Outsourcing to an AAHRPP-Accredited IRB vs. Creating a Local, Regulatory-Compliant IRB

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Today’s Speakers:

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Lynn has nineteen years of experience in research administration and regulatory compliance. Her experience includes Institutional Review Board (IRB) administration, research compliance assessment, conflict of interest management, clinical trials office management, and Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation assistance.
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Jose has over twenty years experience in health care including clinical, operational, administrative and regulatory roles. Presently he provides administrative oversight for the hospital’s research institute including the clinical trial unit and the office of research administration.
Mary has nine years experience in research administration. She currently oversees all research activities for a growing hospital network including grants and contracts, research compliance, biostatistical support services, institutional review board (IRB) administration, institutional animal care and use (IACUC) administration, conflict of interest management, effort reporting, and intellectual property management.
Objectives for this Webinar

- Goals for both models
- Things to consider when faced with this decision
- Cost of IRB review (local and external)
- Two HRPP Directors share the decisions they made and why
  - Jose Perdomo, Esq., Miami Children’s Hospital
  - Mary Klein, Ph.D., Albert Einstein Healthcare Network

Polling Question #1

What is your current IRB model?

- Local IRB review only
- External IRB review only
- Combination of both local and external IRB review
Goals for Both Models
Goals for Both Models

- Protection of human subjects
- Regulatory compliant review
- Efficient customer service
- Eligible for AAHRPP accreditation
Protection of Human Subjects Requires:

- A comprehensive system to ensure the protection of the rights and welfare of subjects in human research.

- All individuals in the organization, along with key individuals and committees fulfilling their roles and responsibilities.

- A commitment to:
  
  • Protect the rights and welfare of subjects in human research
  
  • Comply with ethical and legal requirements for the conduct and oversight of human research
Regulatory-Compliant Review Results in:

- Application of the least restrictive level of review
- Investigator offered options to reduce review level
- Decisions are justified by regulatory criteria
- Appropriate identification and follow-up for UPIRTSOs and serious or continuing non-compliance
- More frequent use of waiver of documentation of consent
- Meet AAHRPP accreditation requirements
- Avoidance of warning letters, negative publicity or worse!
What should investigators expect?

- Full board review within 2 weeks
- Expedited review within 1 week
- Exemption determination within 3 days

This turnaround time can be achieved with efficient policies and procedures and well-trained IRB staff, including professional IRB staff serving as IRB members and non-committee reviewers.
Eligible for AAHRPP Accreditation

- The decision to become AAHRPP-accredited is an Organizational decision
- The right IRB model for your Organization is half the battle
  - AAHRPP’s three domains:
    - Organization
    - Research Review Unit
    - Investigator
Things to Consider
Common Challenges that Drive this Decision:

- Increase in research portfolio
- Increase in research complexity
- Increased demand to improve turnaround time
- Additional project responsibilities (AAHRPP, electronic IRB system implementation)
- Staffing limitations – limited financial resources or limited expertise
- Not enough research activity to justify the cost and effort to create or transform your local IRB (< 200-300 protocols)
Polling Question #2:

Which challenge is driving your decision?

- Increases in study volume or complexity
- Increased demand to improve turnaround time
- Additional project responsibilities (AAHRPP, electronic IRB system implementation)
- Limited financial resources
- All of the above
- Other
Typical Local IRB Model

- A majority of institutions have a single, local IRB*
- A majority of IRBs meet monthly (or less frequently)*
- A majority of IRB Offices have 1-4 support personnel*
- A significant number of institutions have more than one board
- A significant number of institutions rely on an external IRB for all or part of their reviews

*Source: 2010 PRIM&R IRB Workload and Salary Survey
Dealing with Challenges in IRB Composition

- No regulatory obligation to ensure IRB membership from every field of study conducting research
  - When additional expertise is needed to ensure that the science is valid, consultants can be used
  - Large boards (15, 20, 25, 30+) create significant challenges:
    - Scheduling
    - Quorum (common that many members do not attend)
    - Thoroughness of review (common for just 1-2 people to have read materials in enough depth to assess criteria for approval)
    - Level of participation (many discussions are among the two members who have read the materials)
    - Document management
Dealing with Challenges in IRB Composition

- **Scientific members:**
  - The regulations do not specifically require any IRB members to be scientists.
    - ICH GCP requires a physician (or dentist) for clinical trials

- **Nonscientific members**
  - Nonscientists may be employees of the organization or unaffiliated.
  - Common for many IRBs to combine unaffiliated and non-scientific – easier to combine affiliated and non-scientific through identification of employees with non-scientific background
Dealing with Challenges in IRB Composition

- Unaffiliated members
  - “Community member” is not a regulatory requirement
  - “Unaffiliated” member does not have to be a non-scientific member.
    - Common for many IRBs to combine both unaffiliated and non-scientific – easier to combine unaffiliated and scientific through identification of retirees with scientific background
Flexible IRB Models

- Minimal official number of “IRB Members” (5-7 plus at least one scientific, one nonscientific and one unaffiliated)
- Meet 2x to 4x more frequently
- Back by large group of alternates (e.g. >15) and consultants
  - Use consultants to ensure expertise by protocol, not by meeting.
  - Rotate 5-7 members/alternates meeting weekly and ad hoc
- Mix and match for more easy scheduling (sign up sheet) Typically:
  - Agendas are ¼ in size – fewer copies needed
  - Typically all members show
  - Typically all members have reviewed materials in depth
  - Typically discussion is among all members
Outsourced IRB Models

- Total reliance on commercial IRB for all review and oversight – no local IRB
- Partial reliance on commercial IRB for review and oversight over a subset of research (e.g. industry-sponsored clinical trials)
- Reliance on the IRB of a collaborating institution (total or partial)
- Reliance on the IRB of a foundation or funding agency (partial)
- Local IRB review supported by an outside entity (e.g. commercial IRB) for all back office services, using local IRB panel (BOOST-IRB® back office operations services and technology for IRB)
Outsourced IRB Models

Advantages

- Can reduce regulatory risk exposure (core competency)
- Provides extra capacity (surge or continuous)
- Faster than average turnaround times
- Reduced transaction costs (direct billing to sponsors)
- Enhanced sponsor relationships (sponsors prefer)
- Eliminates local political considerations during review
- Can be cost-effective (depending on volume, expertise, technology, professionalism, accreditation, sponsor demands)

Disadvantages

- Can cost more than local review
- Change management during transition phase
- Perceived loss of institutional control
- Local context requires special attention
- “Dirty laundry” syndrome
Outsourcing Still Requires Internal Processes

- **Feasibility**
  - Which protocols will be outsourced?
    - Industry-sponsored
    - Successfully enrolling
  - Which protocols should be closed?
    - Not enrolling
    - Competing studies

- **Financial considerations**
  - Direct-billing to sponsors
  - Verification of departmental support
  - Contract negotiation

- **Administrative considerations**
  - Organizational and investigator responsibilities
  - Liaison between Organization and external IRB
Cost of IRB Review
Cost of Outsourcing

- **Start-up costs**
  - Creation/revision of policies and procedures
  - Feasibility process
  - Transfer of existing protocols

- **Ongoing costs**
  - Recurring IRB fees
    - Industry-sponsored (direct billed)
    - Cooperative Group
    - Organization/department sponsored
Cost of Local IRB include:

- **Start-up costs**
  - Creation/revision of policies and procedures
  - Training on regulatory compliance
  - eIRB license
  - Accreditation support

- **Ongoing costs**
  - Personnel
    - IRB Administrator salary
    - IRB professional staff salaries (one analyst for each 200-300 protocols)
    - IRB support staff (clerical level)
    - IRB chair support
Cost of Local IRB Include:

- Ongoing costs (cont.)
  - Office space (per sq. ft. plus overhead)
  - Office supplies
  - Office furniture
  - Computer equipment
  - Administrative costs (copying, computers, phone, desks, etc.)
  - Annual AAHRPP accreditation fees
Ongoing costs (cont.)

- Opportunity cost for 12 IRB members (for regulatory compliant meetings each member ought to spend at least 30-60 minutes per agenda items reviewing materials in advance.)
  - 6 MD employees
  - 4 non-MD employees
  - (Assume 2 non-employee volunteers)
- Opportunity cost for industry-sponsored studies
  - Many pharmaceutical sponsors limit the studies available to organizations that will not use the external IRB of choice
Cost of Local IRB Includes (Cont.):

- Ongoing costs (cont.)
  - Cost of eIRB system
    - Implementation
    - Licensure fee (initial and continuing)
    - Support and upgrade
    - Hardware
Two HRPP Directors Discuss the Decisions They Made and Why
The decision to outsource to an AAHRPP-accredited IRB

- Enhance research oversight and management
- Increased regulatory complexity
- Timeliness of review process

Why maintain outsourced IRB services?

- Volume of studies
- Accreditation (AAHRPP)
- Increase in sponsored studies
- Regulatory environment
The decision to transform the local IRB

- Push from research community
  - Need to improve review process
  - Lack of clear policies and consistent reviews

- Why stay with local IRB for majority of reviews?
  - Majority of research is investigator-initiated
  - Know our investigators and facilities (strengths and limitations)
  - IRB staff provide one-on-one support for researchers
  - Better understanding of ongoing projects and the issues that come up during course of the research
Have Questions or Need Advice? Contact:

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