GCP Connections: Independent Data Monitoring Committee
ICH E6 1.25 and 5.5.2

**Independent Data Monitoring Committee (IDMC) (aka DSMB):**

- May be established by the sponsor depending on the nature of the study
- Reviews and evaluates study data
  - safety data
  - critical efficacy endpoints
  - recommends to the sponsor whether to continue, modify, or stop a trial
21 CFR 50.24(a)(7)(iv)

Code of Federal Regulations specifically requires the establishment of a DSMB when informed consent requirements are waived in emergency research studies.
Questions:

1. Are IDMCs monitored by clinical monitors?
2. Does the FDA inspect IDMCs?
3. Can and IRB/IEC serve as a IDMC?