The Sponsor: Responsibilities in Medical Device Clinical Trials

Presented by Catherine Parker, RN

Consumer Safety Officer
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and Radiological Health
Objectives

- Define “medical device research sponsor.”
- Identify the 10 sponsor responsibilities discussed in the presentation.
- Contrast the role of monitoring with the role of a Data Monitoring Committee.
- Identify the six categories of records sponsors may be required to maintain.
Presentation Topics

- Regulatory Definition of a Sponsor
- Sponsor Responsibilities
- Monitoring
  - Monitoring vs. Data Monitoring Committee
- Sponsor Records
- Documentation
- Inspections
- Sponsor Reports
A Sponsor Initiates a Study

21 C.F.R. 812.3(n)
A Sponsor is a Person

21 C.F.R. 812.3(l)
General Sponsor Responsibilities

- Select qualified investigators
- Provide them with the information they need to conduct the study
General Sponsor Responsibilities

- Ensure proper monitoring
- Ensure IRB review and approval
- Submit IDE application to FDA
- Ensure IRB and FDA are informed of significant new information about an investigation
Sponsor Responsibilities

- Ship investigational device(s) only to qualified investigator(s)
- Obtain signed investigator agreements and financial disclosure from all investigators
- Select qualified monitors
Monitor

- An individual designated by a sponsor or CRO to oversee the progress of an investigation
- It is a sponsor’s responsibility to select monitors that are qualified by training and experience

21 C.F.R. 812.3(j)

21 C.F.R. 812.43(d)
Monitoring

- The act of overseeing the progress of an investigation.
- Used to assure the protection of human subjects and data integrity
- Ongoing continuous process
- The task of monitoring can be delegated but, it is ultimately the sponsor’s responsibility

21 C.F.R. 812.3(j)
Monitors Review

- IRB approvals
- Informed Consent Documents
- Source documents
- Case Report Forms (CRF)
Monitoring Investigations

- Secure investigator compliance
- Conduct an evaluation of any unanticipated adverse device effects
- Obtain FDA and IRB approval before resuming a terminated study

21 C.F.R. 812.46
Monitoring vs. DMC

Data Monitoring Committee (DMC)
Sometimes referred to as a Data and Safety Monitoring Board

- Monitoring is a different process than oversight by a Data Monitoring Committee
Data Monitoring Committee

- A group that reviews data from a trial
- They advise the sponsor regarding the continuing safety of trial subjects
- Evaluate data for continuing validity and scientific merit
Sponsor Records

- All correspondence with another sponsor, monitor, CI, IRB, and FDA
- Shipment and disposition of the device

21 C.F.R. 812.140(b)
Sponsor Records

- **Shipment**
  - Name and address of consignee
  - Type and quantity of device
  - Date of shipment
  - Batch number or code

- **Disposition**
  - Batch number or code
  - Reasons for
  - Method of disposal

21 C.F.R. 812.140(b)
Sponsor Records

- Signed investigator agreements & financial disclosure information
- Non-significant risk device records

21 C.F.R. 812.140(b)(4)
Sponsor Records

- Adverse device effects and complaints
- Other records required by FDA

21 C.F.R. 812.140
Sponsor Records

- Retention period is 2 years after
  - end of the study
  - pre-market approval application
- Custody can be transferred

21 C.F.R. 812.140
If it is not documented, it never happened.
Inspections

- Permit access to FDA
- Permit inspection and copying of documents
Sponsor Required Reports

- Unanticipated Adverse Device Effects (UADE)
- Withdrawal of IRB approval
- Withdrawal of FDA approval

21 C.F.R. 812.150(b)
Sponsor Required Reports

- Investigator list
- Annual progress report
- Recall and device disposition
- Final report

21 C.F.R. 812.150(b)
Sponsor Required Reports

- Use of device without informed consent
- Significant risk determination
- Other reports

21 C.F.R. 812.150(b)
Summary

- A sponsor initiates the investigation
- Sponsor responsibilities are designed to:
  - Protect human subjects
  - Promote the collection of quality data
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