Tip #1: As the Sponsor-Investigator, what are my reporting responsibilities for submitting a final report on my IDE to the FDA?

- As Sponsor-Investigator and holder of an IDE of a significant risk device, you are required to notify FDA and all reviewing IRBs within 30 working days of the completion or termination of the investigation.
- As the sponsor of the IDE you are also required to submit a final report to the FDA and all reviewing IRBs and participating investigators within 6 months after the completion or termination of the investigation.
- For a non-significant risk device, as the sponsor-investigator you must submit the final report to all reviewing IRBs within 6 months after completion or termination of the investigation.

Tip #2: Suggested Format for IDE Final Report

1. Basic Elements
   - IDE Number
   - Device name and indication for use
   - Sponsor’s name, address, phone number, and fax number
   - Contact person

2. Study Progress. Data from beginning of the study should be reported, unless otherwise indicated.
   - Brief summary of study progress in relation to investigational plan
   - Number of investigators/investigational sites (attach list of investigators)
   - Number of subjects enrolled (by indication or model)
   - Number of devices shipped
   - Disposition of all devices shipped
   - Brief summary of results
   - Summary of anticipated and unanticipated adverse effects
   - Description of any deviations from the investigational plan by investigators (since last progress report)

3. Risk Analysis
   - Summary of any new adverse information (since last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
   - Reprints of any articles published from data collected from this study

4. Other Changes
   - Summary of any changes in manufacturing practices and quality control (including changes not reported in an IDE supplement)
   - Summary of all changes in investigational plan not required to be submitted in an IDE supplement

5. Marketing Application or Future Plans
   - Progress toward product approval/clearance, with date (or projected date) of PMA or 510(k) submission; or indication that marketing of device is not planned.
   - Any plans to submit another IDE application for this device or a modification of this device.

Tip #3: How do I prepare the package for shipment to the FDA?
• Use one of these fonts: Times New Roman or Courier (11 point)
  o Print area for all pages should fit on 8.5 by 11 inches paper
  o Allow margin of 1.5 ” 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.
  o 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)
• When the materials can be securely held together with a standard office staple, then there is no need to place the
  report in any type of binder.
• When using a binder, indicate on the binder front that the submission is for a Final Report
  o In the report, begin each section on a new page, use index tabs to mark each section of the submission
    packet.
  o Provide a table of contents
• Use sequential page numbers
  o For pages in landscape orientation, allow ¾ “ at the top to allow more information to be displayed
    legibly on the page.
• Use single sided copies
• Keep the copy of the shipping form/air bill for your files

Tip #4: How many copies of the Final Report do I submit to the FDA?
• Submit 3 sets of documents to the FDA (1 original and 2 copies)
• Make an additional copy for your own records, additional copies maybe required for other parties such as 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 #5: Where do I send Progress Reports?
  □ Check your IDE approval letter for details and instructions.
  • Unless otherwise noted, all Progress Reports are mailed to:

    Food and Drug Administration
    Center for Devices and Radiological Health
    Document Mail Center - WO66-G609
    10903 New Hampshire Avenue
    Silver Spring, Maryland 20993-0002

Tip #6: For more information, go
to:  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/Investigatio
    nalDeviceExemptionIDE/ucm046717.htm
or call the Clinical Research Support Center at (303) 724-1111