FOI Teleconference # TC150122

The Care & Feeding of Your IND:

FDA Expectations for Compliance

Presented by:

Michael Hamrell

President, MORIAH Consultants

When:

Thursday, January 22

Eastern Standard Time: 1:00pm – 2:30pm (GMT-5)

Central Time: 12:00pm – 1:30 pm

Mountain Time: 11:00am – 12:30pm

Pacific Time: 10:00am – 11:30am

Prepare:

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The Care & Feeding of Your IND

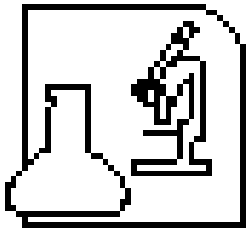
What you need to know and do to keep your Investigational New Drug Application healthy, happy, and up-to-date.

Developed & Presented by:

Michael R. Hamrell, Ph.D.

MORIAH Consultants

www.moriahconsultants.com

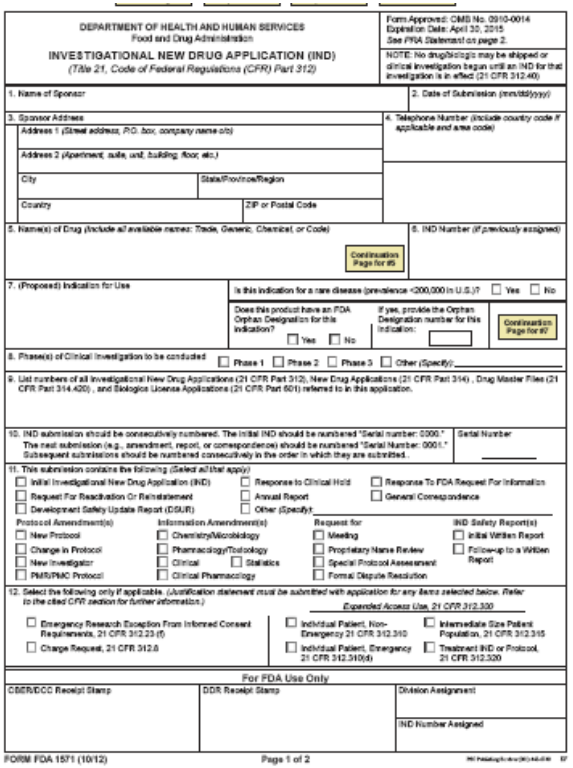


An FOI Services Teleconference • January 2015

What is an IND?

What is an IND?

- 21 CFR §312
- Application to FDA to seek permission to test a new drug (or biologic) in humans
- Investigational New Drug Application
  - Notice of Claimed Investigational Exemption for a New Drug
- Usually begins in Phase 1
  - (But not necessarily)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See PRA Statement on page 2.

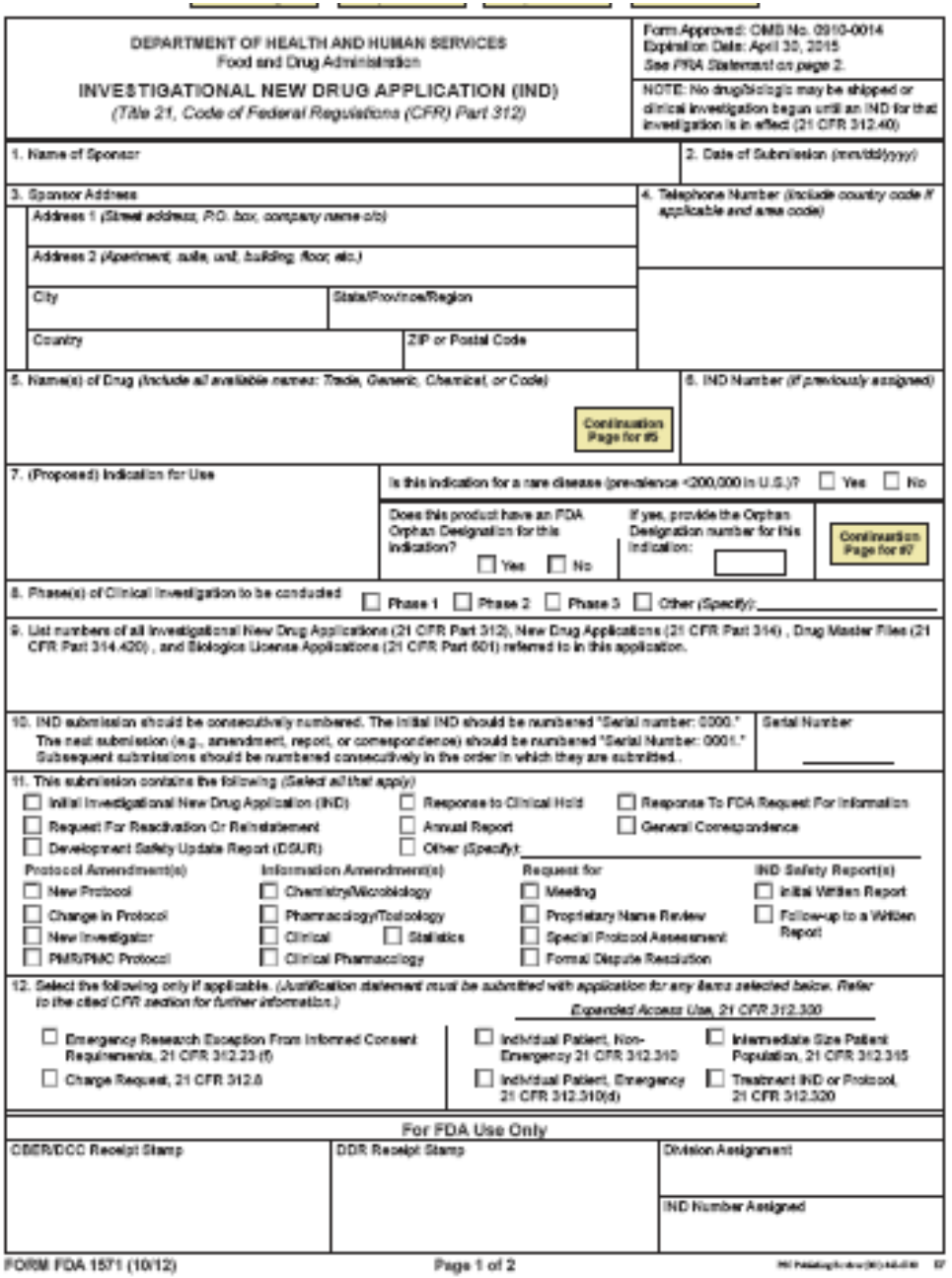
NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

1. Name of Sponsor
2. Date of Submission (mm/dd/yyyy)
3. Sponsor Address
Address 1 (*Street address, P.O. box, company name c/o*)
Address 2 (*Apartment, suite, unit, building, floor, etc.*)
City
State/Province/Region
Country
ZIP or Postal Code
4. Telephone Number (*Include country code if applicable and area code*)
5. Name(s) of Drug (*Include all available names: Trade, Generic, Chemical, or Code*)
Continuation Page for #5
6. IND Number (*If previously assigned*)
7. (Proposed) Indication for Use
Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No
Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No
If yes, provide the Orphan Designation number for this indication:
Continuation Page for #7
8. Phase(s) of Clinical Investigation to be conducted ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Other (Specify):
9. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.420), and Biologics License Applications (21 CFR Part 601) referred to in this application.
10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.
Serial Number
11. This submission contains the following (*Select all that apply*)
☐ Initial Investigational New Drug Application (IND)
☐ Request For Reactivation Or Reinstatement
☐ Development Safety Update Report (DSUR)
☐ Response to Clinical Hold
☐ Annual Report
☐ Other (Specify)
☐ Response To FDA Request For Information
☐ General Correspondence
Protocol Amendment(s): ☐ New Protocol ☐ Change in Protocol ☐ New Investigator ☐ PMR/PMC Protocol
Information Amendment(s): ☐ Chemistry/Microbiology ☐ Pharmacology/Toxicology ☐ Clinical ☐ Statistics ☐ Clinical Pharmacology
Request for: ☐ Meeting ☐ Proprietary Name Review ☐ Special Protocol Assessment ☐ Formal Dispute Resolution
IND Safety Report(s): ☐ Initial Written Report ☐ Follow-up to a Written Report
12. Select the following only if applicable. (*Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.*)
Expanded Access Use, 21 CFR 312.300
☐ Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f)
☐ Charge Request, 21 CFR 312.8
☐ Individual Patient, Non-Emergency 21 CFR 312.310
☐ Individual Patient, Emergency 21 CFR 312.310(d)
☐ Intermediate Size Patient Population, 21 CFR 312.315
☐ Treatment IND or Protocol, 21 CFR 312.320

For FDA Use Only
CBER/OCC Receipt Stamp
CDR Receipt Stamp
Division Assignment
IND Number Assigned

FORM FDA 1571 (10/12)
Page 1 of 2

IND Form



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Address 2 (*Apartment, suite, unit, building, floor, etc.*)

City

State/Province/Region

Country

ZIP or Postal Code

4. Telephone Number (*include country code if applicable and area code*)

5. Name(s) of Drug (*Include all available names: Trade, Generic, Chemical, or Code*)

Continuation Page for #5

6. IND Number (*if previously assigned*)

7. (Proposed) Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No

If yes, provide the Orphan Designation number for this indication:

Continuation Page for #7

8. Phase(s) of Clinical Investigation to be conducted ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Other (Specify):

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

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☐ Development Safety Update Report (DSUR) ☐ Other (Specify):

Protocol Amendment(s)
☐ New Protocol
☐ Change in Protocol
☐ New Investigator
☐ PMR/PMC Protocol

Information Amendment(s)
☐ Chemistry/Microbiology
☐ Pharmacology/Toxicology
☐ Clinical ☐ Statistics
☐ Clinical Pharmacology

Request for
☐ Meeting
☐ Proprietary Name Review
☐ Special Protocol Assessment
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IND Safety Report(s)
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☐ Individual Patient, Non-Emergency 21 CFR 312.310
☐ Individual Patient, Emergency 21 CFR 312.310(d)
☐ Intermediate Size Patient Population, 21 CFR 312.315
☐ Treatment IND or Protocol, 21 CFR 312.320

For FDA Use Only

CBER/DCC Receipt Stamp

DDR Receipt Stamp

Division Assignment

IND Number Assigned

FORM FDA 1571 (10/12) Page 1 of 2

When is an IND Submitted?

- Whenever clinical studies are initiated:
  - New drug or biologic in the U.S.*
  - For a new indication or different route of administration of an already approved drug for FDA submission

* Not required for studies conducted outside of U.S.

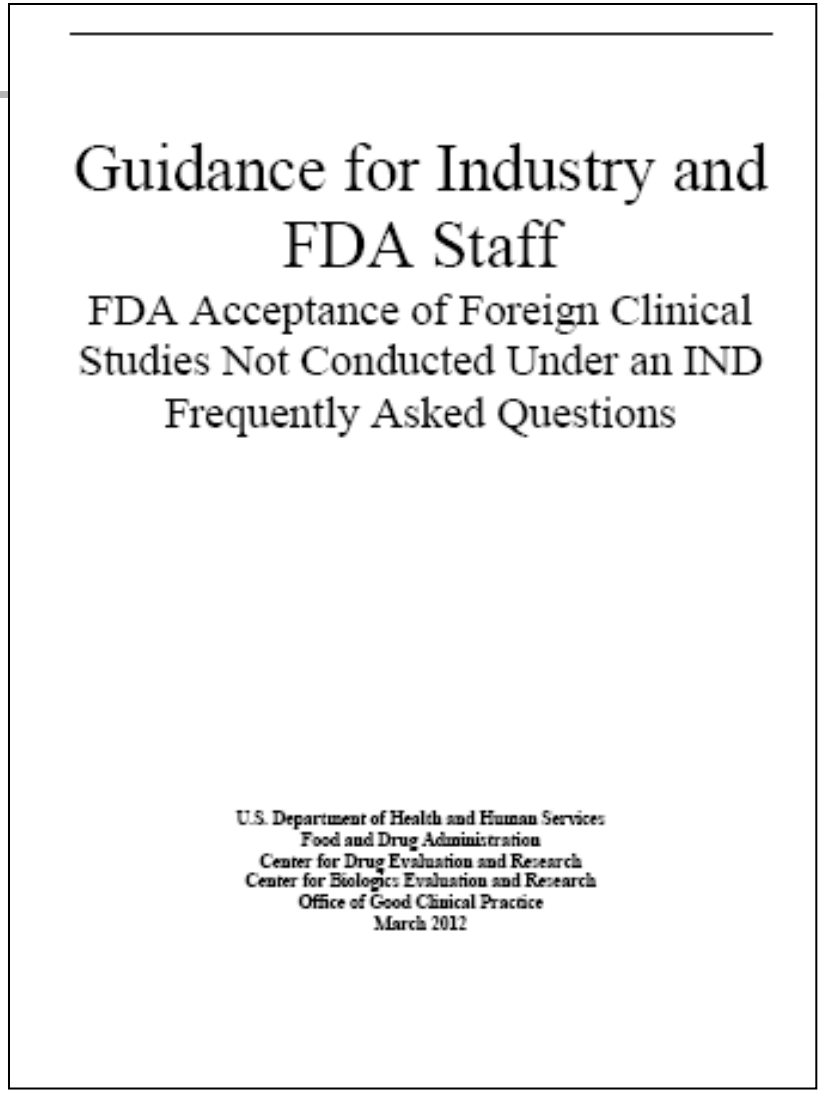
An IND is Not Needed For:

- Clinical trials conducted outside U.S., unless you want to include the trials under the IND
  - Not required to be able to use data

- However, there may be some strategic and business reasons to do so (or not)
  - Export of drug
  - Acceptance by local health authorities
  - U.S. paperwork for foreign investigators

Acceptance of Foreign Studies

Considerations for foreign studies and need for an IND



Guidance for Industry and FDA Staff

FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Office of Good Clinical Practice
March 2012

When is an IND not Required?

- Marketed drugs using approved dosage/indication

  and

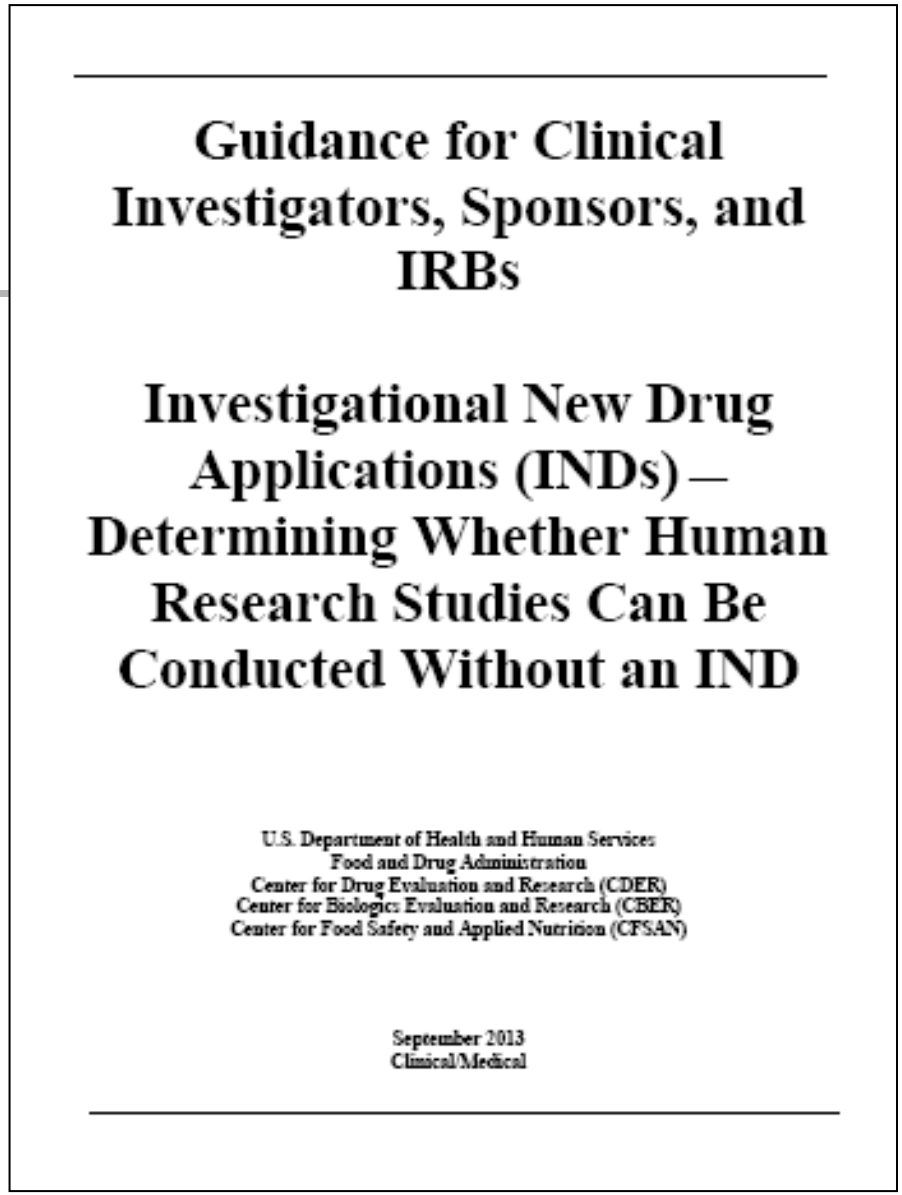
  Does not support significant labeling change

  and

  Does not put patients at increased risk

- Intended only for *in vitro* or animal testing
- Most bioavailability/bioequivalence studies

When is an IND not Required?



Guidance for Clinical Investigators, Sponsors, and IRBs

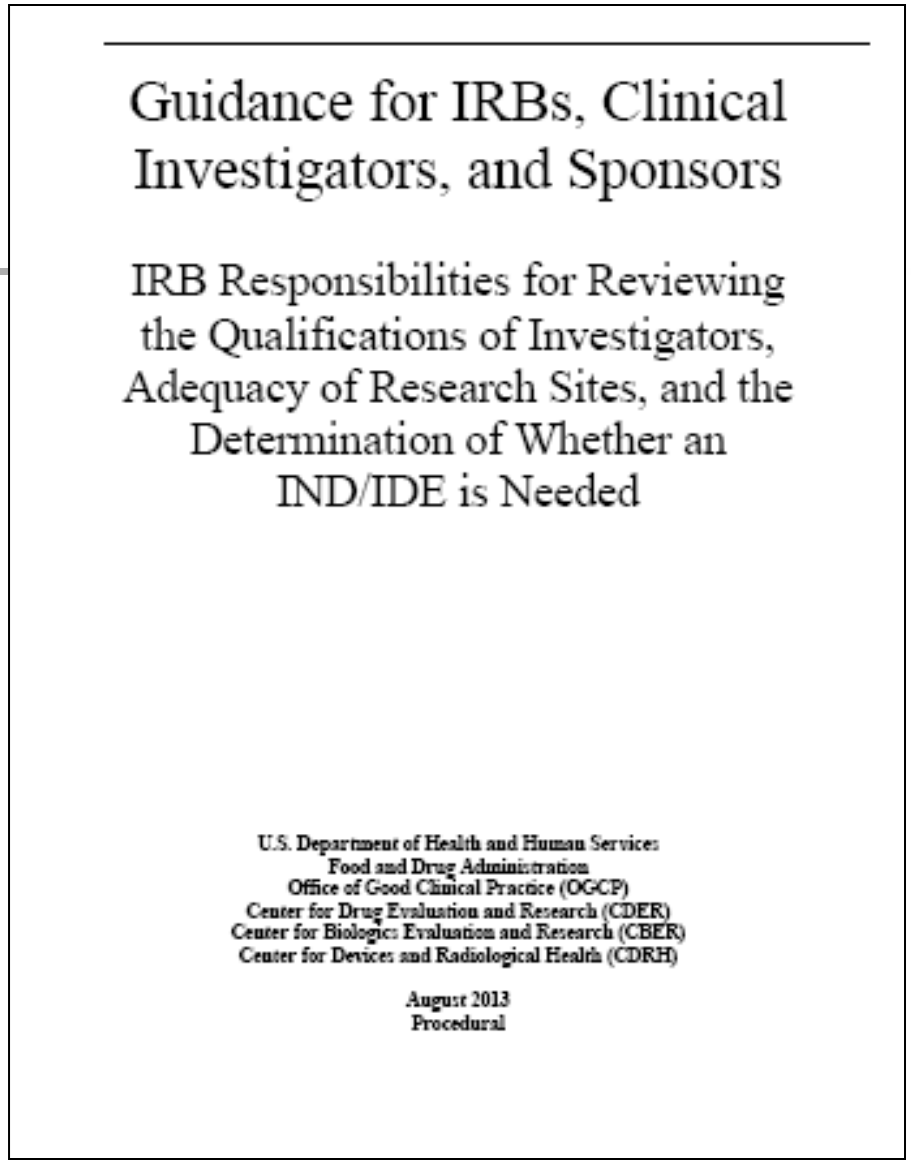
Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Food Safety and Applied Nutrition (CFSAN)

September 2013
Clinical/Medical

See: IND Exemption Guidance & Checklist

If you believe an IND is not required, the IRB has a role in confirming this decision



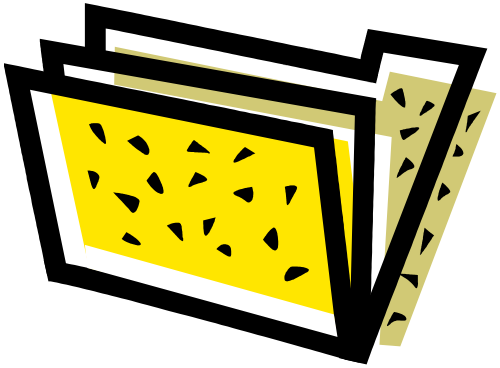
Guidance for IRBs, Clinical Investigators, and Sponsors

IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice (OGCP)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

August 2013
Procedural

Types of INDs



Types of INDs

- Initial IND
- Sponsor-Investigator (SI) IND
- Treatment Use IND
- Emergency Use
  - Compassionate use
- Exploratory INDs

Expanded Access

Initial IND

- Submitted to seek permission to begin clinical trials of an investigational (unapproved) product in the U.S.

- Do not have to commence trials at Phase 1
  - Can start at any point that is justified by the data

Sponsor-Investigator (SI) INDs

21 CRF §56.102(k), §312.3(b) & §312.22(d)

- IND sponsored by an individual investigator
  - Investigator serves as PI and as sponsor
- Same requirements as company sponsored INDs
- Not intended to replace traditional sponsor IND as a mechanism to initiate clinical trials

IND for SI (SI IND)

- INDs for Sponsor-Investigators must contain all information for FDA to make a determination of safety

- A letter of cross-reference from the drug owner can be used to allow FDA to reference any information not belonging to the investigator

See: Sponsor Investigator IND Checklist

Expanded Access for Treatment

- Revised and updated regulation on patient access for serious and immediately life-threatening conditions
- August 2009
- Added new SubPart I on Expanded Access at §312.300
  - Replaces older regulations

Treatment Use INDs

21 CFR §312.320

- Serious or immediately life-threatening disease
- No comparable or satisfactory alternative drug or therapy is available
  - Designed to treat many subjects
- Drug is under investigation in controlled-clinical trial
- **Must comply with IRB & informed consent regulations**

Treatment Use INDs (cont'd)

- Must be actively pursuing marketing approval
  - Drug may be made available for treatment use earlier than Phase 3
- Separate application for Treatment use INDs needed
  - FDA (Commissioner) may deny
- Reimbursement possible for drug

Emergency Use of an Investigational New Drug

21 CFR §312.310(d)

- Designed for one time use only
  - Single patient or small population
- Emergency situation that does not allow time for advance submission of IND
- FDA may authorize drug shipment before IND

Compassionate Use

- No statutory definition
- Considered an "emergency situation" where subject has no options for treatment and is seeking compassionate relief
- Covered under revised regulations on Expanded Access for Treatment Use
  - August 2009 Final Rule

Exploratory INDs

- Exploratory IND clinical trial
  - Sometimes called Phase 0
  - Conducted prior to Phase 1
  - very limited human exposure
  - Has no therapeutic/diagnostic intent
    - e.g., screening studies, microdose studies

- Once drug is chosen for full development, the exploratory IND is inactivated or withdrawn and replaced by a traditional IND

See: Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies – January 2006

FDA Guidance For Industry

- Content And Format Of Investigational New Drug Applications (INDs) For Phase 1 Studies Of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (Nov 1995)
  - Clarifies requirements for data and data presentation related to initial entry into human studies

So what goes into an IND?

What Studies are Needed?

- Consult FDA Web page on specific types of guidance for studies

- ICH Guidelines are also a vast source of information on types of studies and data needed for clinical trials and to develop a new drug

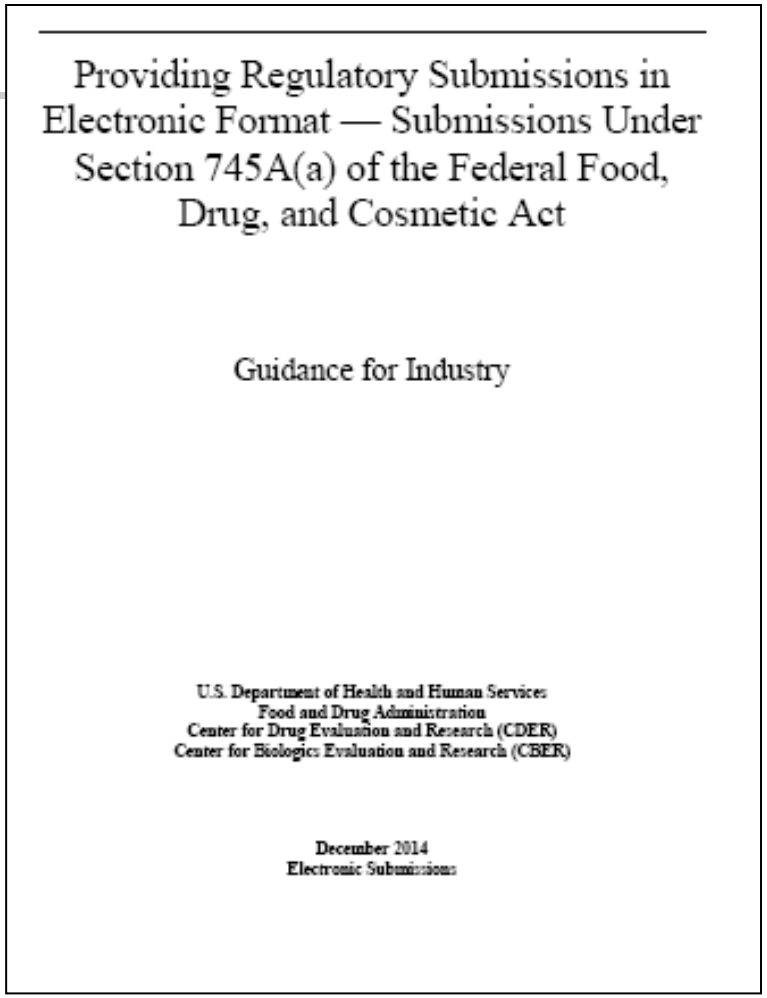
IND Format

- The IND Form lists the required elements and order of presentation
  - Form FDA 1571
  - Should now use CTD format
    - See FDA guidance for details
    - eCTD format only will be required in the near future
- The Form is always used as a cover sheet and tracking tool

See: Filing checklists

IND Format

- Although the regulations and form still reflect the old format, the FDA highly prefers (and will soon require) the CTD format as an electronic submission only
- This will be described in a future guidance document



Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

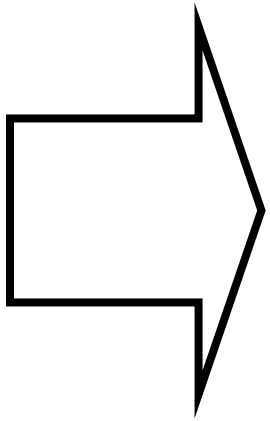
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2014
Electronic Submissions

Mapping of FDA IND & CTD Tables of Contents

- Cover letter (M-1)
- Item 1. Application Form – 1571 (M-1)
- Item 2. Table of Contents (M-2)
- Item 3. Introductory Statement (M-2)
- Item 4. General Investigational Plan (M-2)
- Item 5. Investigators Brochure (M-1)
- Item 6. Protocol (M-5)
  - Study protocol
  - Investigator data (1572)
  - Facilities data (1572)
  - IRB data (1572)
- Item 7. Chemistry, Manufacturing & Control Data (M-3)
- Item 8. Nonclinical Pharm/Tox (M-4)
- Item 9. Previous Human Experience (M-5)
- Item 10. Additional Information (M-1)



MODULE 1 (M-1)

MODULE 2 (M-2)

MODULE 3 (M-3)

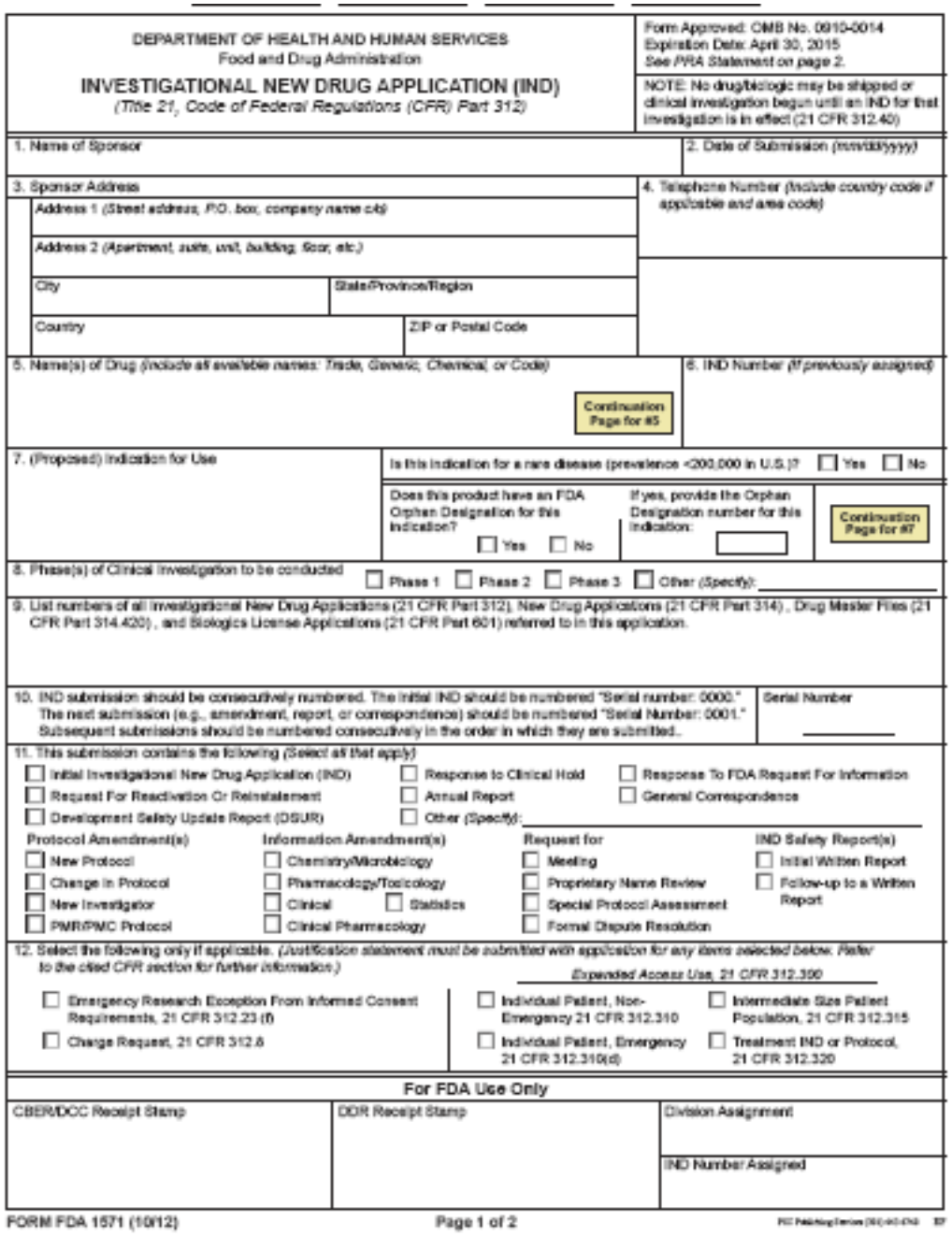
MODULE 4 (M-4)

MODULE 5 (M-5)

Cover Letter

- Every submission to FDA should have a cover letter
  - Describe what is in submission
  - Why it is being submitted
  - What action you expect/desire
- If you have a timeline, when you expect (hope) to get a response
- Good business practice to include a cover letter

IND Item 1: FORM FDA 1571



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Continuation Page for #5

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Continuation Page for #7

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☐ Change in Protocol	☐ Pharmacology/Toxicology	☐ Proprietary Name Review	☐ Follow-up to a Written Report
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For FDA Use Only

CBER/DOC Receipt Stamp	DDR Receipt Stamp	Division Assignment
		IND Number Assigned

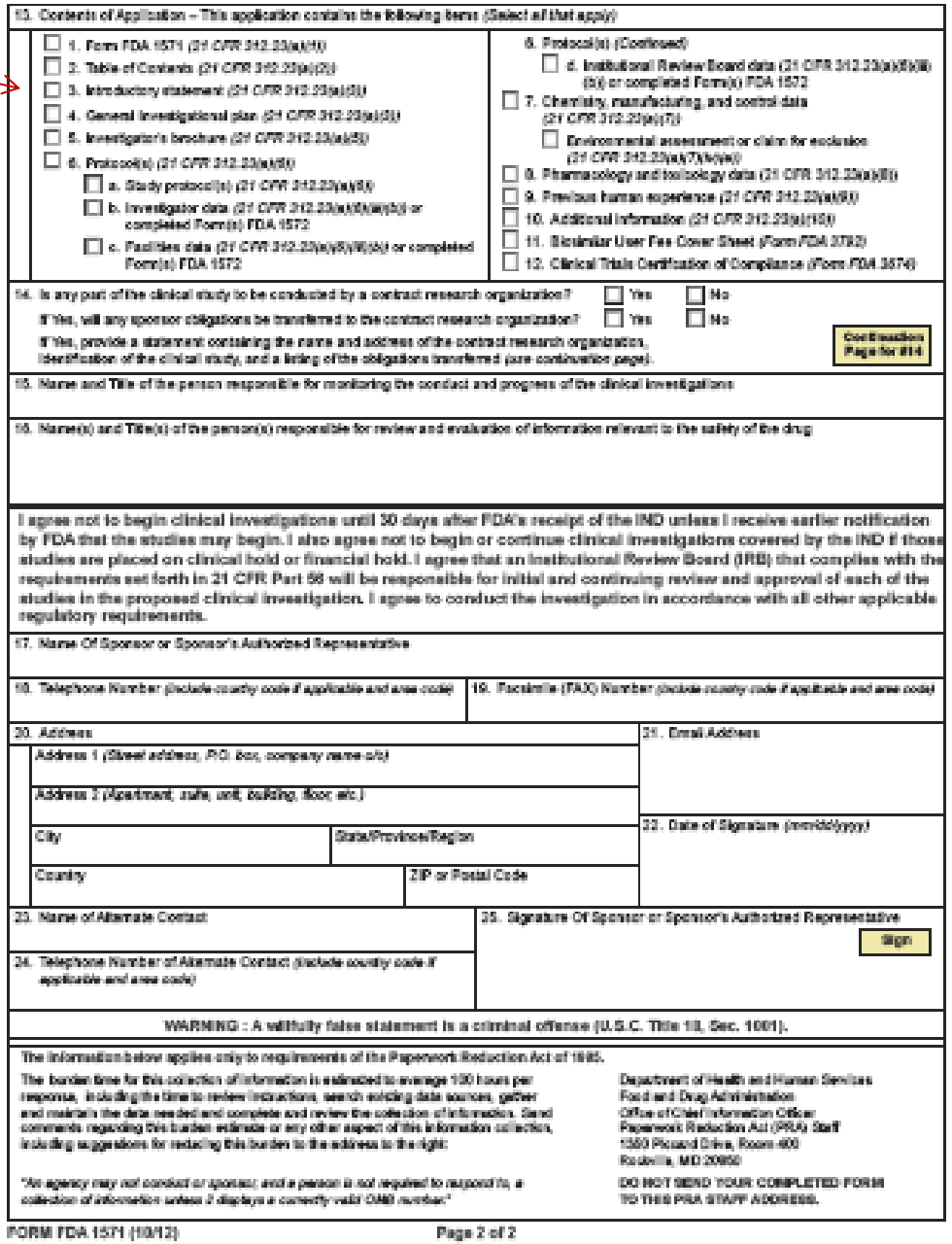
FORM FDA 1571 (10/12) Page 1 of 2

IND Item 2:
Table of Contents

IND Item 2: Table Of Contents

- Initial planning tool
  - Can help you to organize information
- Should be clear, concise and user-friendly
  - Remember, the FDA reviewer has likely never seen this information before
- If submission is an electronic IND, then this will be the XML backbone file

FDA Form 1571



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

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

14. Is any part of the clinical study to be conducted by a contract research organization? ☐ Yes ☐ No

If Yes, will any sponsor obligations be transferred to the contract research organization? ☐ Yes ☐ No

If Yes, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred (use continuation page). Continuation Page for #14

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

16. Name(s) and Title(s) of the person(s) responsible for review and evaluation of information relevant to the safety of the drug

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

17. Name Of Sponsor or Sponsor's Authorized Representative

18. Telephone Number (Include country code if applicable and area code)

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

20. Address

Address 1 (Street address, P.O. Box, company name c/o)

Address 2 (Apartment, suite, unit, building, floor, etc.)

City | State/Province/Region

Country | ZIP or Postal Code

21. Email Address

22. Date of Signature (mm/dd/yyyy)

23. Name of Alternate Contact

24. Telephone Number of Alternate Contact (Include country code if applicable and area code)

25. Signature Of Sponsor or Sponsor's Authorized Representative

Sign

WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).

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

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

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF ADDRESS.

FORM FDA 1571 (10/12) Page 2 of 2

FDA Form 1571

- Be sure to complete all sections on the form (as applicable)
- Carefully complete sections 14-16
- Must be signed by Sponsor or Authorized Representative
  - Pay attention to commitments listed

Sections 14-16

- Section 14:
  Information on any clinical CRO used

- Section 15:
  Person responsible for monitoring the progress of the investigation

- Section 16:
  Person responsible for safety evaluation for the drug

Other Forms

- Clinical Trials Certification of Compliance
  - Form 3674
- Biosimilar User Fee Cover Sheet
  - Certain biosimilars require user fee during IND development
  - Form 3792
    - Requires creating an account

IND Item 3:
Introductory Statement

IND Item 3: Introductory Statement

- Basic information about drug
  - Name of drug
  - Active pharmaceutical ingredient(s)
  - Pharmacological class
  - Structural formula
  - Formulation of dosage form
  - Route of administration covered in IND

IND Item 3: Introductory Statement (cont'd)

- Broad objectives & planned duration of proposed clinical studies
- Brief summary of previous human experience, if studied outside of U.S.
- Non-U.S. regulatory actions

IND Item 4:
General Investigation Plan

IND Item 4: General Investigational Plan

- Provide a rationale for drug/clinical research
- What indication(s) to be studied
- What is the general approach to be followed in evaluating the drug
  - Kinds of clinical trials to be conducted in following year
- Any risks anticipated: Nonclinical data; Previous human experience, including information from related drugs

How Do You Develop a Plan?

- Consider a Target Product Profile (TPP)
- A summary of your drug development program plans
  - Described in terms of labeling concepts
- Facilitates early discussions about development plans and goals for labeling
- Embodies the notion of "beginning drug development with the end in mind”

Target Product Profile

- Document is evolving and dynamic
- Should be multidisciplinary
  - Include input from all departments
- Usually provided in briefing packages for meetings
- Not required by FDA
- Not legally binding on FDA or sponsor
  - Just another tool to facilitate development

See: Draft Guidance for Industry and Review Staff: Target Product Profile - A Strategic Development Process Tool, March 2007

IND Item 5: Investigator's Brochure

Item 5: IND Investigator's Brochure

- "Labeling" supplied to investigator
- **Summary** of all data known to sponsor
  - Watch your document length!
- Regulatory References
  - 21 CFR §312.23(a)(5)
  - ICH E6 GCP Guideline – includes information on format and content of Investigator Brochure

IND Item 6: Protocol

IND Item 6: Protocol for Each IND Study

- Protocol provides plan for the conduct of the clinical investigation
- Need information on what the study is, how it will be conducted, who will be included, etc.
  - ICH E6 GCP Guideline – includes information on format and content of Clinical Protocol

IND Item 6: Protocol for Each IND Study

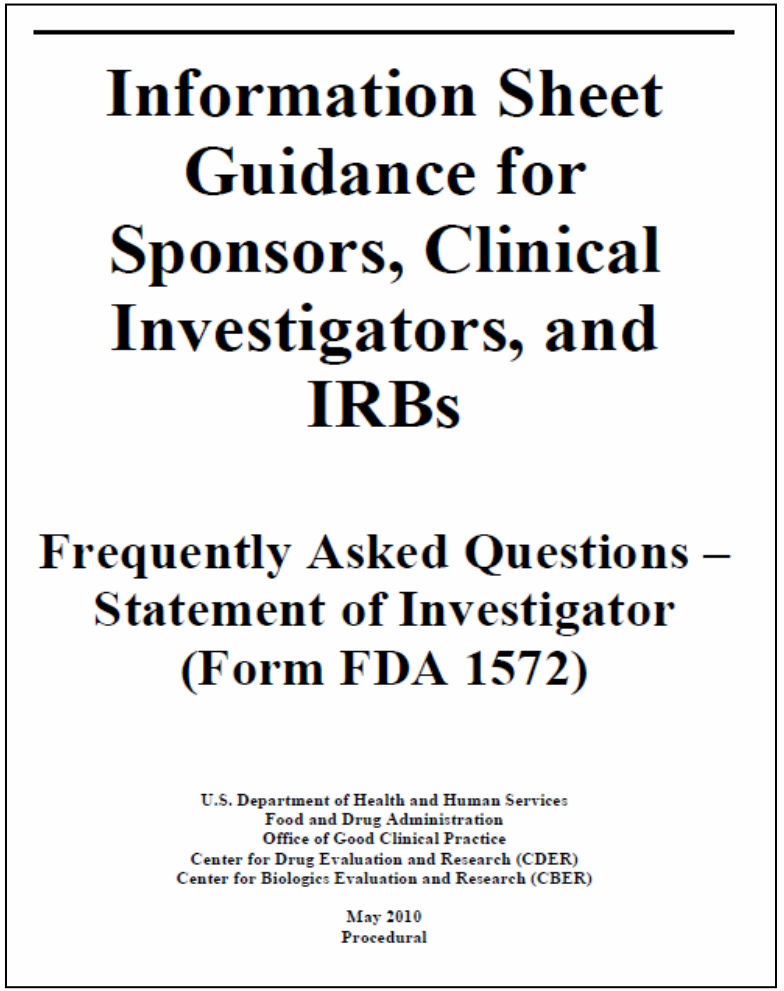
Need supporting data on who & where study will be conducted

- Include Investigator Information
  - Signed Form FDA 1572
    - Facilities Data
    - IRB Data
    - List of sub-Investigators
  - Investigator's documentation of qualifications (Curriculum Vitae, license, etc.)
- Make sure you collect Financial Disclosure information from each PI and subinvestigator (submitted at NDA/BLA time)
- For Device Studies: No Form used for Investigator information
  - Collected via Investigator Agreement

What Is Form FDA 1572?

Information Sheet Guidance

- Frequently Asked Questions – Statement of Investigator (Form FDA 1572)
  - Final - May 2010



Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs

Frequently Asked Questions – Statement of Investigator (Form FDA 1572)

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2010
Procedural

FDA Form 1572

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: August 31, 2011
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Sponsor/Applicant/Submitter or Other

Address 1	Address 2	
City	State	ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select one of the following.)*

Curriculum Vitae Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility

Address 1	Address 2	
City	State	ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY CONTINUATION PAGE for Item 4

Name of Clinical Laboratory Facility

Address 1	Address 2	
City	State	ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) CONTINUATION PAGE for Item 5

Name of IRB

Address 1	Address 2	
City	State	ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select one or both of the following.)*

__ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

__ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

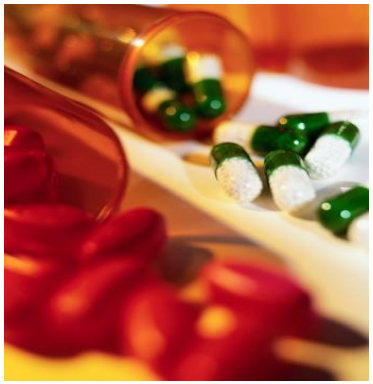
INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)	11. SIGNATURE OF INVESTIGATOR Sign

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

IND Item 7: Chemistry, Manufacturing and Controls (CMC)



Product Quality Information

CMC Information

- Provides all the information to determine the Identity, Strength, Quality and Purity of the drug that will be tested in humans
  - Extensive guidance exists on what is needed and how to document

Drug Substance (DS)

Details about the active ingredient

- Description of Drug Substance
  - Physical, chemical, biological properties
  - Molecular formula
  - Structural formula
  - Elucidation of structure
  - Reference Standard
  - Can be somewhat brief for Phase 1 Studies

Drug Substance (DS) (cont'd)

- Name and address of manufacturer
- Route of Manufacture (synthesis or formulation) of drug substance
- Specifications and analytical methods to assure the identity, strength, quality, purity of the drug substance
- Stability

Drug Product (DP)

The formulated dosage form to be given to humans

- List of components
- Quantitative composition
- Name and address of manufacturer
  - Drug product
  - List any contract packager, labeler or laboratory used
  - List suppliers of all components (compendial vs. non-compendial)

Drug Product (DP) (cont'd)

- Method of manufacturing and packaging
- Specifications and analytical methods for inactive components
- Specifications and analytical methods for the drug product
- Stability

GMP Requirements

- In general, any product that is administered to humans must be made according to GMP
- Recent FDA Final Regulation and guidance on GMP requirements for Phase 1 studies
  - Relaxes some requirements for GMP
    - Only applies to Phase 1 studies

See: cGMPs for Phase 1 Investigational Drugs – July 2008

Additional CMC Items

- Placebo Information
- Investigational Labeling
  - Specifics defined in §312.6
- Environmental Assessment
  - Need to define any impact on environment from the manufacture of product - 21 CFR §25
    - INDs are usually categorically excluded from EA requirements based

Chemistry and Manufacturing Information

Importance of CMC Information

- Signal of potential risk
  - Are there any metabolites or breakdown products that have toxicity
  - Chemistry and manufacturing differences between drug for clinical use and that used in toxicology trials
    - May affect safety profile

Product Master Files (DMF/BMF)

- Sometimes your vendor indicates that the information regarding what they supply to you is proprietary
- File of information owned by third-party suppliers of drug substance or packaging
  - Proprietary to third-party; not available to IND/NDA holder
- Cross-reference letters needed for inclusion in IND

Product Master Files (DMF/BMF)

- Information is submitted to FDA by DMF holder
  - FDA does not "approve" the DMF
- DMF is reviewed relative to a pending submission (IND/NDA)
  - Will only communicate any questions or deficiencies to DMF holder
- You need a good communication relationship with your DMF suppliers

IND Item 8: Nonclinical Pharmacology and Toxicology

Nonclinical Pharmacology and Toxicology

- Summary of animal pharmacological, pharmacokinetics and toxicological studies that support the clinical development of the compound

- Written summary followed by individual study reports

Pharmacology

- Description of the pharmacological effects and mechanisms of actions
  - Primary and Secondary pharmacodynamics
  - Safety Pharmacology studies
- *In vitro* and *In vivo*
- Extrapolation to humans

Toxicology Study Reports

- Description of design of trials and dates when studies conducted

- Systematic presentation of findings from animal toxicology and toxicokinetic studies
  - Highlight possible signals of human risk
  - If tox "signal" not considered evidence of human risk, give reason
  - Findings are also discussed in Investigators Brochure

Special Studies

- For IV or IM administration, hemolysis studies
- For IV administration, venous irritation study
- For topical clinical application, dermal irritation studies
- For ophthalmic administration, corneal abrasion studies

IND Item 9:
Previous Human Experience

IND Item 9: Previous Human Experience

- Summary of non-U.S. investigational experience
- Summary of published clinical experience (including pharmacologically-related drugs) & copies of reprints
- Non-U.S. marketing experience
- List of countries where marketed outside U.S. & any significant regulatory actions

IND Item 10:
Additional Information

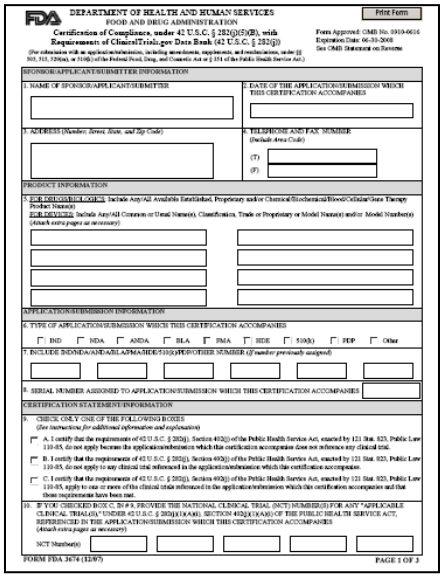
IND Item 10: Additional Information

- Pre-IND meeting minutes
- Translation information
  - Any materials not available in English must be translated
- Radio-labeled product information

Other Information

Clinical Trial Registration

- FDAAA of 2007 requires all clinical trials submitted to FDA be listed in a public database of clinical trials at www.clinicaltrials.gov
  - Must list all trials in the database
    - Keep information up-to-date
  - Include FDA Form 3674 with each clinical submission to an IND


DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

Form Approved: OMB No. 0910-0616
Expiration Date: 06-30-2008
See OMB Statement on Reverse

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
3. ADDRESS (Number, Street, State, and Zip Code)
4. TELEPHONE AND FAX NUMBER (Include Area Code)

PRODUCT INFORMATION

5. FOR DRUG/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES
(See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

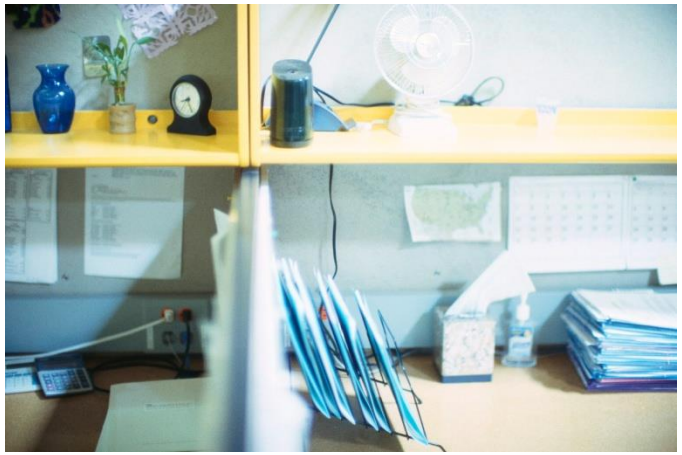
C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN # 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)" UNDER 42 U.S.C. § 282(j)(5)(A)(i). SECTION 402(j)(5)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
(Attach extra pages as necessary)

NCT Number(s)

FORM FDA 3674 (12/07)
PAGE 1 OF 3

Submission of an Original IND



Submission

- Assemble all the pieces
- Create a detailed Table of Contents
  - For e-submissions, this will be the XML backbone file
- Number and index all sections and reports
  - Follow rules for e-subs and CTD
- Use only FDA designated folders (“jackets”) for paper submissions
  - For e-subs, use the guidance on e-submission rules

Submission Hints

- Begin at the IND phase to develop a plan for document generation, review, approval, archive and finalization (publish)

- This will be EXTREMELY valuable to your company when you get ready to prepare the NDA/BLA

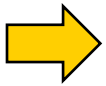
See IND filing checklists

IND Submission & Review Process

- FDA logs in IND and assigns an IND number
  - If e-submission, number will be preassigned
- Submission → FDA assigns Reviewing Division
- Submission sent to Division for review

FDA Action

- All reviews coordinated [Chemistry, Pharm/Tox, Clinical and Microbiology (if applicable)]



- IND on clinical 'wait'
  - If no concerns by day 30, study can start

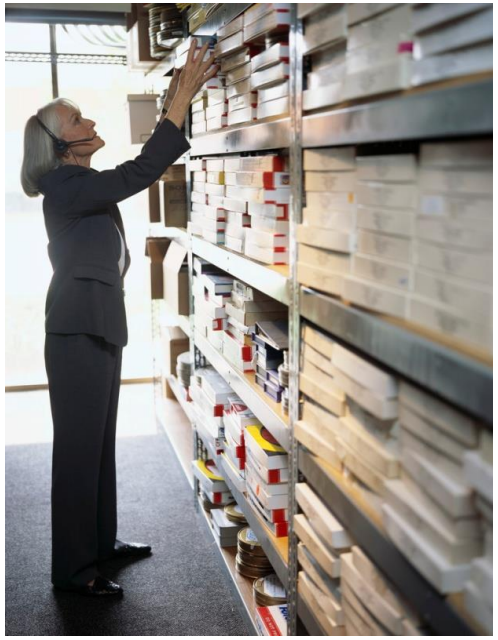
Review of INDs by CBER

- Biologics are drugs for investigational regulatory purposes
  - Follow IND regulations (21 CFR §312)
- All reporting documentation requirements are the same
  - INDs, updates, SAEs, Annual Reports, etc.

Starting Your Trials

- Although you can start your studies if you have not heard from FDA that study is 'on hold' (at 30 days), it is ALWAYS a good idea to check and confirm with FDA Review Division before proceeding.

Actions on the Original IND and Amendments



30 Day IND Wait vs. Clinical Hold

- 30 Day IND Wait
  - Clinical investigations will not be initiated until 30 days after FDA's receipt of IND
    - Allows time for review and evaluation
- Clinical Hold
  - Studies put on hold either by FDA or sponsor or IRB

Grounds for IND Clinical Hold

- A clinical trial or program can be placed on hold for the following reasons:
  - IND does not contain enough data to assess safety
  - Human subjects will be exposed to unreasonable risk
  - Investigators are not qualified
  - Investigator Brochure (IB) is incorrect, misleading, erroneous, or materially incomplete

Administrative IND Actions

Administrative IND Actions

- Your IND is an asset
- If not continuing development:
  - Inactivation
  - Withdrawal
  - Termination

Strategic Management of Your IND

- Your IND is a corporate asset
  - Can be transferred, sold or donated to another sponsor/organization
- Need to evaluate its strategic interest to your company
  - What is its fate if you stop development?

Inactive Status - §312.45

- Action taken by sponsor or FDA when:
  - No clinical activity for 2 years
  - IND is on hold for 1 year or more
  - Sponsor request
  - If inactive – no annual reports required

Withdrawal - §312.38

- Sponsor can withdraw an IND at any time:
  - Sponsor must notify FDA that clinical investigations have been discontinued and that clinical supplies have been returned/disposed.
  - If IND is withdrawn for safety reasons sponsor must notify investigators (and IRBs) of the safety reason for withdrawal.

Termination - §312.44

- Action taken by FDA when:
  - Safety risk unacceptable *
  - Chemistry, manufacturing & controls inadequate *
  - Clinical trials not conducted in accordance with protocol *
  - Investigational drug is being promoted
  - Sponsor fails to submit annual reports
  - Lack of compliance with Adverse Events reporting requirements
  - IND inactive for 5 or more years

* Potentially could result in clinical hold prior to termination

Amendments to the IND

IND Amendments

- Two types of IND amendments
  - Information amendments
  - Protocol amendments

    (A type of IND amendment)

All submissions to INDs, including original submissions, are serially numbered.

[See the box provided on the front of the IND Form.]

IND Protocol Amendments

21 CFR §312.30

- Four types or categories
  - New protocol
  - Changes in protocol
  - New investigator
  - PMR/PMC Protocol (post-approval studies)

Also: Check appropriate box on FDA Form 1571

IND Submissions

Remember to:

- Always provide a cover letter explaining what you are submitting and why
- Send the appropriate number of copies (if paper)
- Number submissions and keep track
  - Don’t skip or repeat numbers
  - Use sequence numbers for e-submissions

Protocol Amendments

New Protocol

- Submitted whenever sponsor intends to conduct a clinical trial that is not covered by a protocol included in the IND

The Content & Format of a New Protocol IND Amendment

- Study may begin, provided –
  - Sponsor has submitted IND amendment
  - IRB approval obtained*

*Can submit amendment prior to IRB approval

No 30-Day Wait is required once clinical studies have begun

Changes in Protocol Amendment

- Change may be implemented, provided that:
  - IND amendment has been submitted
  - IRB approval for change has been obtained
    - May submit amendment prior to obtaining IRB approval of change, but don't recommend

Examples of Changes Which Require an IND Amendment

- Any increase in dosage or duration of exposure of subjects/patients to drug
- Increase in number of subjects exposed
- Any significant change in trial design
- Addition or deletion of testing procedures

Changes in Protocol

- Phase 1 study
  - Submit protocol amendment for any change that significantly affects the **SAFETY** of the subjects
- Phase 2 or 3 study
  - Submit protocol amendment for any change that significantly affects the **SAFETY** of the patients, the **SCOPE** of the investigation or the **SCIENTIFIC QUALITY** of the study

Changes in Protocol (cont'd)

- For changes intended to eliminate an apparent immediate hazard to the patients, change may be implemented immediately, provided that FDA and IRB are subsequently notified

IND Amendment

New Investigator

- Submit protocol amendment when a new investigator (new or change) is added to carry out a previously submitted protocol
  - Multi-center studies
  - Transfer of investigator responsibility

Content of New Investigator Protocol Amendment

- Include:
  - Investigator name, address, clinical study site, IRB name and address
    - Form 1572
  - Investigator's CV or similar evidence of qualifications

Information Amendments
21 CFR §312.31

- New nonclinical data
- CMC changes
- Clinical study report
  - Clinical pharmacology or clinical study
- Discontinuation of study for reasons other than safety

Content of Information Amendments

- Statement of nature and purpose of the amendment
- Organize submission of data in format appropriate for scientific review

Prominent Identification of Amendment Contents

Check the appropriate box on Form 1571

- Information Amendment: Chemistry
- Information Amendment: Pharmacology-Toxicology
- Information Amendment: Clinical

Annual Reports
21 CFR §312.33

- IND annual reports are due within 60 days of the anniversary date that IND went into effect*

***Not** the date you submitted the IND

Annual Report Submission

- The goal is to submit on the anniversary date
  - The window is to provide some latitude for submission

- Target to submit around that date and use the window to make sure it is on time

Goal of Annual Report

- The purpose of an Annual Report is to provide a yearly update to FDA on status of your development program and studies

- FDA has a continuing role is safety oversight and thus needs this information

See: IND Annual Report checklist

IND Annual Report Content

- Brief summary of status of clinical studies in progress & those completed during period of report
  - Status of study (in progress, completed, terminated)
  - Total number of patients planned for inclusion in study
  - Number of patients entered to date, tabulated by age group, gender, and race
  - Number of patients who have dropped out (for any reason)
  - Brief description of study results (if study completed or interim analysis done)

Other IND Report Information

- Safety Summaries
  - Summary of all SAE and AE information
- Description of any new information pertinent to understanding of action of drug
- Tabular summary of nonclinical studies completed or in progress and summary of major pre-clinical findings; includes Pharmacology, Toxicology, Pharmacokinetics
- Summary of significant manufacturing or microbiological changes made during reporting period

IND Annual Report

Additional information to provide

- Updated general investigational plan
- Updated Investigator's Brochure
- Foreign marketing developments
- Log of outstanding business (optional)

DSUR

DSUR = Development Safety Update Report

- ICH E2F Guidance, August 2011
  - Intended to be a common format for periodic reporting on drugs under development for ICH regions
- CAN replace IND annual report in US

DSUR

- Allows designation of Development International Birth Date (DIBD) to coordinate submission timing
- Contains recommendations about the Table of Contents and format
- Includes examples of tables and listings

Other IND Submissions

- All expedited SAEs
  - Submitted according to SAE regulations in §312.32
    - Revised regulation effective March 2011
  - Attend other FOI seminars to learn what is required
- Study reports or updates
  - Non-clinical
  - Clinical
  - Changes/modifications to CMC information
- Meeting requests

Key Considerations for IND Submissions

- Keep your submissions straightforward
- Include a cover letter with each submission
- Don’t mix items
- Some things can be batched and submitted less frequently
  - e.g., 1572 for new investigators

Going Forward…

Where do I find the guidance documents, forms and other material I need?

- Check the resources provided to support this presentation: www.foiservices.com/care1914.htm
- Browse FDA's website
  - Look under guidance
- Search FOI Services' library of FDA documents
  - May be able to see reviewer comments on how others have completed forms or structured data
- ASK your friends, colleagues, consultants for help

Thank You! Questions?

To ask a question.
The operator will explain how you can ask a question. For privacy reasons, each question will be announced only by the first name of the person reported at dial-in, but anyone in your group may ask the question(s). Please try to avoid using a speakerphone while asking your question.

If you have a question later or would like to arrange a private discussion, you are invited to contact Michael Hamrell of MORIAH Consultants at reg@moriahconsultants.com or +1-714-970-0790 (Pacific Time).

Additional information.
Checklists, links, and instructions for ordering the audio package of the recording and all handouts for this presentation at the 50% attendee discount are available at:
www.foiservices.com/care1914.htm

We value your feedback.
Please return the evaluation at the end of this handout to enter a prize drawing for a $100 amazon.com gift card and/or arrange to receive a certificate of attendance verifying your participation in this 1.5 hour educational session.

EVALUATION

"The Care & Feeding of Your IND: FDA Expectations for Compliance"

Presented by: Michael Hamrell, MORIAH Consultants

January 22, 2015

Thank you for attending this FOI Services teleconference – we're glad you could join us & appreciate your help in evaluating the program.
Indicate your rating of the presentation in the areas below by circling the appropriate number, using a scale of 1 (low) through 5 (high).

How do your rate the content of this session?	1	2	3	4	5
Were the handouts clear, understandable and helpful?	1	2	3	4	5
Was the material presented at an appropriate pace?	1	2	3	4	5
Was the speaker knowledgeable about the subject matter?	1	2	3	4	5
Did the speaker explain the content clearly and articulately?	1	2	3	4	5
Overall, would you be likely to attend another presentation by this speaker?	1	2	3	4	5
How would you rate your overall opinion of this presentation?	1	2	3	4	5

Additional thoughts? Use the space below to add comments about any aspect of this presentation.

_____

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Please complete & fax this page to +1-301-569-7506 or send a scanned copy to teleconferences@foiservices.com.
PRIZE DRAWING: Evaluations received by Thursday, January 29, 2015 will be entered into a drawing for a $100 amazon.com gift certificate!

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