TIP Sheet

IDE SPONSOR-INVESTIGATOR REPORTING REQUIREMENTS TO THE FDA

Significant Risk Devices

Tip #1: As IDE holder, what are my reporting responsibilities to the FDA and IRB?

As the Sponsor-Investigator who holds an IDE, you are required to submit certain reports to the FDA. All reports to FDA should be identified as IDE Supplements on Form FDA 3514 and submitted in triplicate (one original and two copies):

- **Unanticipated Adverse Device Effects**
  - The sponsor-investigator must report the results of an evaluation of an unanticipated adverse device effect to FDA and all reviewing IRBs and investigators within 10 working days after the sponsor first receives notice of the adverse effect.

- **Withdrawal of IRB Approval**
  - The sponsor-investigator must notify FDA, all reviewing IRBs and participating investigators of the withdrawal of IRB approval of an investigation (or any part of an investigation) within 5 working days of receipt of the withdrawal of approval.

- **Withdrawal of FDA Approval**
  - The sponsor-investigator must notify all reviewing IRBs and participating investigators of any withdrawal of FDA approval within 5 working days after receipt of the notice.

- **Current List of Investigators**
  - Every six months the sponsor-investigator must submit to FDA a current list of the names and addresses of all investigators participating in a significant risk device investigation.

- **Recalls and Device Disposition**
  - The sponsor-investigator must notify FDA and all reviewing IRBs of any request that an investigator return, repair, or dispose of any unit of an investigational device. The notice must be made within 30 working days after the request is made and must state why the request was made.

- **Informed consent**
  - The Sponsor-investigator must submit a copy of any report by an investigator of the use of a device without first obtaining informed consent. The report must be made to FDA within 5 working days after receipt of the notice of such use. Such a report may be required to be submitted to the specific IRB reviewing that investigator’s work.

- **Other Reports**
  - The sponsor-investigator must provide accurate, complete, and current information about any aspect of the investigation upon request from the reviewing IRB or FDA.

- **Progress Reports (or Annual Reports)**
  - At regular intervals but at least yearly, the sponsor-investigator must provide progress reports to all reviewing IRBs. For a significant risk device, the sponsor must also submit the progress report to FDA.
  - Please see Tip Sheet on Progress Reports for guidance on format and information to be included.

- **Final Report**
  - The regulations require that for a significant risk device, the sponsor must notify FDA and all reviewing IRBs within 30 working days of the completion or termination of the investigation. The sponsor must also submit a final report to FDA and all reviewing IRBs and participating investigators within 6 months after the completion or termination of the investigation. A suggested format is provided below.
  - Please see Tip Sheet on Final Reports for guidance on format and information to be included.

Tip #2: How do I prepare the package for shipment to the FDA?

- Use one of these fonts: Times New Roman or Courier (11 point)
• Print area for all pages should fit on 8.5 by 11 inches paper
• 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.
• 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 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.
• When using a binder, indicate on the binder front that the submission is for a IDE Supplement.
• If applicable, provide a table of contents
• Use sequential page numbers
• 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
• Have a naive reader proofread your submission
• Keep the copy of the shipping form/airbill for your files

Tip #4: How many copies need to be submitted?
• The FDA requires 1 original and 2 copies to be sent as part of the package
• Make and keep a 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),
• Scan a copy of the entire package including shipping form/air bill to the Clinical Research Support Center

Tip #5: Where do I send the Reports?
• Check your IDE approval letter for details and instructions.
• Unless otherwise noted, all 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 20937-0002

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