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 syster
- 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.)

- Grants/Contracts
- Tech Transfer
- Pharmacy

- 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

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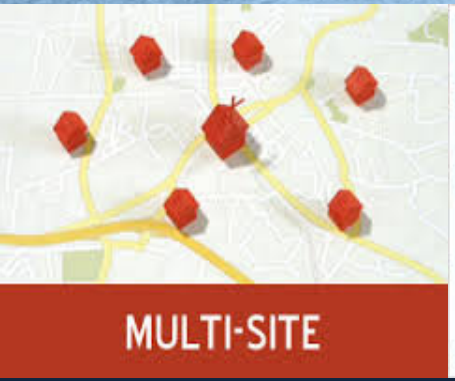
Interview Topics for Research Teams

- 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

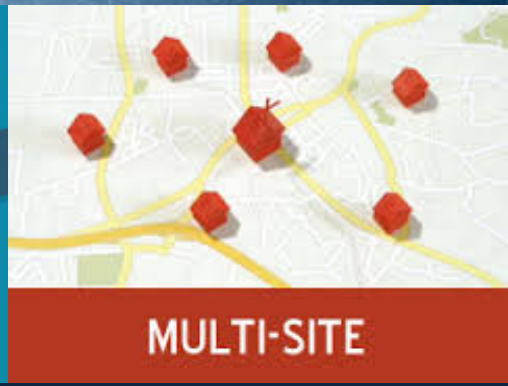
- The go-to-jail guy
- All about you (background, training, experience, studies reviewed)
- What rules/standards followed and how do you know about them
- Institutional engagement and when IRB review required
    - Exempt studies

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

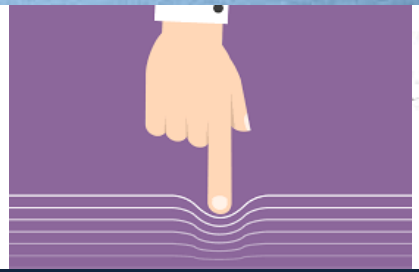
- Scientific merit review (IRB or other)
- Study document congruency (contract, protocol, ICD, etc.)
    - Research related injury
- Applicable laws here and there, support from legal counsel
- How informed of cultural differences

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
  - 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/
    - 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
- Watch for more information
  - From HRPP, IRBMED
  - Regarding Itinerary, site visitors, etc.


AAHRPP Site Visit
Survival Kit