**TIP Sheet INVESTIGATIONAL NEW DRUG APPLICATION (IND)**

### Tip #1: What is an IND?
An Investigational New Drug Application (IND) is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. There are three IND types:

- **An Investigator IND** is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.

- **Emergency Use IND** allows the FDA to authorize use of an experimental drug in an emergency situation and is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.

- **Treatment IND** is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.


### Tip #2: What forms are required for an IND submission and where can I find instructions for them?
- FDA form 1571 – the **Investigational New Drug Application** form
- FDA form 1572 – the **Statement of Investigator** form
- FDA form 3674 – the **Certificate of Compliance with Requirements for ClinicalTrials.gov databank** form

### Tip #3: What other documentation need to be submitted to the FDA?
- Cover letter
- IND application
- Study protocol
- Curriculum vitae (CV) of the principal investigator and sub-investigators of the study
- Investigator Brochure (if available) or Package Insert (if FDA approved drug is used for study)
- Letter of cross reference from the drug manufacturer (if referring to an investigational drug on FDA form 1571)

### Tip #4: How does the IND package need to be submitted?
- Until further notice from the Office of Regulatory Compliance, all submissions need to be submitted to the FDA as hardcopies
Tip #5: What is the current mailing address?

**For a Drug (CDER):**
Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
5901-B Ammendale Road  
Beltsville, MDs 20705-1266

**For a Therapeutic Biological Product* (CDER):**
Food and Drug Administration  
Center for Drug Evaluation and Research  
Therapeutic Biological Products Document Room  
5901-B Ammendale Road  
Beltsville, MDs 20705-1266

*The therapeutic biological products now under CDER's review include:
- Monoclonal antibodies for in-vivo use
- Cytokines, growth factors, enzymes, immunomodulators; and thrombolytics
- Proteins intended for therapeutic use that are extracted from animals or microorganisms, including recombinant versions of these products (except clotting factors)
- Other non-vaccine therapeutic immunotherapies

Tip #6: Additional Information

- Have a naive reader proofread your submission
- Print area for all pages should fit on 8.5 by 11 inches paper
- Allow margin of at least 1 inch on the left side of page (to avoid obscuring information when the pages are subsequently printed and bound) and 3/8 of an inch on the other sides.
- For pages in landscape orientation, allow 3/4 of an inch at the top to allow more information to be displayed legibly on the page.
- Header and footer information can appear within these margins as long as it is not within 3/8 of an inch of the edge (to avoid text is lost when pages are subsequently printed and bound)
- Use one of these fonts: Times New Roman or Courier (11 point)
- The complete IND submission package to the FDA should:
  - Be in triplicate to the FDA (1 original and 2 copies)
  - Using single sided copies
  - **CDER:** Have triplicates hole-punched and collated in 3 separate binders: red (originals), orange and green
  - **CBER:** Have triplicates hole-punched and collated in 3 separate binders: grey (originals), red, any other color
  - Have individual forms and documents in your submission marked with tabs (not colored paper)
- Keep one copy for your own records, additional copies for other parties if needed (e.g. outside funding entity or company providing the investigational drug for the study), and scan a copy of the entire package to the Clinical Research Support Center.
- Be available for the 30 days following your submission. If you are not available and a question cannot be answered the FDA may be forced to place the submission on clinical hold.
- Do not submit a revision to the original protocol within the 30 days post initial application period

**For a Vaccine, Blood or Biologics Product (CBER):**
Food and Drug Administration  
Center for Biologics Evaluation and Research  
HFM-99, Room 200N  
1401 Rockville Pike  
Rockville, MD 20852-1448

For a Therapeutic Biological Product* (CDER):
Food and Drug Administration  
Center for Drug Evaluation and Research  
Therapeutic Biological Products Document Room  
5901-B Ammendale Road  
Beltsville, MDs 20705-1266

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- Other non-vaccine therapeutic immunotherapies
- If your project depends on external funding but funding is declined, withdraw the application

**Tip #7: How to I label the outside of the three binders:**
- Label the outside using Times New Roman or Courier (18 point), with the following information
  - Name of sponsor: _____(PI name)___________
  - Name of product: ________________________
  - IND number: (leave blank for initial submission)
  - Date of submission: _____________________

**Tip #8: What else do I need to think about:**
- You will need to collect financial interest/financial disclosure information from everyone who is listed on Form 1572 for this study before they perform any study-related tasks.
- The reporting requirements for the FDA differ from those for UCD.
- You can use the UCD template to document each individual’s disclosure.

**Tip #9: For more information, go to:**