

IRB Rules for Compliance Officers AudioCourse

Course Syllabus



All lectures are 60 minutes with a 15 minute Q&A session.
All lectures begin at 12 pm CT/1 pm ET.

October 27

Lecture 1: Federal Protection of Human Subjects

- What is research?
- When does OHRP have jurisdiction?
- When does FDA have jurisdiction?
- Filing the FWA
- Who should sign it?
- Should "the box" be checked?
- Hospital sponsorship of IRB versus contracted external IRB
- Special problems of community hospitals

October 29

Lecture 2: Membership of the IRB

- Who should be a member?
- Investigators
- Community members
- Clinical backgrounds
- Ethics representatives
- Principal goals of the IRB
- Obligations of IRB members

November 3

Lecture 3: Types of Research Review

- Research that is exempt from review
- Expedited Review
- Full Board Review
- Continuing Review
- What should be submitted to the IRB?
- Reports to IRB: serious adverse events; research misconduct
- Impact of reports on provider quality initiatives

November 5

Lecture 4: Conducting the Meeting

- Quorum
- What should be reviewed for each submission
- Voting eligibility
- Importance of Minutes
- Structure of Minutes
- Communicating with investigators

November 10

Lecture 5: Research Informed Consent

- The parts of the informed consent form
- Risks & Benefits
- Potential side effects
- Added costs section
- Research-related injury
- Financial disclosure
- Stamped approval
- Keeping signed copies of informed consent

November 12

Lecture 6: Incorporating Clinical Research into the Compliance Program

- How to identify unique IRB risks
- Auditing sample of minutes
- Auditing sample of files
- Sit in on IRB meeting
- Recent cases and trends in government enforcement