Division of Bioresearch Monitoring

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Program Enforcement Branch (PEB)
Viola Sellman, Branch Chief

Responsible for the development and issuance of inspection assignments and review and classification of resulting establishment inspection reports (EIRs) related to: Investigational Device Exemptions (IDEs), Premarket Approval Applications (PMAs), Product Development Protocols (PDPs), Humanitarian Device Exemptions (HDEs), Premarket Notifications (510(k)s); and the routine surveillance of Institutional Review Boards (IRBs) and non-clinical laboratories conducting research on animals with medical devices (Good Laboratory Practice).

Special Investigations Branch (SIB)
Vacant, Branch Chief

Responsible for the development and issuance of inspection assignments and review and classification of resulting establishment inspection reports (EIRs) related to allegations of research misconduct or data integrity issues.

Division of Bioresearch Monitoring

Business of Integrity, Monitoring, and Oversight

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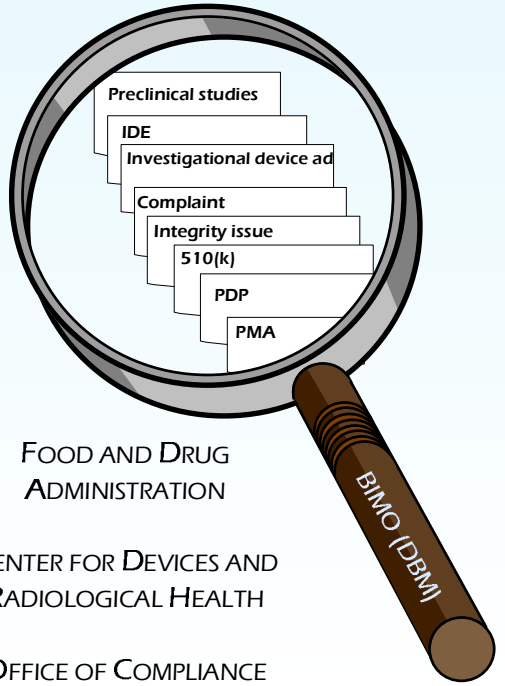


Food and Drug Administration

Center for Devices and Radiological Health

Office of Compliance

Assuring research integrity through human subject protection & data integrity audits

Bioresearch Monitoring Responsibilities

Inspection and data auditing of medical device research - a program of domestic and foreign on-site inspections of clinical investigators, sponsors, monitors, contract research organizations, non-clinical laboratories, and institutional review boards

Implementation of the Application Integrity Policy (AIP) - with the ODE integrity officer

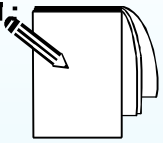
Enforcement of promotion & advertising regulations for investigational devices

The overall focus of the bioresearch monitoring program is to assure compliance with the FDA regulations, assure the integrity and reliability of the research data we inspect, and determine that the rights and welfare of human research subjects are adequately protected.

What We Do

- Serve as a member of application review teams:
  - participate in pre-IDE and pre-PMA meetings
  - participate in PDP meetings
  - participate in PMA filing & day-100 meetings
  - determine, with the ODE lead reviewer, appropriate inspections, assigned by DBM & conducted by FDA field investigators
  - facilitate necessary ODE/field interactions
  - analyze inspectional findings & provide recommendations regarding:
    - clinical data
    - human subject protection
    - preclinical study data
- Provide recommendations regarding inspections of 510(k) clinical studies
- Address complaints & data integrity issues that arise, in conjunction with the field & ODE
- Co-implement AIP with ODE's integrity officer
- Enforce promotion & advertising regulations for investigational devices
- Participate in development of Center & Agency policy on human subject protection issues

Contact DBM When:



- A pre-IDE or pre-PMA meeting is scheduled
- Non-clinical studies raise concerns due to new biomaterial(s), unfamiliar procedures, data integrity, &/or new or unknown lab
- An IDE annual report or other study information raises data integrity and/or subject safety concerns
- A complaint raises data integrity and/or subject safety concerns
- You have not been contacted by a BIMO reviewer for your PDP or PMA
- A PDP "notice of completion" is imminent
- A 510(k) has clinical data pertinent to a decision or that raises data integrity concerns
- A submission-related meeting is planned

Remember:

The BIMO reviewer is a member of the review team

DBM can assist you with data integrity and/or subject safety concerns