TIP Sheet

FORMAL REQUEST FOR
INVESTIGATIONAL NEW DRUG APPLICATION (IND) EXEMPTION FROM THE FDA

Tip #1: What is an IND exemption (AKA IND waiver)?
The regulations allow the PI (sponsor) to determine that the research use of a marketed and approved drug is exempt from the requirements for an IND. However, at times, the investigator or the IRB may determine that an ‘official’ FDA exemption is warranted. If the FDA grants the IND exemption, the FDA will send an IND EXEMPT letter to the Principal Investigator, the study is then exempt from the IND requirements under 21 CFR 312, and no annual reports are due to the FDA.

- If the FDA does NOT grant the IND exemption, additional documents need to be submitted to the FDA (see Tip sheet for IND submission), an IND number will be issued by the FDA, the study must follow the requirements under 21 CFR 312, and annual reports are due to the FDA. Please read and follow the instruction in the letter from the FDA that provides you with the IND number for details.

Tip #2: What forms are required for an IND exemption request 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 ClinicalTrials.gov Certification form

Tip #3: How do I find the FDA /CDER Division responsible for this drug and the Division’s Director’s name?
- Go to: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/ to find information about the FDA approved marketed drug. Pull up the pdf of the latest FDA Approval, and find out which FDA Division approved the drug, and who the Division’s Director was at the time.
- Go to http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ContactCDER/UCM070722.pdf to find the contact info for the Project Manager of that Division.
- Email that person <firstname.lastname>@fda.hhs.gov to confirm that this is the correct division for your request and that you have the correct name for the Director to address the cover letter to.

Tip #4: What other documentation need to be submitted to the FDA?
- Cover letter; addressed the cover letter to the Director of the specific therapeutic division at the FDA
- Study protocol
- Package Insert for investigational product
- Curriculum vitae (CV) of the principal investigator and sub-investigators of the study

Tip #5: 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 #6: 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  
Beltville, Md. 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  
Beltville, MDs 20705-1266

*The therapeutic biological products now under CDER's review include:

1. Monoclonal antibodies for in-vivo use  
2. Cytokines, growth factors, enzymes, immunomodulators; and thrombolytics  
3. Proteins intended for therapeutic use that are extracted from animals or microorganisms, including recombinant versions of these products (except clotting factors)  
4. Other non-vaccine therapeutic immunotherapies

### Tip #7: Additional Information
- Have a naive reader proofread your submission  
- Use continual page numbers  
- **Follow regulatory format instructions (CRSC can provide a template)**  
  - 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  
  - Have triplicates hole-punched and collated in 3 separate binders:  
    - **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)
Binder should be labeled with:
- IND EXEMPTION REQUEST
- Name of Sponsor-Investigator
- Name of product
- Date of submission

- 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
- If your project depends on external funding but funding is declined, withdraw the application

Tip #8: For more information, go to:
or call the Clinical Research Support Center at (303) 724-1111