Segment Objectives:

• Appreciation of the role of the IRB
• Understanding the basics of completing the eIRB application
• Awareness of the eIRB application elements that require PI planning and input
IRBs and Investigators and Sponsors/CROs...

• Not always a match made in heaven

• Problems and complaints abound:
  • The time from application submission to approval/start up is long
  • Sponsors/CROs approve “amendments,” but PIs fail to submit
    change-in-research to their IRBs
  • Tediousness of submitting numerous protocol amendments
    received from sponsors
  • Timeliness of IRB submissions is not compliant, e.g., Unanticipated
    problems reported to the IRB in 10 days
  • Collecting/Collating CVs, licenses, certifications, etc.
The Role of the Institutional Review Board (IRB)

- Per the Institution's Federal Wide Assurance (FWA), IRB review is required, using two mechanisms:
  - Convened (more than minimal risk)
  - Expedited/Exempt (minimal risk or Non-HSR)
- The IRB reviews protocols and supporting materials for:
  - Compliance with regulatory and institutional requirements
  - Scientific soundness
  - Human subject safety and well-being (ethics)
    - Benefit is maximized
    - Harm is minimized
    - Fairness is safe-guarded
What the IRB is not... (despite what you’ve heard!):  

• The “Infernal Review Board”  
• An implacable apparatchik  
• A “rubber stamp”  
• An obstinate mechanism bent solely on delaying study-start up  
• A face-less group that can’t be talked to, insensitive to institutional dynamics and outside pressures.
The eIRB application: Gather and Upload

- Protocol
- Informed Consent Form
  - Will be revised by the IRB Consent Form Specialists
- Supplemental Documents
  - FDA documents (e.g., IND letter, etc.)
  - Study team member training certificates
  - Drug/Device information
  - Investigator Brochure
- For Industry-sponsored clinical trials, most documentation is provided
- Coordinate with your sponsor/CRO CRA to be sure you all you need.
The eIRB Application: Additional Elements

- Study team member agreements
- High Risk determination
- Conflict of Interest
- Informed Consent process description
  - Who, when, where, how?
- Recruitment narrative (including recruitment materials)
  - Who, when, how?
- Incidental findings response
- Data Safety Monitoring Plan
- HIPAA forms (e.g., For future contact)
Other IRB approval issues...

• Changes in Research
  • Get IRB approval before initiation of any non-emergent change
  • Protocol exemptions/exceptions approved by sponsor still require prior IRB approval
  • Emergent/Ad hoc changes, communicate with IRB ASAP

• Problem-event reporting
  • AEs, SAEs/Unanticipated Problems
  • IND Safety Letters
  • Any of the above requiring immediate submission and IRB acknowledgement

• Continuing Reviews
  • Submit on time
The IRB Approval Process: Pain Reduction

• Pain: eIRB application returned “incomplete”
  • Prophylaxis: Complete the eIRB application fully and correctly

• Pain: IRB review questions (generated with a “tabled” study)
  • Treatment: Answer all questions completely (“Done” isn’t always acceptable)

• Pain: Uncertainty about any IRB application element or process
  • Preventative Medicine: Ask, Ask, Ask... Do not “self-medicate” or ignore
  • Review online resources (e.g., policies and guidelines)

• Prognosis: Improved turn-around time/through-put
Questions?

• IRB Website:
  [http://www.hopkinsmedicine.org/institutional_review_board](http://www.hopkinsmedicine.org/institutional_review_board)

• IRB Policies and Guidelines:
  [http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/)

• IRB Help and Training:
  [http://www.hopkinsmedicine.org/institutional_review_board/training_requirements/eirb_training.html](http://www.hopkinsmedicine.org/institutional_review_board/training_requirements/eirb_training.html)