

# 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



# 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

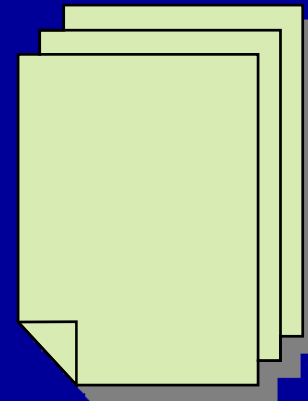
- CRFs and supporting data
  - Written notes, lab reports, test results
- Informed consent document
  - All versions
- Exposure to the device
- Relevant observations
  - Adverse device effects
    - Anticipated and **unanticipated**

# 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

REPORT CARD				
GRADING PERIOD	1	2	3	4
READING	A			
WRITTEN COMMUNICATION	A			
MATHEMATICS	C			
SCIENCE/HEALTH	B			
SOCIAL STUDIES	B			
ART	A			
MUSIC	A			
PHYSICAL EDUCATION	C			
Grade Average	B			
Attendance:	Present	40		
	Absent	0		
	Tardy	1		
A = Excellent • B = Good • C = Satisfactory • N = Needs Improvement U = Unsatisfactory • I = Insufficient / Incomplete				
Student: _____ Grade: _____ Year: _____				

# 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

