Tip #1: As the Sponsor-Investigator and IND holder, what are my reporting responsibilities to the FDA?

- As Sponsor-Investigator and holder of an IND, you are required to submit reports to the FDA until the study is completed, the IND is inactivated, or is withdrawn.
- Annual reports should be submitted as long as the IND is active regardless of what activity there is. It is possible however, to request the IND to be on hold for up to 5 years if there was no activity under the IND and that would suspend the requirement to submit the annual reports to the FDA.
- The typical reporting period for a progress report 12 months.
- The reporting period for the first report starts on the date the IND went into effect. The date the IND went into effect is either:
  - 30 days after the receipt of the IND was acknowledged in writing with an “IND Acknowledgement” letter, or
  - The date the FDA stated that the human clinical trial may proceed. This may be communicated via letter, email, and/or phone call from the FDA stating the safety review was complete and that the clinical trial may be started, or when a clinical hold was removed.
- The date when the IND went into effect becomes the IND’s anniversary date.

Tip #3: What do I need to submit?

IND annual report format

Individual Study information:
- A brief summary of the status of each study in progress and each study completed during the previous year. The summary is expected to include the following information for each study:
  - The title of the study (with any appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient population, and a statement as to whether the study is completed.
  - The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; the number of participants who completed the study; and the number who dropped out of the study for any reason.
  - A brief description of any available study results.

Summary Information:
- Information obtained during the previous year’s clinical and nonclinical investigations conducted under the IND application, including:
  - A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.
  - A summary of all IND safety reports submitted during the past year.
  - A list of subjects who died during participation in the investigation, with the cause of death for each subject.
  - A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.
  - A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug’s actions, including, for example, information about dose response, bioavailability, or relevant information from controlled trials.
  - A list of the preclinical studies (including animal studies) completed or in progress during the past year and a summary of the major preclinical findings.
  - A summary of any significant manufacturing or microbiological changes made during the past year.

Update to general investigational plan:
- A description of the general investigational plan for the coming year to replace that submitted 1 year earlier.

Update to Investigator’s Brochure:
If the Investigator’s Brochure has been revised, a description of the revision and a copy of the new brochure.

**Significant Protocol Updates:**
- A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.

**Update on foreign marketing developments (when applicable):**
- A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.

**A log of outstanding business:**
- If desired by the sponsor, a log of any outstanding business with FDA with respect to the IND application for which the sponsor requests or expects a reply, comment, or meeting.
  - FDA form 1571
  - FDA form 1572 – if needed (e.g. changes to sub-investigators)
  - CVs – if needed (e.g. new sub-investigators)
  - FDA form 3674 – if not previously submitted, or NCT# was not yet provided to FDA (see template)

**Tip #4: How do I prepare the package for shipment to the FDA?**
- If the annual report can be securely held together with a standard office staple, then there is no need to place the report in any type of binder.
- If the report is 15 pages or less, stapling is sufficient. If the report is longer than 15 pages or it cannot be securely held together with a staple, then it will need to be bound by another means.
- If you are sending additional documents (see optional documents above), place the entire submission package in a 3-ring binder.
- When using a binder, indicate on the binder front that the submission is for an Annual Report (you can use an extra copy of the Cover page for this).
- In the report, begin each section on a new page, use index tabs to mark each section of the submission packet. Don’t use colored paper to separate sections.
- Print area for all pages should fit on 8.5 by 11 inches paper
- Provide a table of contents
- Use sequential page numbers
- Allow margin of at least 1 “ on the left side of page (to avoid obscuring information when the pages are subsequently printed and bound) and 3/8 “ on the other sides.
- For pages in landscape orientation, allow ¾ “ 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 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)
- Use single sided copies

**Tip #5: How many copies need to be submitted?**
- Submit these materials in triplicate to the FDA (1 original and 2 copies)
  - CDER: Hole-punch and collate in 3 separate packs or binders: red (original), orange and green
  - CBER: Hole-punch and collate in 3 separate packs or binders: grey (original), red, and any other color
- Create an additional copy for your own records, and additional copies for other parties if needed (e.g. outside funding entity or company providing the investigational drug for the study),
- Scan a copy of the entire package including shipping form/airbill to the Clinical Research Support Center.

**Tip #6: Where do I send Annual Reports?**
- Check your IND approval letter for details and instructions.
- Address it to the FDA Division that reviewed and approved your IND
- Typically all communication needs to be mailed to one of these addresses:
  - For a Drug (CDER):
  - For a Therapeutic Biological Product* (CDER):
Tip #7: For more information, go
to: http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm362663.htm

or call the Clinical Research Support Center at (303) 724-1111