Sponsor/Investigator Responsibilities

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Topics

• Sponsor responsibilities
  – Starting up a clinical trial
  – Monitoring
  – Records and Reports
  – Lessons learned from FDA inspections

• Investigator responsibilities
  – Human subject protections
  – Records and Reports
  – Lessons learned from FDA inspections
What is a Sponsor/Investigator?

• **Dual role**
  – An *individual* who both initiates and actually conducts the study

• **Dual responsibilities**
  – Sponsor and Investigator
Sponsor/Investigator

- Ensure investigational device is correctly designated either SR or NSR
- Determine if you need an IDE for the study
- Follow 21 CFR 812
- Follow IRB requirements; ensure rights, safety and welfare of subjects and data integrity
- [Http://www.fda.gov/cdrh/devadvice/](http://www.fda.gov/cdrh/devadvice/) – Regulatory information on medical devices
Responsibilities

Sponsor

Investigator
Sponsor Responsibilities

• Select qualified investigators
  – Provide them with information they need to conduct study

• Ensure IRB approval is obtained
  – May not start the study without approval
Sponsor Responsibilities

• Obtain signed investigator agreements and financial disclosure from all investigators
• Ship investigational device(s) only to qualified investigator(s)
• Maintain device shipment and distributions records
• Submit reports to IRBs and FDA
Sponsor Responsibilities

- Ensure investigator compliance
- Ensure proper monitoring
- Select qualified monitors
Monitoring

• On going process of overseeing the progress of a clinical trial and ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, IRB and FDA requirements

• Purpose of monitoring: Protect human subjects and ensure reliability of the data
Sponsor
Maintain Records

• Correspondence with investigators, IRBs, and FDA
• Signed investigator agreements
• Anticipated and unanticipated adverse device effects
• Device shipment and distributions
• Any other records
Sponsor
Device Accountability

• Records:
  – Shipment and disposition of devices including:
     Name and address where shipped
     Type and quantity
     Batch number or code
     Disposition of device
     Any returns or methods of disposal
     Batch number or code
Sponsor Lessons Learned

Failure to

• Monitor study
• Secure investigator compliance
• Analyze and report AE/UADE
• Report to investigators, FDA, or IRB
• Control investigational devices
• Obtain signed Investigator’s Agreement
• Ensure informed consent
Clinical Investigator Responsibilities
Clinical Investigator Responsibilities

• Obtain IRB approval prior to enrolling subjects
  – and maintain continuing approval

• Obtain and document informed consent before enrolling subjects

• Follow the protocol
Clinical Investigator Responsibilities

• Implant/use device only in/on subjects enrolled on study

• Ensure adverse effects (AEs) are appropriately documented and reported
  – Unanticipated adverse device effects must be reported within 10 days

• Maintain adequate records
Clinical Investigator Records

• Maintain all correspondence with
  – other investigators
  – the IRB
  – the monitor
  – FDA
Clinical Investigator Device Accountability Records

- Records of receipt, use, and disposition of device including:
  - Type and quantity of the devices, dates of receipt, and **batch number or code mark**
  - Name of all persons who received, used, or disposed of each device
  - Why and how many devices have been returned, repaired, or otherwise disposed of
Clinical Investigator Records

• All IRB correspondence
  – protocol approval
  – continuing review approval
  – amendment approval
  – deviations

• Maintain records of each subject’s case histories and exposure to the device
Clinical Investigator Records

• Protocol
  – All versions

• Changes and deviations from protocol
  – obtain prior approval from sponsor, IRB, FDA

• Emergency deviations
  – reported to the sponsor and IRB within 5 days
Clinical Investigator Records

• CRFs and supporting data
  – Written notes, lab reports, test results
• Informed consent document
  – All versions
• Exposure to the device
• Relevant observations
  – Adverse device effects
    • Anticipated and unanticipated
What is an Unanticipated Adverse Device Effect?

• Any serious adverse effect on the health or safety of a subject or any life-threatening problem or death caused by or associated with the device that was not previously identified in nature, severity, or degree of incidence in the investigational plan, or any other unanticipated serious problem associated with a device.
Clinical Investigator Reports

- Unanticipated Adverse Device Effects
- Withdraw of IRB approval
- Progress reports
- Deviations from the investigational plan
- Failure to obtain informed consent
- Final report
- Other
Investigator Lessons Learned

Failure to

• Follow investigational plan, investigator agreement, or protocol
• Document case history/device exposure
• Obtain adequate informed consent
• Control investigational device
• Report UADEs
• Obtain FDA/IRB approval to conduct study
Summary

• Sponsor responsibilities
  – Starting up a clinical trial
  – Monitoring
  – Records and Reports
  – Lessons learned from inspections

• Investigator responsibilities
  – Human subject protections
  – Records and Reports
  – Lessons learned from inspections
Questions