

# Alternative IRB Models - Liability

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***“The Institution bears full responsibility for all research involving human subjects covered under its Assurance.”***

Source: OHRP Human Subject Assurance Training

# IRB vs. HRPP

# Use of External IRBs

- Nature of Review Relationship
- Body of Research to be Reviewed
- Impact on FWA
- Coordination with Other Components in the HRPP

# Example 1 – Use of WIRB

- Evaluate WIRB Operations
  - Accredited
  - Visit
- Develop Clear Agreement
- Identify Body of Work
  - Types of Trials
  - Relationship to FWA

- Investigator Submits WIRB Application
- Develop Linkages to Other HRPP Components
  - Pre-review by Ancillary Committees
    - P&T, COI, IBC, MRPC, Cancer Center
  - Subject Injury Language
  - HIPAA
  - Completed Contract Negotiations
  - Post-Approval Monitoring Program

# Benefits

- Less Demand on the Local IRB for
  - Initial Review
  - Continuing Review
  - Modifications
  - AE's

# Example 2 – CIRB

- “Facilitated Review”
- Must Still Undergo Internal “Expedited” Review
- CIRB ***MUST*** be Listed on Institution’s FWA

# CIRB Process

- CIRB Reviews Prior to Release of Protocol
- PI Requests Acceptance of CIRB Review
- Local IRB Reviews CIRB Records, Evaluates and Modifies for Local Context.
- CIRB Conducts Continuing Review, AE Review, Modifications
- Local IRB Reviews Local AEs

# Benefits

- Less Demand on the Local IRB
- Potential for Faster Start-up
- No Full-Board Submission by PI

# Other Considerations

- Approval Under Local FWA
- Coordination with Ancillary Committees
- Other HRPP Activities Still Necessary

# Serving as the IRB or Institutional Oversight Body for Others

- Individual Investigator Agreements
- Other Institutions

# Conclusion

- Alternative models may reduce workload for full board.
- Use of these models will increase complexity for IRB support staff and, perhaps, for investigators.
- Complexities increase as the number of alternatives used increases.