Track 2: Committees

Session 1: Committee Review: A How-To Guide
Session Presenters

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The opinions expressed are those of the presenters and may not necessarily reflect Montana State University.
Session Goals

1. Promote strong research using Compliance Committees
2. Empower and support researchers
3. Provide an environment for research rigor WITH room for innovation
4. Entrust your Program Managers as facilitating cog
AACUC: How to Remodel and Transition Compliance Committee Oversight

The Why?

• Provides structure for continuous quality improvement

• Promote “engagement” and cooperation between research compliance office and research community

• Helps ensure research integrity, innovation and high quality outcomes
The How

- Plan Carefully
- Be Transparent & Create Communication Roadmap
- Provide Training
- Invite Participation
- Don't Expect Immediate Change
- Monitor and Measure
- Model and Build on Strong Leadership
Research Compliance Committee
Building Blocks

Institutional Support
Chair
Committee Members

Administrators, Coordinators, and Program Managers
Protocols
Committee Review
Institutional Support

- President
- Vice President
- Institutional Official
- Director
- Legal Counsel

- The 10K Why
- Risk Assessment
- Credibility
- Public Relations
Chair

• Spokesperson
• Teammate
• Compensated when possible
Committee Members

- Interest
- Time
- Availability
- Rising Star
- Prior engagement/interaction
Onboarding
New Members
Member Engagement

Volunteer Burdens
- Attendance
- Time
- Technology

Committee “Perks”
- Involvement in Process
- Topical Training
- Recognition
- Meals
Research Compliance Committee
Building Blocks

Institutional Support
Chair
Committee Members

Administrators, Coordinators, and Program Managers
Protocols
Committee Review
Administrators, Coordinators, and Program Managers

- Program Managers = Point person and center of supporting committee mission and operations
- Must possess a broad skill set and prioritize communication, problem solving and anticipate serving multiple roles and responsibilities at any given time
Program Managers – the Juggling Act
No need to reinvent the wheel
Protocol Systems

- Paper
- Electronic Document Management
- Databases
Protocol Application Forms

### Animal Protocols

- Open Active Forms
- Save

### Biosafety Protocols

- Open Active Forms
- Save
- Activate
- Deactivate

### Human Protocols

- Open Active Forms
- Save

Outline:

**Animal Protocols**

1. Protocol Information
2. Funding Information
3. Study Objectives
4. Alternatives/3 Rs
5. Aversive Stimuli
6. Food/Fluid Restriction
7. Experimental Agents
8. Guard Animals
9. Species Information

**Biosafety Protocols**

1. Protocol Information
2. Personnel
3. Funding Information
4. Microorganisms/Infectious Materials
5. Biological Toxins
6. Recombinant/Synthetic Nucleic Acid Molecules
7. Human and Non-Human Primate Material
8. Animal Research
9. Plant Research
10. Biosafety Operating Procedures

**Human Protocols**

1. Protocol Information
2. Additional Personnel
3. Funding Information
4. Conflict of Interest
5. Research Activities
6. Subjects
7. Recruitment
8. Compensation
9. Risks
The Research Protocol: Proposal Questions & Constraints

- Understanding function and format of research proposals is key.
- Questions should be designed to garner the necessary information from applicants.
- Questions and proposal language and structure should evolve as needed.
Form Instructions

Be sure to list information only once in the section it belongs. **SAVE AFTER EVERY SECTION IS COMPLETED** as form does NOT auto-save.

All required questions are marked with a **red asterisk** *.
6.3

**Rationale and Purpose**

Explain in lay terms the rationale and purpose of the research. What research question is being asked?
Committee Review Flow

PI submits protocol for review → Submission administratively reviewed by office staff for completeness → Submission assigned to Admin or Veterinary Review (7 day timeline) → Submission may require modification → Requires RFM modification to secure approval → Approved w/o modification

Submission returned to PI for revision & resubmission → Process continues until AACUC requirements to secure approval are met → Revisions are returned to AACUC for review → Requirements for approval met → Submission is approved
Group Guidelines

• Stories stay, lessons leave
• Make sure everyone is heard in your small group discussions
  • Limit your comments to a couple of sentences so that you don’t dominate the discussion.
  • Three and me principle where you allow three people to speak before you speak again.
• Speak with the expectation you will be heard and listen with the opportunity to be changed.
• Use “I” statements so that you are speaking from your personal experience.
• Take risks and expect discomfort: We ask that you contribute to discussions and exercises by sharing your thoughts, feelings, and experiences. Sometimes this may involve personal discomfort and risk taking. It is up to you the degree of risk or disclosure you make.
Process Flow Activity

1. Plot out current process flow using paper and sticky notes.
2. Identify hurdles or challenges
3. Find a partner/group to share with
Committee Review Flow

1. PI submits protocol for review
2. Submission administratively reviewed by office staff for completeness
3. Submission assigned to Admin or Veterinary Review (7 day timeline)
4. Requires RFM modification to secure approval
5. Submission may require modification
6. Approved w/o modification
7. Process continues until AACUC requirements to secure approval are met
8. Revisions are returned to AACUC for review
9. Submission is approved
10. Requirements for approval met

AACUC Approval Process

PI Action

AACUC Action
Process Flow Discussion

1. Share

2. What areas are currently challenging?

3. Ideas or changes that have worked?
Research Compliance Committee
Building Blocks

- Institutional Support
- Chair
- Committee Members
- Administrators, Coordinators, and Program Managers
- Protocols
- Committee Review
Key Takeaways

1. Promote strong research using Compliance Committees
2. Empower and support researchers
3. Provide an environment for research rigor WITH room for innovation
4. Entrust your Program Managers as facilitating cog