Single IRBs

Can the promised goals of efficiency and timeliness be met?

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Collaboratory Ethics and Regulatory Core

Basic IRB Logistics

Note:

IRB Committee - reviews and approves a protocol

IRB Office – which handles all the logistics

- Federal regulations mandate review by an IRB ***committee*** prior to study initiation
- The IRB ***committee*** can be internal or external
  - Another academic IRB committee or a commercial IRB committee
- A formal institutional agreement is required
  - ***AND is specific to reliance on the external IRB Committee review***

Critical Context: The IRB exists within the Human Research Protection Program (HRPP)

Think the pimento in the olive

- Institutional review board (IRB) or Ethics Committee (EC) **
- Organization
  - Grants and contracts
  - Policies: Conflict of interest, Noncompliance, Research Misconduct
  - Other review committees
    - Ancillary reviews; e.g., radiation safety, biomed engineering, CMS review, pharmacy, data security, ESCRO,
  - Legal resources
- Researchers and research staff
  - Appropriate credentials and resources
  - Completion of mandated education

** The only review covered by the sIRB

As a result…when relying on an external IRB

- Institutional review is required - most commonly delegated to and/or coordinated by the IRB OFFICE (not committee)
  - Usual sign-offs (e.g., department head, research official)
  - Tracking in the institutional research database
  - Identification of and communication with ancillary review committees
  - Institution-specific issues: state and local laws, local policies,
  - Does the research make sense at your institution. E.g. SOC issues, eligible populations
- Usually requires submission of a protocol to the local IRB Office
  - Allows tracking
  - Triggers communication/coordination with other institutional requirements
- Communication with the reviewing IRB
  - For initial review and ongoing review (think amendments to the protocol)
  - Issues of noncompliance, protocol holds, study closure

BUT…there is some good news!

- Although initial review may still be clunky…
- Reliance agreements have been stream-lined: SMART IRB
- Consistency achieved
  - Approved protocol across all sites
  - Handling of adverse events, unanticipated problems
  - Continuing review

Areas for improvement

- Foster realistic expectations
- Better understanding of:
  - The reliance process
  - The whole olive
    - Institutional versus IRB-Committee responsibilities

- Standardization/harmonization of forms and processes between institutions
- Better coordination between relying and reviewing institutions