Working with Outsourced IRBs: Where to Draw the Line

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Presented by:
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Established in 1983
US and Canadian boards fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
Superior audit history with FDA—five consecutive audits with no findings.
21 CFR Part 11 compliant electronic systems
Compliant with FDA, OHRP and Health Canada requirements
About Schulman Associates IRB

- Full board meetings **five days a week**
- Dedicated **daily expedited review** of qualifying minimal risk protocols
- **Phase I Board** with streamlined processes tailored to Phase I timelines
- **Oncology Review Board** for all phases of oncology research
- Customized services for **institutions and AMCs**
- **Experienced primary points of contact** for sponsors, CROs, institutions and sites
About Schulman Associates IRB

- Clinical Quality Assurance (CQA) and Human Research Protection (HRP) consulting services provided by Provision Research Compliance Services

Provision is a joint venture between Schulman Associates IRB and Falcon Consulting Group

www.provisionrcs.com
Bette Bayne
Director, Institutional and Phase I Services

- With Schulman since 2011
- Primary pre-submission point of contact for Phase I and Institutional clients
- Responsible for the development of Schulman’s Phase I service line
- Helped launch Institutional service line
- BS in Biology and Chemistry from the University of Texas
Karen Christianson, RN, BSN, CCRP
Consultant, HRP Consulting Group

- Formerly Human Research Protection Program Director at Baystate Health
- Former Accreditation Site Visitor, AAHRPP
- BS in Nursing, Minor in Management from Hartwick College
- With HRP Consulting Group since 2013
About HRP Consulting Group

- Founded in 2005 as a consulting firm focusing solely on human research protections
- Over 100 years combined experience in the human research protections field
- Broadened services in 2010 to include all areas of research compliance
- Committed to providing expert advice to institutions seeking to develop or improve their research program
- Dedication to strong relationships and personal service with our clients as key to success

To learn more, visit thehrpconsultinggroup.com
“Change is the law of life. And those who look only to the past or present are certain to miss the future.”

John F. Kennedy
Change

- Landscape is changing for central IRB usage
- Strict use of Local versus Central IRB is evolving
- Recent examples of support of Central IRBs for multi-site trials
  - CTTI: Central IRB Advancement Project
  - FDA Guidance, March 2006
Change

➢ Additional Reasons to Work with a Central IRB
  • Compliance Issues
  • Rebuild Internal HRP Staff
  • Resource Issues
  • Faster Turnaround Times to Remain Competitive
  • Sponsor Request
  • Seeking Extension of Therapeutic Areas
Key Questions

- Decision to work with a central IRB is made; now what?
  - What is outsourced to a central IRB?
  - What stays with the Institution?
  - What is shared/negotiated between the IRBs?
Responsibilities of Central IRB

- Assess investigator qualifications as part of submitted material
- Assess investigators and research staff as part of the review
- Maintain central IRB registration with FDA and OHRP
- Notify designated institutional officials of accreditation changes
- Review and ensure compliance with IRB requirements for management of conflicts of interest
Responsibilities of Central IRB

➢ Assume regulatory responsibility for IRB’s actions.
➢ Provide copies of IRB decisions and board rosters to investigators and local IRB.
➢ Report any serious or continuing noncompliance determinations, unanticipated problems in research, and suspension or termination of central IRB approval to governing Agency. Provide such Agency reporting documentation to local IRB.
Responsibilities Maintained at Institution

- Assess investigator qualifications prior to submission to central IRB to ensure local institution requirements are fulfilled
- Communicate any identified changes to investigator qualifications or conduct that would negatively impact subject safety or local affiliation
- Provide continuing education to investigators and appropriate research staff
- Maintain the approved FWA(s)
- Manage necessary site-specific information for inclusion in the informed consent
- Review conflicts of interest in accordance with internal policy
Responsibilities Maintained at Institution

- Assume regulatory responsibility for IRB actions of local IRB
- Ensure investigator compliance and conflicts of interest are managed in accordance with local policy
- Decide whether to participate in a study or to limit an investigator’s involvement prior to submitting to central IRB
Responsibilities Maintained at Institution

- Ensure the submission of any relevant state laws or local concerns regarding the research in the central IRB’s submission material (e.g., compensation for research-related injury, local contact information, ethical religious directives and costs of participation)

- Include the assessment of local context in the central IRB’s submission material to be considered during review of research proposals
Responsibilities to Be Shared/Negotiated Between Central IRB and Institution

- Review and approve partial or full waivers in authorization as required by HIPAA
- Ensure compliance with ethical standards and regulations in approved research
- Review and approve the research protocols for a period of no greater than one year contingent on the approval of both the central IRB and institution
- Review and approve informed consents that meet the requirements of the central IRB and institution
- Review and approve recruitment and study related materials in accordance to central IRB and institution policy
Five Things Nobody Tells You

1. Must identify primary contact at each organization and maintain frequent contact (team approach preferred)
2. Carefully define roles and responsibilities of each organization
3. Understand semantics, definitions and acronyms
4. Promote flexibility
5. Communication is Paramount
Noncompliance – failure to adhere to the research protocol, federal regulations, relevant guidelines and/or the requirements and determinations of the Board Planning, Planning, Planning

- What will be outsourced?
- Fees/Billing
- COI
- HIPAA
- Subject Issues
- Federal Reporting

- Institutional Approval
- Submission Process & Follow up
- Tracking & Reporting
- Quality Assurance
- Documentation
What Will Be Outsourced?

- Decide what will be outsourced:
  - New Studies
  - Existing Studies
  - All studies or only certain categories
    - Industry-Sponsored
    - Federal
    - Investigator-Initiated
    - Clinical Trials
    - Social-Behavioral
  - Emergency Uses, Compassionate Uses, Humanitarian Use Devices
  - Exempt Determinations
Discuss Fees and Billing Arrangements

- **Fee Schedule – Set or Negotiable?**

- **Invoicing**
  - To Institutional Office
  - To Investigator
  - To Sponsor or CRO

- **Payment Terms**
  - Upon submission
  - Prior to approval letter being issued
Noncompliance – failure to adhere to the research protocol, federal regulations, relevant guidelines and/or the requirements and determinations of the Board.

Use a spreadsheet of current research to think through which categories of studies or review types to outsource and to project anticipated volume and cost. Discuss with leadership and potential commercial IRB partners. Transparency is key to success.
Conflicts of Interest

How Will COI Work?

- COI Reporting & Determinations
  - Compare Institutional requirements, IRB requirements
  - Information sharing

- Management Plans
  - Process for sharing
  - IRB with final determination
  - Compliance monitoring

- PHS COI Compliance
Don’t Forget HIPAA

- Who will be responsible for review of waivers and alterations?
- Are authorizations incorporated into main consent or stand-alone?
- Screening for data transfer & use – BAAs, DUA, Confidentiality
- Reporting of potential breeches
- State law compliance
Subject Issues

Think about:

- Consent Form Language
  - Institutional Requirements
  - Central IRB Approval
- Advertisement and Recruitment Standards
- Contacts for
  - Subject Injuries
  - Subject Complaints
  - Compensation & Reimbursement
- Information sharing
Federal Reporting

Review Definitions and Processes for Federally Reportable Events:

- Unanticipated Problems, Serious Noncompliance, Continuing Noncompliance, Suspensions, Terminations
  - Advance Notice
  - Opportunity to Provide Additional Information
  - Opportunity to Comment
  - CAPA plan development
Institutional Approval

Process for Verification of Institutional Approval:

➢ Is there a requirement for department chair or leadership approval prior to submission?
  • Costs
  • Resources
  • Feasibility

➢ Institutional Training Requirements

➢ Other Committees – Biosafety, Radiation Safety, etc.

➢ Impacted Services – Nursing, Pharmacy, Lab, etc.
Learn about the Submission Process & Follow-up:

- How to submit (e.g. web portal)
- Forms requirements & submission standards
- Process once an item is submitted
- Response time expectations
- Action “lingo” (e.g. deferred vs. tabled vs. on hold)
- Post-approval requirements
Consider What Information You Wish to Track and Report on Locally:

- Institutional Approval
- Investigators & Study Personnel
- Study Status (Open to Enrollment, Closed to Enrollment, etc.)
- Study Closures
- Participant Summary — how many, local problems, etc.
- FDA-Regulated
- Funding Source(s) — Federal, Industry, Foundation, etc.
- Vulnerable Populations
Discuss Quality Assurance Activities:

- Who conducts random and targeted auditing?
  - Notice
  - Information-sharing
  - Who will have access to study documents and local information
- CAPA plan compliance
- COI management plan compliance
Noncompliance – failure to adhere to the research protocol, federal regulations, relevant guidelines and/or the requirements and determinations of the Board

Documentation

Once all of the decisions have been made…

- Written Agreement between Institution and IRB
- SOPs
- Investigator Guides & Instructions
- Roll-Out Plan
Noncompliance – failure to adhere to the research protocol, federal regulations, relevant guidelines and/or the requirements and determinations of the Board

Communication, Communication, Communication...

- Take the time to identify the right partner(s) and to develop a comprehensive plan
- Frequent communication is essential especially at beginning
- Ongoing communication is necessary to provide proper oversight and coordinate effort
- Schedule regular meetings to ensure this happens
- A good working RELATIONSHIP is key to success!
Contact Information

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