Post Approval Monitoring in Challenging Times

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Disclaimer

- No right answer
- No required approach
- Different approaches successfully used at various institutions
- Goal is to identify areas of consideration

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To Have or Not to Have a Dedicated PAM Program?

- Regulations include language such as "providing assurance that institutions will comply with the requirements set forth," "ensuring prompt reporting of any proposed changes"……
- Some federal guidance provides clarification on this point "Monitoring of animal care and use is required, though neither the PHS Policy nor the *Guide* explicitly address or require specific or separate post approval monitoring (PAM) procedures to compare the practices described in approved protocols and SOPs against the manner in which they are actually conducted."

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To Have or Not to Have a Dedicated PAM Program?

- Some of the choices:
  - dedicated PAM
  - part of the compliance committee's responsibilities
  - monitoring committee (e.g., sub of full committee)

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What we did……

- Compliance committees' work load was already significant
- Benefits of a PAM from our perspective include:
  - Review of individual studies
  - Verification of no material changes since approval
  - Significantly more studies could be reviewed
  - One-on-one educational resource
  - Assistance in identifying trends
  - Assistance to investigators in preparation for audits from granting, regulatory and accreditation agencies

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What to Include in the Program? It Depends!

- Everything – humans, animals, biosafety, select agent, radiation safety, RCR education, conflict of interest, grants and contracts, chemicals, occupational medicine, clinical research, material transfers
- One or two areas of research
- Areas of research presenting more institutional risk
- Availability of funding

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ISU's PAM Includes

- Research and teaching involving live vertebrate animals and humans
- Excludes conflict of interest, RCR, misconduct
- Excludes radiation safety and biological audits
- Decision driven by funding, avoiding duplication of effort, and volume of studies

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Potential Homes for the PAM Program?

- Report to the President, Institutional Official, a compliance committee, a compliance office
- Existing structure (e.g., do you have a compliance office)
- Location of PAMs in your peer institutions

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Where it Resides at ISU

- Reports to the Director of Responsible Research
- Rationale:
  - Monitor may review committee functions and therefore should be separate from the committees
  - We have a compliance office designed using the COGR document "Managing Externally Funded Programs at Colleges and University - Guidelines to Good Management Practices,"
  - Director reports directly to the IO
  - Peer institutions had similar organizational charts

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Should the Monitor be Member of a Compliance Committee?

- Not prohibited by the regulations.
- Our monitor is not a member because we felt:
  - Can better serve as a communication channel between research staff
  - More easily accepted
  - Avoid potential to put the monitor in an awkward situation regarding objectivity

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Implementation Options

- Announce the program and conduct audits
- Implement without announcements
- Implement following approval from IO, committees
- Use a "market plan"

We Chose

- The "market plan"
- The plan involved:
  - Meetings with Faculty Senate Research Committee
  - Presentations to Vice President's Research Council
  - Meetings with Dean's Cabinets
  - Announcements in our newsletter
  - One-on-one introductory visits with investigators
  - Letters of introduction to all investigators
- The reaction from investigators has been positive

The Approach for the Visits

- Choices –
  - the cops
  - "internal audit" approach where audit is conducted, findings presented and plan to correct findings is submitted by the investigator
  - educational
  - educational with goal of documenting compliance

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Educational/Documentation Approach at ISU

- First is educational - no written report
- Subsequent visits documented
- Report shared with PI for review of content and accuracy of facts
- Final report submitted to Director
  - Goal is to have all concerns addressed before final disposition
- Committees updated on finding and progress at aggregate level whenever possible
- Follow-up and support includes assisting with modifications, identifying resources and training

Additional note – the monitor generally does not participate in compliance investigations

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What Should Be Reviewed During a PAM Visit?

It DEPENDS – ☺

On the focus of your program.

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What is Reviewed At ISU

- IACUC
  - Protocol and Personnel
  - Study Procedures
  - Anesthesia
  - Surgery
  - Post-surgical care
  - Euthanasia
  - Recording Keeping
  - More as needed
- IRB
  - Protocol and Personnel
  - Study Procedures
  - Recruitment Process
  - Informed Consent
  - Study Records and Documentation
  - Subject Payments
  - More as needed

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How PAM Visits are Determined

- Not possible at ISU to annually review every study
- Studies presenting higher risk have priority
- All active protocols
- Random selection
- PI Requested

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What the PAM is NOT!

- Not the "cops"
- Not a replacement for the IACUC/IRB
- Not responsible for maintaining compliance for investigators
- Not a repeat of information provided by committees

Our mantra….. "Trust, but verify, and treat everyone with respect"

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Questions?