staff. This shadow file will include all applications, reports, and communication between the study team and the FDA.

#### Service Types

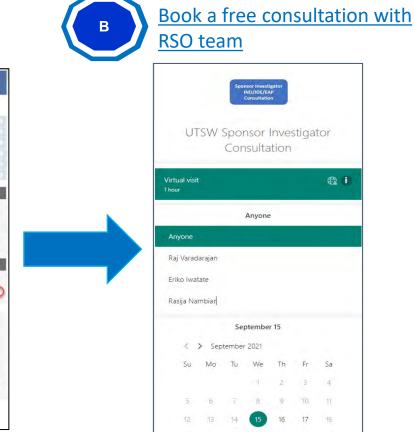
Consultation Schedule a one-on-one consultation today! The SI Support staff assist with

- · Determination of regulatory pathway
- · Drug/biologic/device development · Pre-IND meeting requests to FDA
- Material Review
- The SI Support staff review IND/IDE/EAP applications including
- · FDA required forms
- Original IND/IDE/EAP applications
- Courr Letters . Protocol
- Informed Consent
- · Manufacturing information
- · Animal Pharmacology/toxicology data

#### Submission

- The SI Support staff provide assistance with submission to the FDA. The staff · can submit materials on behalf of the investigator to the FDA, if requested. This will ensure timely processing and responses to any concerns raised by the FDA
- · can assist with the preferred electronic submissions to the CDER NextGen Portal for INDs.

#### Maintenance The SI Support staff assist with preparation of (and responses to FDA comments)



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About Sponsor Investigator (SI) Support The Human Research Protection Program's Sponsor Investigator Support provides assistance to investigator-sponsors in preparing, submitting, and maintaining applications to the Food and Drug Administration (FDA) in the conduct of FDA-

UT Southwestern requires oversight of sponsor investigators. To provide necessary

 FDA IND Quick Guidance · FDA IDE Quick Guidance · sIRBINDIDE to gev Application and Reporting Timeline FOA Sponsor-Investigator

**Quick Links** 

HRPP Policies and Procedures

Training and Resources

Frequently Asked Questions

leiptul Documents

ncillary Reviews

Contact Us

Responsibilities FDA Submissione - Quick Links

### Contact Us

SI Support Email Book a 1:1 consultation with

the SI support team

SI Support Team

General SI Support: Email Rai Varadaraian, PhD Requistory Sciences

Rasia Nambiar, MSc. PGDPM Regulatory Scientist

- Frike Iwatate, PhD, MPH, MA, CIP Direttor, Regulatory Support Office
- Ernal

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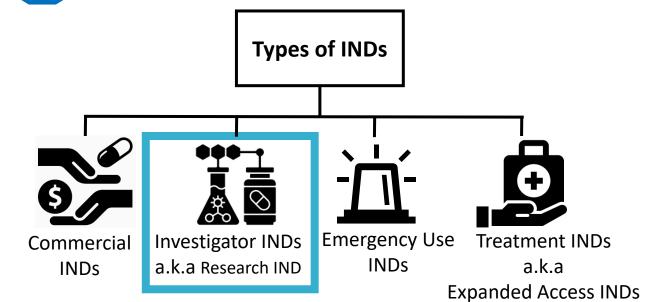
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   Guidance

5. Preparation of other parallel requirements

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- ClincialTrials.gov registration



## Meet with RSO team: Determination of appropriate regulatory pathways



Non-Commercial INDs

Step



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- IRB submission
- ClincialTrials.gov registration



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

me	elRB	IND/IDE	CT.gov
Lia	Register trial in Velos	Consultation Does study require an IND/IDE?	Consultation Does study require an IND/IDE?
Before T	Trial pushed to eIRB,	Submit application	Register trial in CT.gov
a	Submit trial in eIRB, Address IRB stipulations	(paper or electric) Address FDA comments	Address major comments
	Green light (study activation)	Safe to proceed	Trial approval/NCT assigned
	Modification	Protocol Amendment	Update Record
During	Submit Reportable Event	Submit Safety Report	Annual record verification Record verification date
-	Continuing review	Annual reports	Record verification date     Recruitment status     Completion date
rial			Posting approved unsigned ICF
After Tr	Notice of study closure	Termination	Results submission Protocol Statistical Analysis Plan

Step



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- Types of IND -Research Intent -Commercial intent

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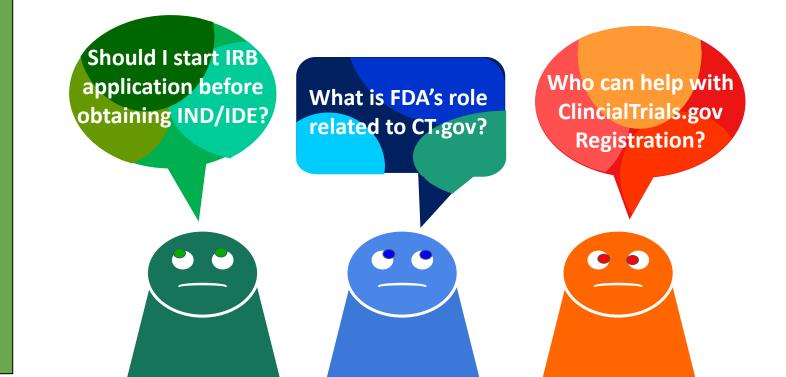
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Meet with RSO team: Provide guidance on other parallel requirements (IRB submission & ClinicalTrials.gov registration)



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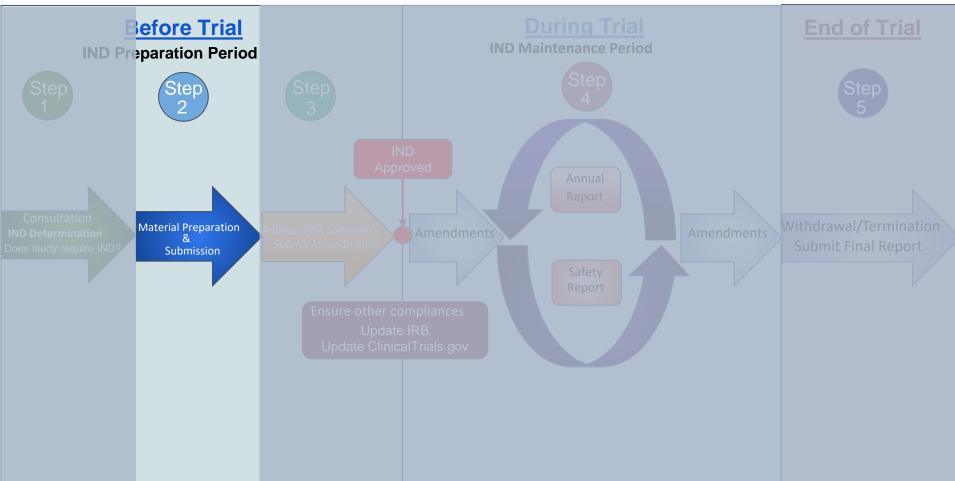
# Meet with RSO team: Needs assessment for pre-IND consultation/meeting with FDA

Office of Drug Evaluation I Office of Drug Evaluation II Office of Drug Evaluation III Office of Drug Evaluation IV Office of Antimicrobial Office of Hematology and Products: Pre-IND **Oncology Drug Products** Consultation Program Division of Anesthesia. Division of Cardiovascular **Division of Oncology** Division of Gastroenterology **Division of Nonprescription** Analgesia, and Addiction and Renal Products Products (1) and Inborn Error Products **Clinical Evaluation** Products **Division of Anti-Infective** Edward Fromm Christy Cottrell Richard (Wes) Ishihara Dan Brum 301-796-2240 Parinda Jani Products 301-796-4256 301-796-0578 301-796-1232 Carrmen DeBellas Brian Strongin FAX 301-796-9841 Alice Kacuba FAX 301-796-9899 Matt Sullivan 301-796-1203 301-796-2120 301-796-1381 301-796-1245 Maureen Dillon-Parker FAX 301-796-9906 FAX 301-796-9845 FAX 301-796-9722 301-796-0706 FAX 301-796-9881 Division of Neurology **Products Jacqueline** Division of Metabolism and Division of Oncology Ware Division of Dermatology and Division of Medical Imaging Division of Transplant and Endocrinology Products Products (2) 301-796-1160 Dental Products Barbara **Ophthalmology Products** Julie Van der Waag Products Monica Hughes FAX 301-796-9842 301-796-1280 Gould Kyong Kang Products 301-796-9225 Pamela Lucarelli 301-796-4224 301-796-2050 **Dianna Willard** 301-796-3961 Melanie Pierce 301-796-1600 FAX 301-796-9895 FAX 301-796-9849 FAX 301-796-9712 FAX 301-796-9880 301-796-1273 FAX 301-796-9849 Division of Psychiatry Products Division of Anti-Viral Division of Pulmonary, Steve Hardeman Division of Reproductive and Products Allergy, and Rheumatology 301-796-1081 **Division of Non Prescription** Urologic Products Nina Mani Products FAX 301-796-9838 **Regulation Development** Division of Hematology Karen Winestock Sandy Barnes Jennifer Mercier Products 301-796-1500 Dan Brum 301-796-1174 301-796-0934 FAX 301-796-9883 Theresa A. Carioti 301-796-0578 FAX 301-796-9728 Margie Kober 301-796-2848 FAX 301-796-9899 301-796-0937 Amy Baird FAX 301-796-9897 301-796-4969 FAX 301-796-9848 **Botanical Review Team** Division of Hematology. Oncology, Toxicology Jagit Grewal 301-796-0846 (Please reference any of FAX 301-595-7865 the point of contacts listed above.)

### CENTER FOR DRUG EVALUATION AND RESEARCH PRE-IND Consultation Contacts



# Investigational New Drug (IND) Life Cycle



Step



## Meet with RSO team: Review IND Content and Format

Assigned SI-Support staff help with:

Contact Us

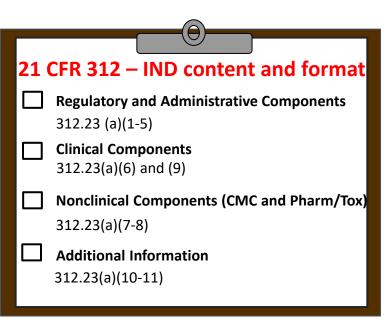
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- Templates
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   Guidance

## 5. Preparation of other parallel requirements

- IRB submission
- ClincialTrials.gov registration



Step



## Meet with RSO team: Review IND initial application package

Assigned SI-Support staff help with:

Contact Us

1. Determination of regulatory pathway based on:

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-Research Intent -Commercial intent

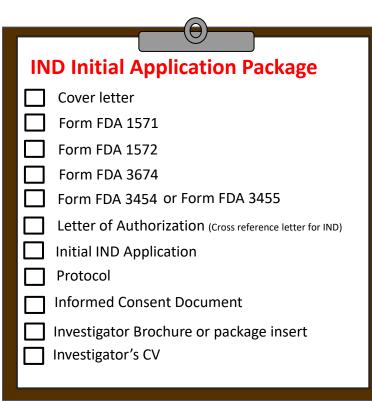
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## 5. Preparation of other parallel requirements

- IRB submission
- ClincialTrials.gov registration



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



- 2. Once completed, contact SI office for review
- 3. Submit initial IND applications
- molecule drug
- CBERDCC eMailSub@fda.hhs.gov antibody, gene therapy agent

division or Document Control Center Choose the division based on the Descriptions of specific indications can be found **CDER** Offices & Divisions

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Prepare IND Contents

## **IND Initial Application Package**

Cover letter

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- $\mathbf{\nabla}$ 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

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# **Cover Letter**

# **Contractual agreement**

Sponsor

agreement between Sponsor & FDA



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## Form 3455

Disclosure Statement

Form 3674 Form 3454 Certification of Financial registration at CT.gov Certification

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- via CDER NextGen Portal for research IND involving small molecule drug
- via emailing
   <u>CBERDCC\_eMailSub@fda.hhs.gov</u>
   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 <u>CDER Offices & Divisions</u> <u>CBER Key Staff Directory</u>



## IND Initial Application Package

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Cover letter

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- V Form FDA 1571
- **Form FDA 1572**
- Form FDA 3674
- V Form FDA 3454 or Form FDA 3455
  - Letter of Authorization (Cross reference letter for IND)
  - Initial IND Application
  - Protocol

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- Informed Consent Document
- Investigator Brochure or package insertInvestigator's CV

## Letter of Authorization (LOA)

<u>A permission letter</u> from sponsor (manufacture of investigational products) allowing the FDA to <u>cross-</u> <u>reference confidential information of sponsor's</u> <u>existing IND on file</u> 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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**Prepare IND Contents** 

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Contents 1. Introduction. 1.1. Introductory Statement. 1.1.1. Name of the Drug and All Active Ingredients. 1.1.2 Pharmacological Class of the Drug. Structural Formula of the Drug. 1.1.3. Formulation of the Dosage Form(s) to be Used. 114 Route of Administration 1.1.5. 1.1.6. Objectives and Duration of the Proposed Clinical Investigation(s). 1.2. References General Investigational Plan The OTTOTAL COMPANY AND DESCRIPTION OF Rationale 2.1 2.2. Indication to be Studied 2.3. General Approach for Evaluation of Treatment Description of First Year Trial(s) 2.4. 2.5. Number of Subjects to be Evaluated 2.6 Drug Related Risks 2.7. References Investigator Brochure. Proposed clinical research. 4 Chemistry, Manufacturing and Control Information 5.1. Chemistry, Manufacturing and Control 5.1.1. Drug Substance 512 Drug Product Placebo Product IND 5.1.3. 514 Labeling 5.2. Environmental Assessment 6. Pharmacology and Toxicology Information Application 6.1. Pharmacology and Drug Distribution 6.1.1. Pharmacology Summary and Conclusions 6.2. Toxicology: Integrated Summary. Template 6.3. Toxicology: Full Data Tabulation 7. Previous Human Experience. 7.1. Marketed Experience.. 7.2. Prior Clinical Research Experience 7.3. Clinical Care Experience. 7.4. References. Additional Information 8.1. Drug Dependence and Abuse Potential. 8.2. Radioactive Drugs.

Pediatric Studies.

Other Information 8.5. Selected References..

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## 

**Prepare IND Contents** 

## IND Initial Application Package

Cover letter

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	Contents
	1. Introduction
	1.1. Introductory Statement
	1.1.1. Name of the Drug and All Active Ingredients
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	1.1.4. Formulation of the Dosage Form(s) to be Used
	1.1.5. Route of Administration
	1.1.6. Objectives and Duration of the Proposed Clinical Investigation(s)
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	2.3. General Approach for Evaluation of Treatment
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- New York	2.5. Number of Subjects to be Evaluated
Sec Columna.	2.6. Drug Related Risks
	2.7. References 3. Investigator Brochure Study Information <sup>3</sup> / <sub>4</sub>
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	5. Chemistry, Manufacturing and Control Information
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	5.1.2. Drug Product. Quality Section <sup>6</sup> 5.1.3. Placebo Product. 7
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	6.1.1. Pharmacology Summary and Conclusions
molata	6.3. Toxicology: Full Data Tabulation
mplate	7. Previous Human Experience
	7.1. Marketed Experience
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	8.2. Radioactive Drugs
	8.3. Pediatric Studies 12
	8.4. Other Information 12
	8.5. Selected References

## Step 2

# Material Preparation & Submission

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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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1.1.3. Structural Formula of the Drug	
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2.7. References	
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for research IND involving biologic: 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 <u>CDER Offices & Divisions</u> <u>CBER Key Staff Directory</u>

## 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

2.

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



2. Once completed, contact SI office for review

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- via CDER NextGen Portal fo research IND involving small molecule drug

via emailing
 <u>CBERDCC\_eMailSub@fda.hhs.gov</u>
 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 <u>CDER Offices & Divisions</u> <u>CBER Key Staff Directory</u>

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

Good

Investigator Brochure

0

Regulatory

Support Team

Medical Center

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

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molecule drug

CBERDCC eMailSub@fda.hhs.gov antibody, gene therapy agent

division or Document Control Center Choose the division based on the Descriptions of specific indications can be found **CDER Offices & Divisions** 

## 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/eder/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:

3.

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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via emailing
 <u>CBERDCC\_eMailSub@fda.hhs.gov</u>
 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 <u>CDER Offices & Divisions</u> <u>CBER Key Staff Directory</u>

## 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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CBERDCC eMailSub@fda.hhs.gov antibody, gene therapy agent

division or Document Control Center Choose the division based on the Descriptions of specific indications can be found **CDER Offices & Divisions CBER Key Staff Directory** 

#### 5. CHEMISTRY, MANUFACTURING AND CONTROL INFORMATION

#### Chemistry, Manufacturing and Control 5.I.

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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#### PHARMACOLOGY AND TOXICOLOGY INFORMATION

As was true for Section 3, you may use an authorization letter(s) or cite the drag label to satisfy this section.

Per 21 CFR 312.23(8), this section is expected to include information about pharmacological and taxicological (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.fila.gov/downloadr/Drugg/GuidanceCompitanceRe-gulator/Information/Guidancer/C CM073246.mdf

Compliance with Good Laboratory Practice (GLP) is generally expected for pivotal in vitro and in vivo shalles 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 Taxicology information are available at the FDA website http://www.fila.gov/Drugg/GuidanceComplianceReputatoryInformation/Guidancewaem063014.ht

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 taxicological 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 taxicological effects of the drag in animals an in vitro [21 CFR 3]2.23(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 loxicology studies for this section typically include:

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\* 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 <u>CDER Offices & Divisions</u> <u>CBER Key Staff Directory</u>

#### PREVIOUS HUMAN EXPERIENCE

7.

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 formal 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/Druge/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved ApprovalApplications/InvestigationalNowDrugINDApplication/ucm362446.htm

If the drug is a combination of drugs previously investigated or morketed, the information rhould 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 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 sufety or effectiveness, identify the country(jgs) 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 to 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 valications that do not have an FDA approval. This is often termed "off-label" use. Any published literature on the safety of the drug to 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 offlabel use of the drug is similar to the proposed study population for this IND application.

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1. Introduction
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1.1.3. Structural Formula of the Drug
1.1.4. Formulation of the Dosage Form(s) to be Used
1.1.5. Route of Administration 2
1.1.6. Objectives and Duration of the Proposed Clinical Investigation(s)
1.2. References
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2.1. Rationale
2.2. Indication to be Studied.
2.3. General Approach for Evaluation of Treatment
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2.5. Number of Subjects to be Evaluated
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5.1.2. Drug Product
5.1.3. Placebo Product
5.1.4. Labeling
5.2. Environmental Assessment
6. Pharmacology and Toxicology Information
6.1. Pharmacology and Drug Distribution
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6.3. Toxicology: Full Data Tabulation
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ter

1. Prepare IND contents using - Initial application template

- Cover Letter template



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 <u>CBERDCC\_eMailSub@fda.hhs.gov</u> 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 <u>CDER Offices & Divisions</u> <u>CBER Key Staff Directory</u>

#### ADDITIONAL INFORMATION

In certain applications, as described below, information on special lupics may be needed. Such information shall be submitted in this section as sulfined below. Otherwise you may simply state 'out applicable'.

#### 8.1. Drug Dependence and Abuse Potential

If the drug is a psycholropic 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/GuidanceComplianceRegulateryInformation/Guid guese/UCM198650.pdf

#### 8.2. Radioactive Drugs

8

If the drug is a radioactive drug, sufficient data from animal or human studies should be provided, lo allow a reasonable colculation of radiation-abstrated dose to the whole body and critical organs upon administration to a human subject. Phase I studies of radioactive drugs must include studies which will obtain anfilicient data for dostinetry calculations.

If this section is relevant to your investigation, please see the guidance below: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResnarces/acm092895.htt

#### 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/Draus/DevelopmentAuprovalProcess/DevelopmentResources/ucm04 9867.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 trems 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. Investigator 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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## IND Initial Application Package

Cover letter

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- V Form FDA 1571
- **Form FDA 1572**
- Form FDA 3674
- Form FDA 3454 or Form FDA 3455

Informed Consent Document

Letter of Authorization (Cross reference letter for IND)

Investigator Brochure or package insert

Initial IND Application

Investigator's CV

- Protocol

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<u>SCCC Protocol</u> Template

PROTOCOL NUMBER

Case Balance

Marrie Renter



Template

- 1. Prepare IND contents using - Initial application template
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Prepare IND Contents

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- Informed Consent Document
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A second s	
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	
Reting Foundation of the Southwest Southigh Bite for Children	
Texas Health Resources	
Key Information about this Study	
The consent form must begin with a consiste and focused presentation advances where buildometon that is most bi homepoche participant, legally authorized representative, or parent or guardian in understanding the reaso- right not warrish participants in the reasearch.	elji to essist e is why one might or
This section should include a summary of the purpose of the study, denticing of participation, major requirem my potential benefits. This section should static conflam any significant reses of pertopating in the study. The resents of this section may be discussed in greater detail later in the content form.	tents of the study and embimation
Examples of model concise summaries are available at the end of this document or on the UTSW HRPP w https://www.utsouthwestern.edu/research/research-administration/ith/forms/	shaite al
Information about this form	
Enrolling Children or incompetent Adults ment the paragrade only for studies enviroling children or incompetent adults (you are providing consent for someone else, for example your hold, your next-of-kin or someon the legal guardian or are designated as a surrogate decision maker on a madical power of attorns 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 at	out the study.
Please take time to review this information carefully. You should talk to the researchers about the herm any questions you have. You may also with to talk to others (for example, your threads, lar talkod your participation in this study. I you decide to bake part in the study, you talk baked to also you. Sign this form, be sure you understand what the study is about, including the risks and oyou.	ily, or a doctor) ign this form.
Please tell the researchers or study staff if you are taking part in another research study.	
include if recruiting from investigator's own patients: 'Gui doctor is a research investigator in this study. Sinhe is interested in both your medical care a his research study. At any time, you may discuss your care with another doctor who is not part o study. You do not have to take part in any research study offered by your doctor.	
<u>voluntary Participation</u> - You do not have to participate if you don't want to. You may also leave to time. If you decide to stop taking part in this research study, it will not affect your relationship with southwestern staff or doctors. Whether you participate or not will have no effect on your legal rigi your health care.	the UT
f you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be a	flected in any way.
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**Prepare IND Contents** 

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Informed Consent Document

Investigator Brochure or package insert

Investigator's CV

Package Insert is a quick-reference brochure

> Regulatory Support Team UTSouthwestern Medical Center

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## IND Initial Application Package

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Cover letter

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**Form FDA 1571** 

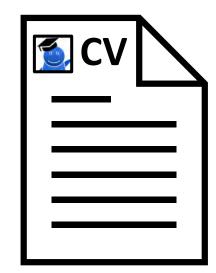


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- Investigator Brochure or package insert

Investigator's CV



# **Device Overview & IDE**

# FDA U.S. FOOD & DRUG

# What is a Medical Device

Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, other meets the definition of medical device per th<u>e FD&C Act</u>

## What is IDE?

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

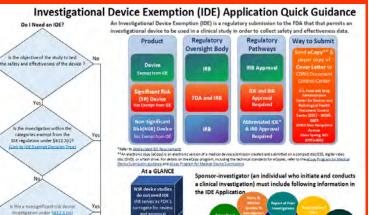
# What are Classes of Medical Device

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)

## Do I Need an IDE?



DA Review Pha 30 days for Response

Sponsor will be notified the date FDA receives prizinal applicatio

Approved Approved proved with cor Draped source



# **Device Overview & IDE**

# **FDA** U.S. FOOD & DRUG ADMINISTRATION

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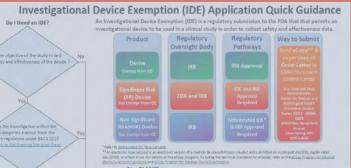
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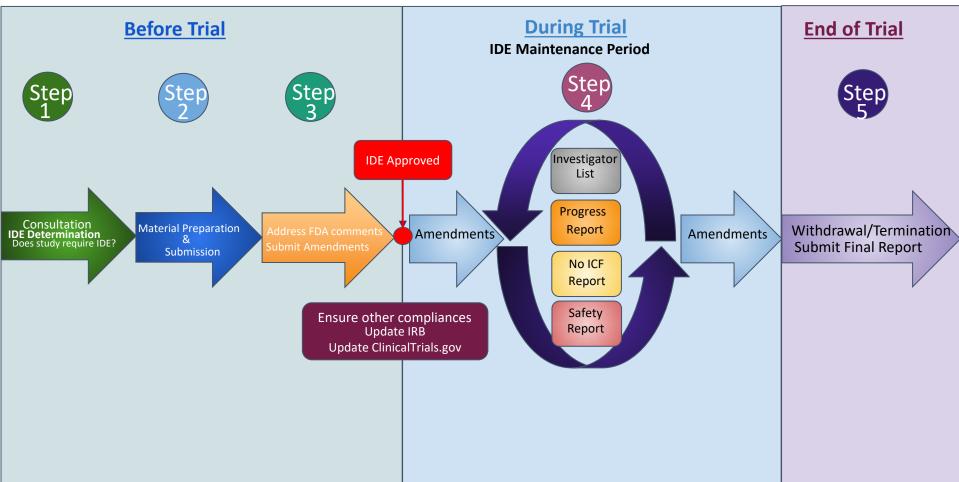
# What is **Non-Significant Risk Device** Devices do not pose a significant risk to the human subjects. Watch on YouTube Somply with abbreviated IDE

# Do I Need an IDE?

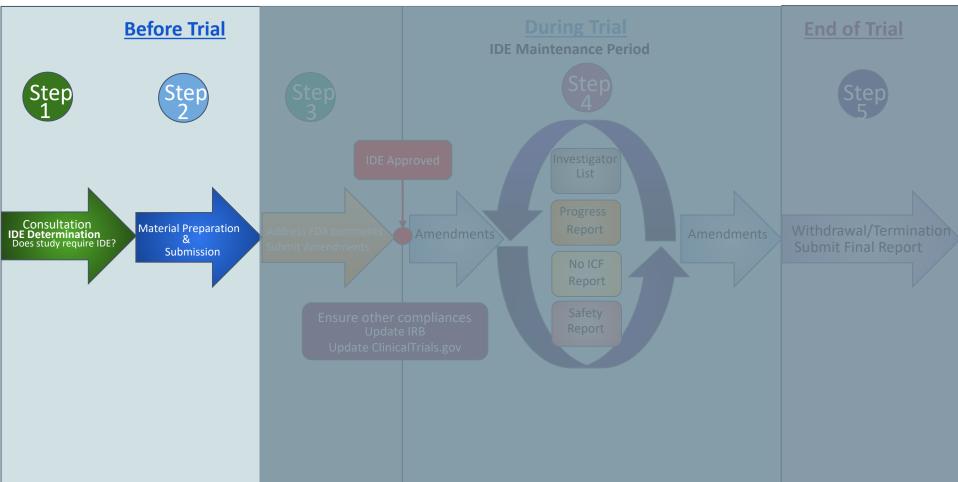




# Investigational Device Exemption (IDE) Life Cycle



# Investigational Device Exemption (IDE) Life Cycle







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)

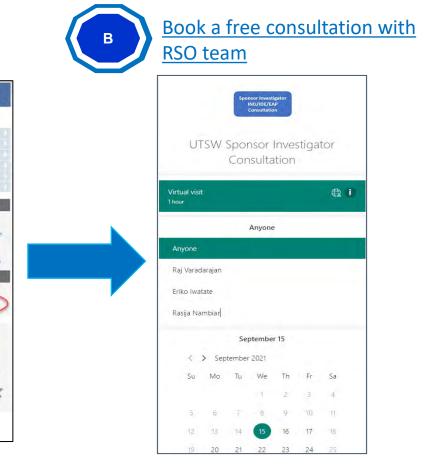
3. IDE application preparation by providing

- Templates
- IDE Submission Guidance

4. Preparation of other parallel requirements

- IRB submission
- ClincialTrials.gov registration





Step 1

Book one-on-one Consultation



Assigned SI-Support staff help with:

1. Determination of regulatory passway based on the product classification

- IDE Exempt Device
- Significant Device (IDE)
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2. Determination of the Document Control Center

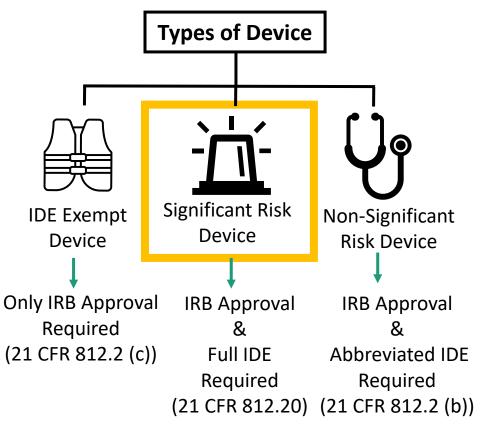
Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors

Significant Risk and Nonsignificant Risk Medical Device Studies





# Meet with RSO team: Determination of appropriate regulatory pathway



Step



Assigned SI-Support staff help with:

1. Determination of regulatory passway based on the product classification

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- Significant Device (IDE)
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Meet with RSO team: Ask your device questions !

Who will initially determine risk level of the device?

I believe my product is a combinational product (both device and biologic). Do I need IDE or IND? Overseen by CDRH or CBER?

Can I seek advice from FDA on non-clinical testing and/or on my clinical protocol?

Step

Contact Us

Assigned SI-Support staff help with:

1. Determination of regulatory passway based on the product classification

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- Significant Device (IDE)
- Non-Significant Device (Abb IDE)

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

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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

Contact Us

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2. Determination of the

Contro Variation Promotion 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.

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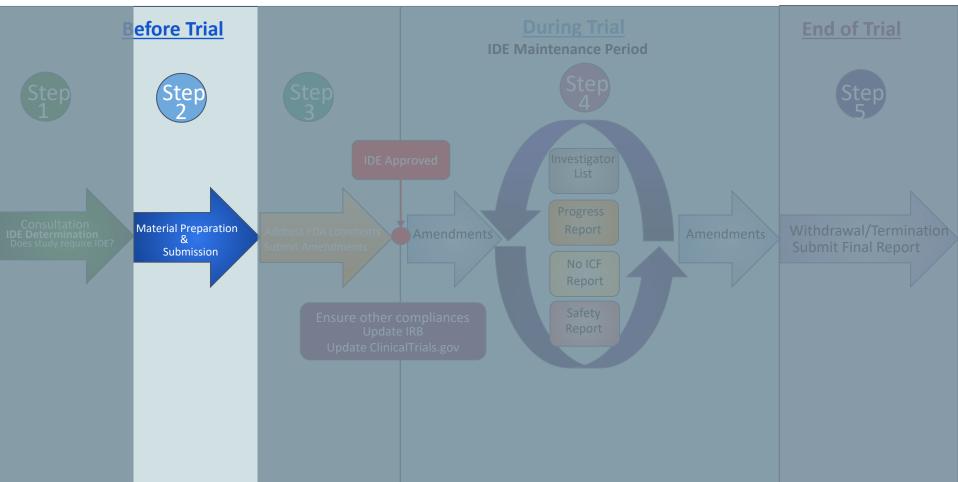
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# Investigational Device Exemption (IDE) Life Cycle



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

2. Once completed, contact SI office for review



# Prepare IDE Contents

# **IDE Initial Application Package**

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- Cover Sheet Form FDA 3514
- Name and Address of the Sponsor
- Report of Prior Investigations
- Investigational Plan

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- Manufacturing Information
- Investigator Agreement
- Investigator Certification
- IRB Information
- Name & Address of Investigator's Institution
- Financial Claims
- Environmental Assessment
- Labeling
- Informed Consent
- Additional Information



Medical Center

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Food and Drug Administration Center for Devices and Radiatogical Health Devanient Mail Center - WO66 (1999) 10901 New Histopolari Avenay Silver Spring, Maryland 20993-0002

100	Initial IDE	Application

Dear Dr. (Division Director);

Per 21 CFR, #12.30, please find enclosed there explore of this initial asylication first a Sponsorbreventgener DDI. We propose to evaluate (name of invertagencies) desires) under the HII be (salety) [cfbcacy] by using it for the [fmathema]. [deagence] of [finamer condition].

This submitter, also contains the initial study protocol (Study AustArt) Precessor (. 1, 0 entitled, "A Multi-contro, Randomized Study of the Effects of [Device] on (Condition) in [Distance]."

If you have any quemions regarding this admission and timer communications with east tarm, plane contain main addition to the following talivitantia Key Meether of Si athurah ware as , constants, project managery (Nerra, plan

rmail). Key member of 0.1999. Regulatory support Office (Ganapathy (Rai) Sanatinaan, 214 548-4000, program in method menosity,

Sincerely,

(Species Name), MD Title Institution Phone marcher

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indemitted in tripticant: Approximate for an Investigeneed Denser Krongson (Study Number) Presently, 7.0



**IDE cover sheet** 

Form 3514

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# Prepare IDE Contents

# ,IDE Initial Application Package

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- Cover Sheet Form FDA 3514
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- Additional Information

#### IDE # XXXXX 20XX Initial Application

Sponsor: Name, MD

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3. ADDITIONAL INFORMATION



- Cover Letter template



#### NAME AND THE ADDRESS OF THE SPONSOR

Sponsor: Name, MD

IDE # WWWW

20XX Initial Application

Name Address Phone number Fax Email address

1.

IDE # XXXXX

Name and contact information of alternate contact (if applicable)

IDE # XXXXX 20XX Initial Application	Sponsor: Name, MD
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# Submission

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#### REPORT OF PRIOR INVESTIGATIONS

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

#### 2.1. General

2.

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 noncompliance.

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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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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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6. INVESTIGATOR CERTIFICATION A certification that all investigators who will participate in agreement, that the list of investigators includes all the inv investigation, and that no investigator will be added to the the agreement. The following statement can be used to satisfy this required we commit to obtain a signed investigator agreement from participating in the investigation. Additionally, no future in have signed the agreement."	vestigators participating in the investigation until they have signed ment: "As required for an IDE study, all current investigators who are	Contents         1. NAME AND THE ADDRESS OF THE SPONSOR	3 



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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 Southwestem Medical Center (UT Southwestem) (IORG0000638) has obtained a Federal wide Assurance (FWA) from the Department of Health and Human Services (DHHS) (FWA00005087). This FWA assures that all UT Southwestem 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 Southwestem IRBs are also in compliance with Title 21 CFR Parts 50 and 56, all other Parts governing the use of investigational devices, drugs, and biologies 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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#### 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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#### 9. FINANCIAL CLAIMS

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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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20XX Initial Application ENVIRONMENTAL ASSESSMENT 10. Per the CDRH Web site, https://www.fda.cov/medical-devices/investigational-deviceexemption-tide/ide-amplication, 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 ñ.

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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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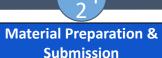
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Consent to be part of a Research Study To be conducted at Study and a study and the study and the The University of Texas Southwestern Medical Center Parkland Health & Hooginal System Children's Medical Center of Dallas and any of its affiliated entities Recine Foundation of the Southwest Soutiak Rate 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 rosearch.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the atudy 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 deal all areas 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 altorney, please note that in the sections that follow, the word' your 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. Sife 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.

<u>Yolundingy Participation</u> - 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 reliatorship with the UT Southwestern staff or dectors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.



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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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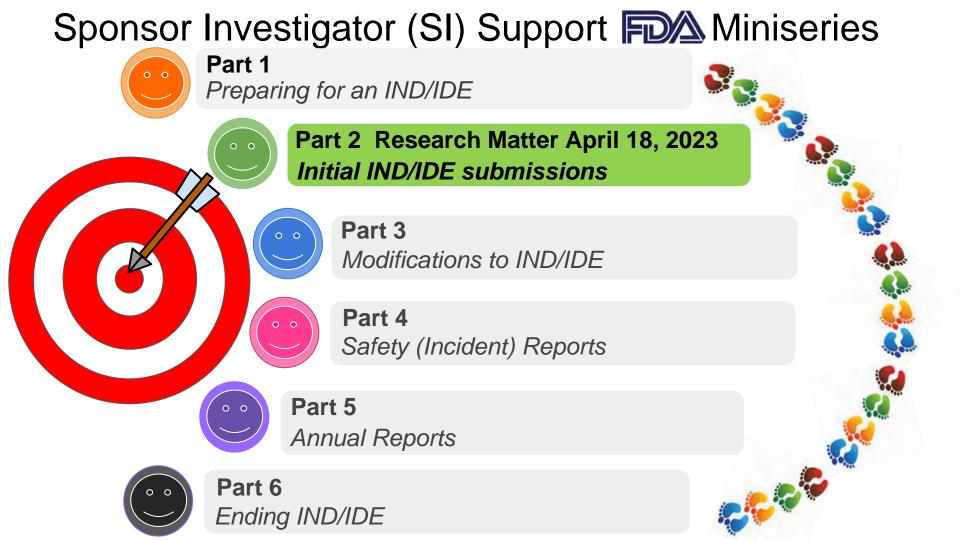
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**Prepare IDE Contents** 

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Medical Center



## Selected Resources for ClincialTrials.gov Support



#### **Selected Resources for** or Investigator FDA Support

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EA Step-by-Step SI Responsibilities



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