The AAHRPP Interview

No Fear!
Pat Ward

- Director, UMMS Office of Regulatory Affairs
  - Chaperone FDA and other inspections
- Former director of accredited IRB and IACUC systems
- Current AAHRPP site visitor
Manage AAHRPP similar to other inspections and site visits

- Know context
- Gather your thoughts
- Relax
Know the inspection/visit context

• Know the organization and its processes
  • Visit its website

• Know the site visit process and expectations
  • Itinerary, objectives, deliverables, outcomes

• Know the visitors
  • Backgrounds, perspectives
Know the AAHRPP **visit** process and expectations

- Detailed visit information provided a few weeks in advance
  - Itinerary
  - Site visitors
  - Documents to pull (rosters, minutes, protocols, ICDs, contracts, etc.)
  - Interviewees
Know the AAHRPP visit process and expectations

- Overall Visit Itinerary
  - Opening session (general organizational information)
  - Daily itinerary
  - Closing session (executive, followed by general)
    - Areas of strength and weakness
    - Specific concerns
Know the AAHRPP visit process and expectations

• Daily Itinerary
  • On-site 8-5, working lunch
  • Tightly and rigidly scheduled – be on time!
  • Document/database review
  • Interviews
  • Executive sessions (5 minutes)
  • Working dinner and evening at hotel (starting night before)
Know the AAHRPP visit process and expectations

• Site Visit Objectives – observe
  • Doing what you said you do
    • Regulatory compliance
    • AAHRPP standards (over and above regulatory de minimis)
  • Regimented (not subjective)

• Site Visitors’ Deliverable
  • Draft Report
    • Template-based
      • Key word or point

• Site Visit Outcomes – see AAHRPP website
Know the AAHRPP visit process and expectations

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The AAHRPP Interview

• Just as for other inspection or site visit interviews…
  • Take your time
  • Clarify question, if needed, before answering
  • Be honest and forthright
  • Resist the urge to expand/elaborate to fill the silence
  • Be patient, but avoid appearance of stonewalling
  • Resist the urge to speculate
  • “I don’t know, but I’d ask ___” is better than a wild guess
  • Appear well-prepared but not over-coached
The AAHRPP Interview

• AAHRPP-specific interview tips…
  • Study up on AAHRPP Tip Sheets
    • These contain those key words and points the site visitors are looking to hear
  • Don’t be rattled if interviewers cut you off or jump abruptly from one topic to another
    • They are trying to cover a lot of territory to fill in gaps for their report
  • Probe for clarification of terms that are not familiar to you
    • Different institutions can use different short-speak
      • UPIRSO vs UaP = Unanticipated problem involving risks to subjects or others
The AAHRPP Interview

- AAHRPP interview format
  - 2 interviewers + 1-5 interviewees (group interview)
  - Usually some commonality

- Investigators (without staff)
- Research staff (without investigators)
  - Drug
  - Device
  - Biomedical
  - Social/Behavioral
- HRPP/IRB – Chairs, members, director, staff, reviewers, educators, QA
- Research leader, scientific merit, central support (CTO, etc.)
- COI
- Safety, IBC, etc.
- Compliance/Audit
- Legal
- Institutional Official (IO)
Interview Topics for Research Teams

- The go-to-jail guy
- All about you (background, training, experience)
- What rules/standards followed and how do you know about them
- What education available, required, tracked
- Accepting or rejecting a study
- Scientific merit review, capacity, feasibility
Most scientists regarded the new streamlined peer-review process as “quite an improvement”.
Interview Topics for Research Teams

• Research in other countries
• Experience with community-based research
• Informing and recruiting from the community
• IRB review requirements, process, communications
• Recruitment and selection equity, strategies, incentives
• Informed consent process, documentation, effectiveness
Interview Topics for Research Teams

- Roles and responsibilities of investigators vs staff
  - Including delegation and supervision
- Disclosure and conflict of interest, including non-financial
- Investigational drugs and devices, INDs and IDEs, GCP
  - Expanded access, including emergency use
  - Sponsor-Investigators
  - Research pharmacy
Interview Topics for Research Teams

- Multi-site studies
- Data and safety monitoring plans, boards, reports
- Deviations, noncompliance, unanticipated problems, stopping rules
- Reporting obligations
- Resources to conduct study as described
Interview Topics for Research Teams

- Privacy (and confidentiality)
- How risks minimized
- Research subject input, feedback, concerns, issues
- Research team input, feedback, concerns, issues
Interview Topics for HRPP/IRB

• The go-to-jail guy
• All about you (background, training, experience, studies reviewed)
• What rules/standards followed and how do you know about them
• Institutional engagement and when IRB review required
  • Exempt studies
Interview Topics for HRPP/IRB

- What education available, required, tracked
- Records, format, and retention
- IRB rosters and member evaluation, use of consultants
- Meeting minutes
- Disclosure and conflict of interest, researchers and IRB members
  - Including non-financial
Interview Topics for HRPP/IRB

- HRPP components and interaction
- Resources, staffing, and budget decisions
- Inter-institutional agreements (including responsibilities) and review of multi-site studies
Interview Topics for HRPP/IRB

- Scientific merit review (IRB or other)
- Study document congruency (contract, protocol, ICD, etc.)
  - Research related injury
- Applicable laws here and there, support from legal counsel
- How informed of cultural differences
Interview Topics for HRPP/IRB

• Informed consent process, documentation, waiver
• Extra protections for vulnerable populations, including unable to consent for self
• Investigational drugs and devices, INDs and IDEs, GCP
  • Expanded access, including emergency use
  • Sponsor-Investigators
  • Research pharmacy
Interview Topics for HRPP/IRB

• Noncompliance definition, process, resolution, reporting
  • Serious, continuing, or non
  • Unanticipated problem
  • Suspension or termination
• Role of sponsored projects and tech transfer in IRB review
• Pressure?
• Approvals, disapprovals, and overturned decisions
Interview Topics for HRPP/IRB

- Communications and relationship with research teams
- Outreach to local community
- Experience with community-based research
- Research subject input, feedback, concerns, issues
- Research team input, feedback, concerns, issues
- Quality improvement, assurance, internal audit, corrective and preventive actions, PDCA
The Aftermath

• “Kiss and cry” room
  • Debrief questions and answers
  • Opportunity to clarify
  • Prepare for post-site visit response
Whew! What should I do now?

- Visit the AAHRPP website
  - [www.aahrpp.org](http://www.aahrpp.org)
  - Read the AAHRPP Tip Sheets and Interview Guides
    - Practice the key terms and concepts
- Visit the UM HRPP and IRB websites
  - [http://research-compliance.umich.edu/human-subjects/](http://research-compliance.umich.edu/human-subjects/)
    - Links to UM IRB sites
    - Link to UM HRPP Operations Manual (OM)
    - Link to UM AAHRPP Re-accreditation site
  - [http://my.research.umich.edu/peerrs](http://my.research.umich.edu/peerrs)
- Watch for more information
  - From HRPP, IRBMED
  - Regarding Itinerary, site visitors, etc.
AAHRPP Site Visit
Survival Kit