

Track 2: Committees

Session 1: Committee Review: A How-To Guide

**Agricultural Animal Care
& Use Committee
(AACUC)**



**Institutional Animal
Care and Use
Committee (IACUC)**



**Institutional Review
Board (IRB)**



**Institutional
Biosafety
Committee (IBC)**



**Conflict of
Interest**



LASER Safety



RAM Safety



Session Presenters

Animal Care
and Use
(AACUC &
IACUC)



Diane Dorgan
AACUC Program Manager

Human Subject
Research (IRB)



Kelly Beiswanger
IRB Administrator & Program Manager

Disclaimer

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

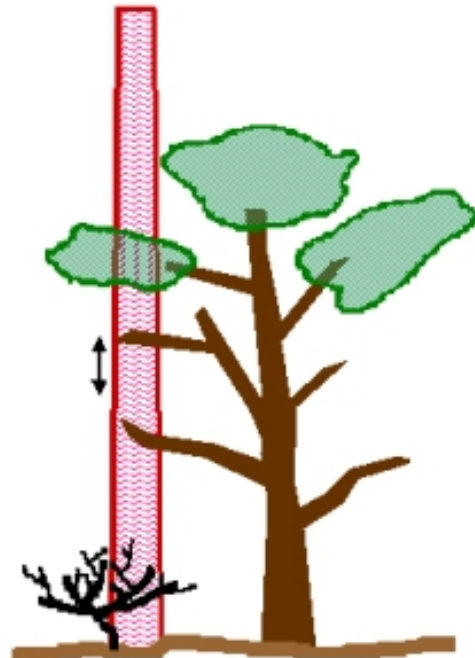
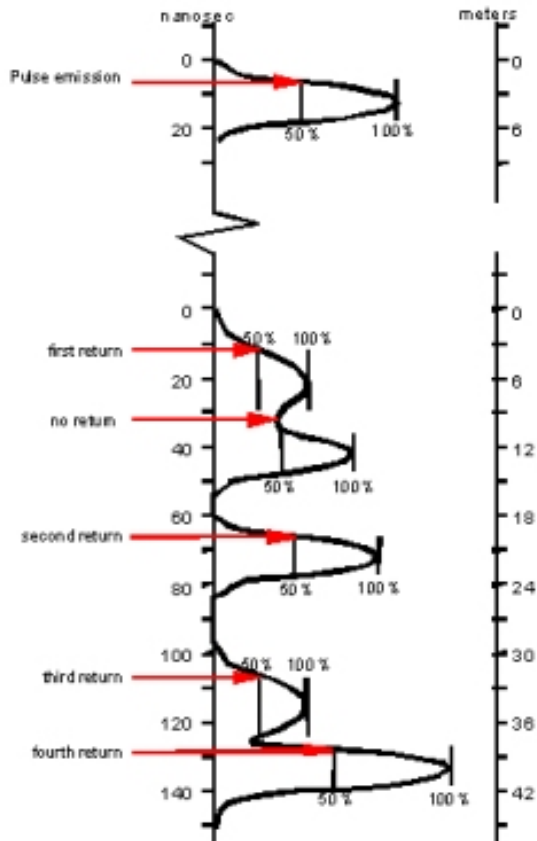
Change is hard at first,
messy in the middle and
gorgeous at the end.

- Robin Sharma



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

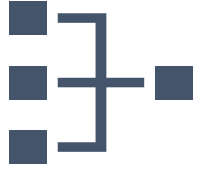


Protocols



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

Committee "Perks"

Attendance

Time

Technology

Involvement in Process

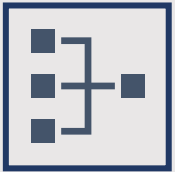
Topical Training

Recognition

Meals



Research Compliance Committee Building Blocks



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Chair



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Administrators,
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Protocols



Committee Review





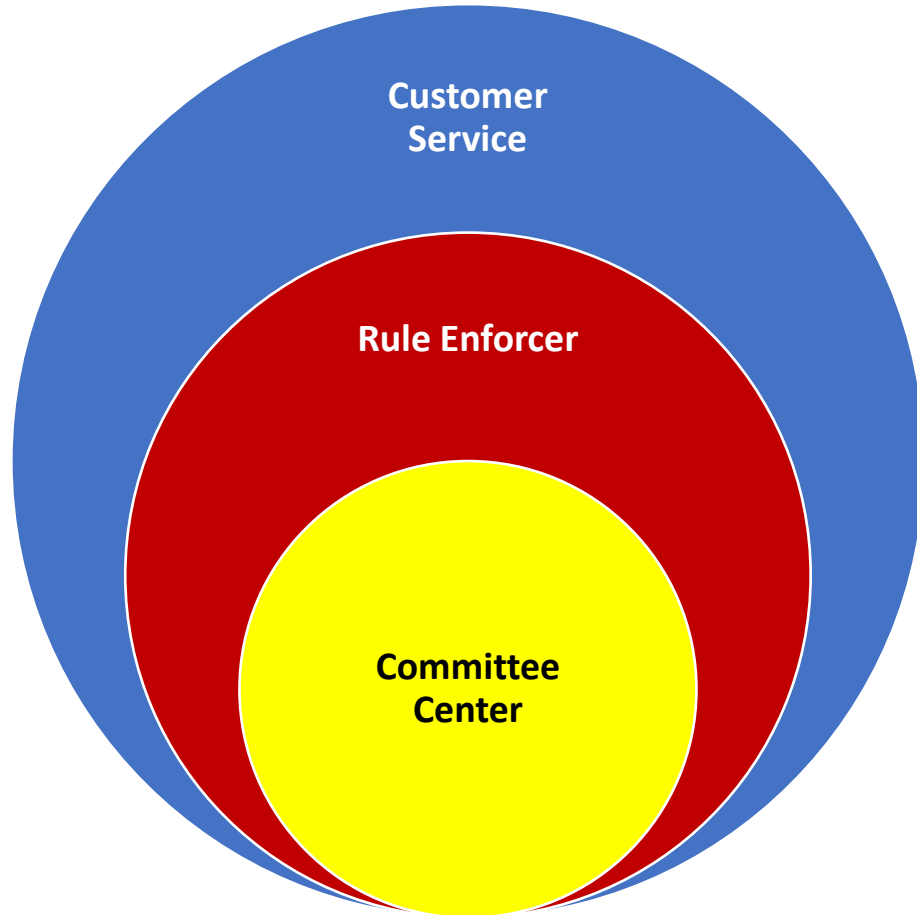
Administrators, Coordinators, and Program Managers

- 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



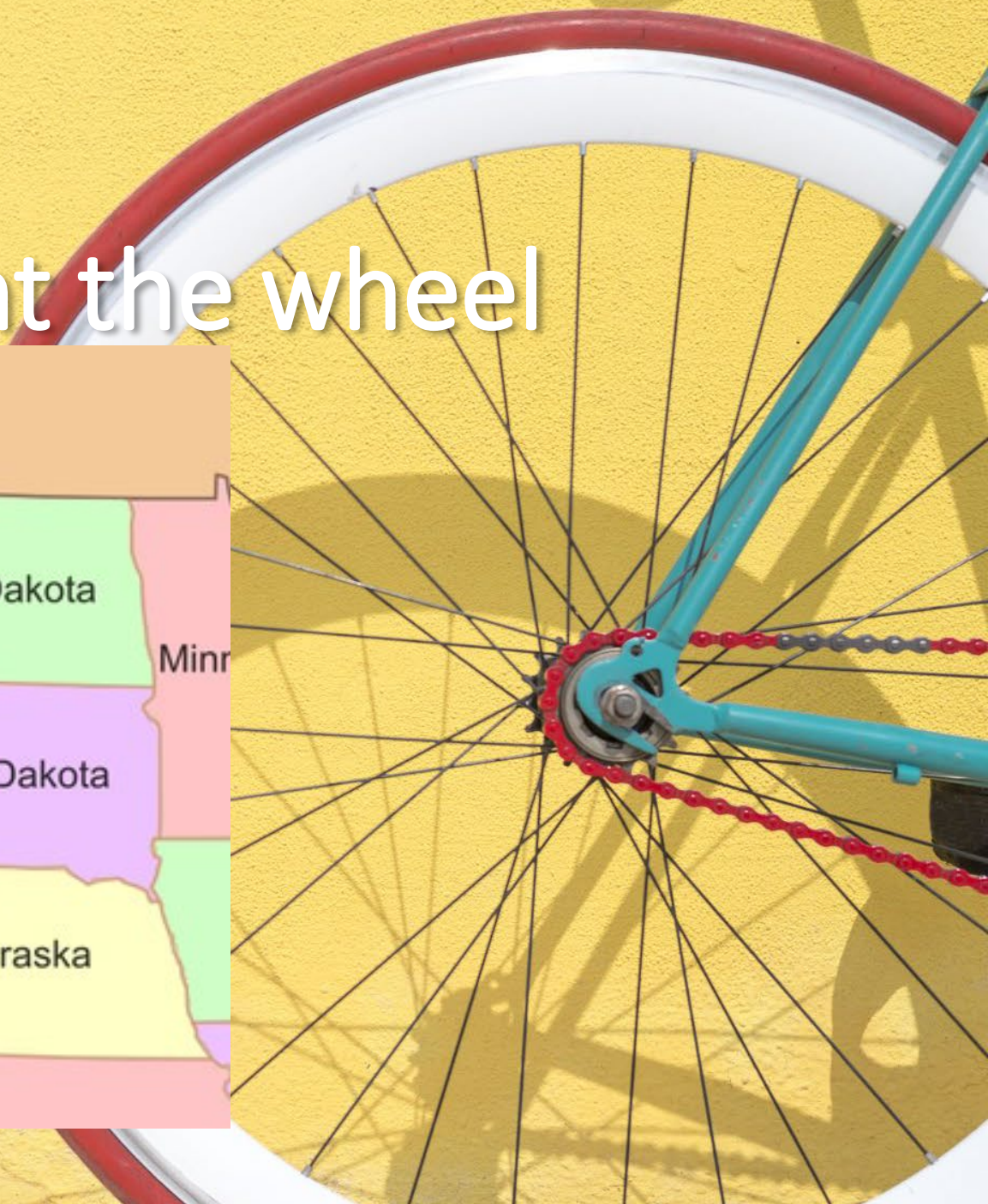


Program Managers – the Juggling Act





No need to reinvent the wheel





American Association
for Laboratory Animal Science



ABSA
INTERNATIONAL
The Association for Biosafety and Biosecurity



BIOSAFETY
Administrators Association

National Institutes of Health
Office of Biotechnology Activities

IAA The IACUC
Administrators
Association

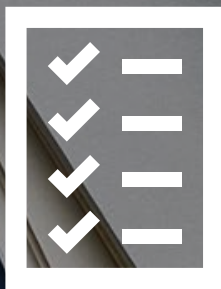
OHRP

Office for Human
Research Protections

PRIM&R

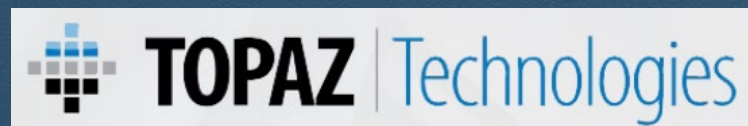
PUBLIC RESPONSIBILITY IN
MEDICINE AND RESEARCH

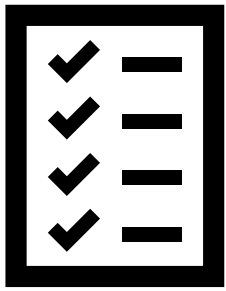





- Paper
- Electronic Document Management
- Databases


Protocol Systems





Protocol Application Forms



 **Animal Protocols**




Open Active Forms  Save

Outline




Quick Finder

- + 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** 


Open Active Forms  Save  Activate  Deactivate

Outline

Quick Finder    1.2

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

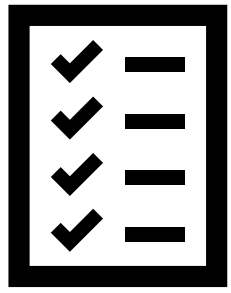
 **Human Protocols**

Open Active Forms  Save

Outline

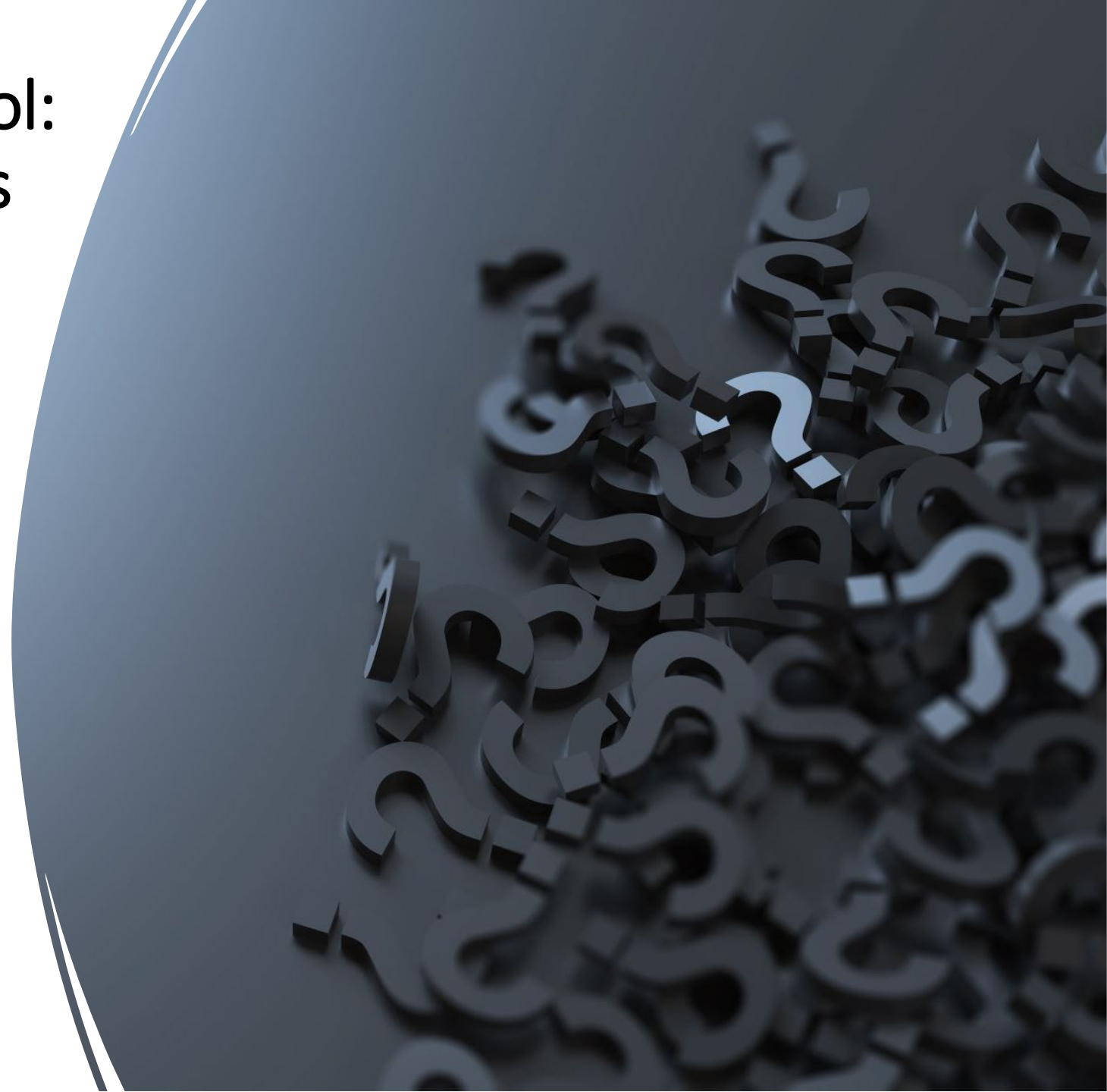
Quick Finder

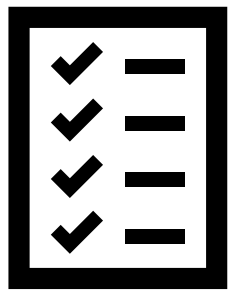
- + 1 Protocol Information
- + 2 Additional Personnel
- + 3 Funding Information
- + 4 Conflict of Interest
- + 5 Research Activities
- + 6 Subjects
- + 7 Recruitment
- + 8 Compensation
- + 9 Risks



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.





Protocol Application Examples

IRB Exempt Research Form

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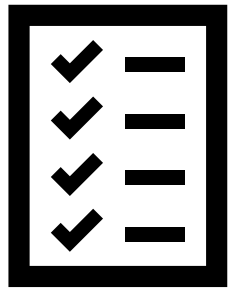
Select this form for Exempt level review.

1.13

Form Instructions

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

All required questions are marked with a red asterisk *.



Protocol Application Examples

6.3

Rationale and Purpose

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

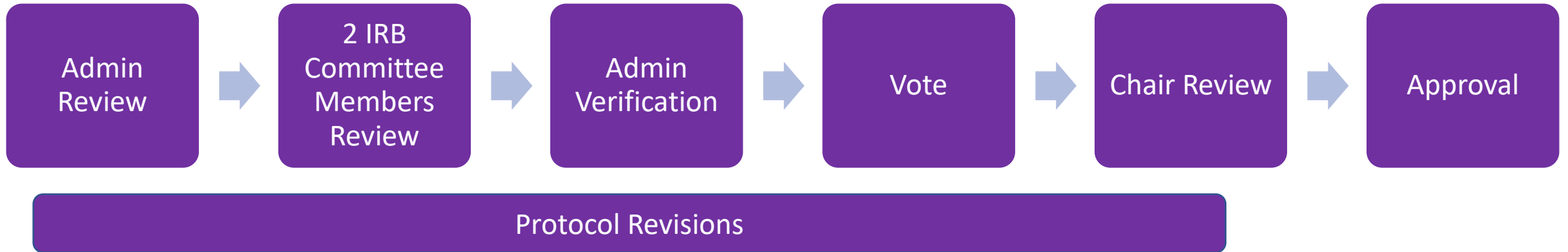


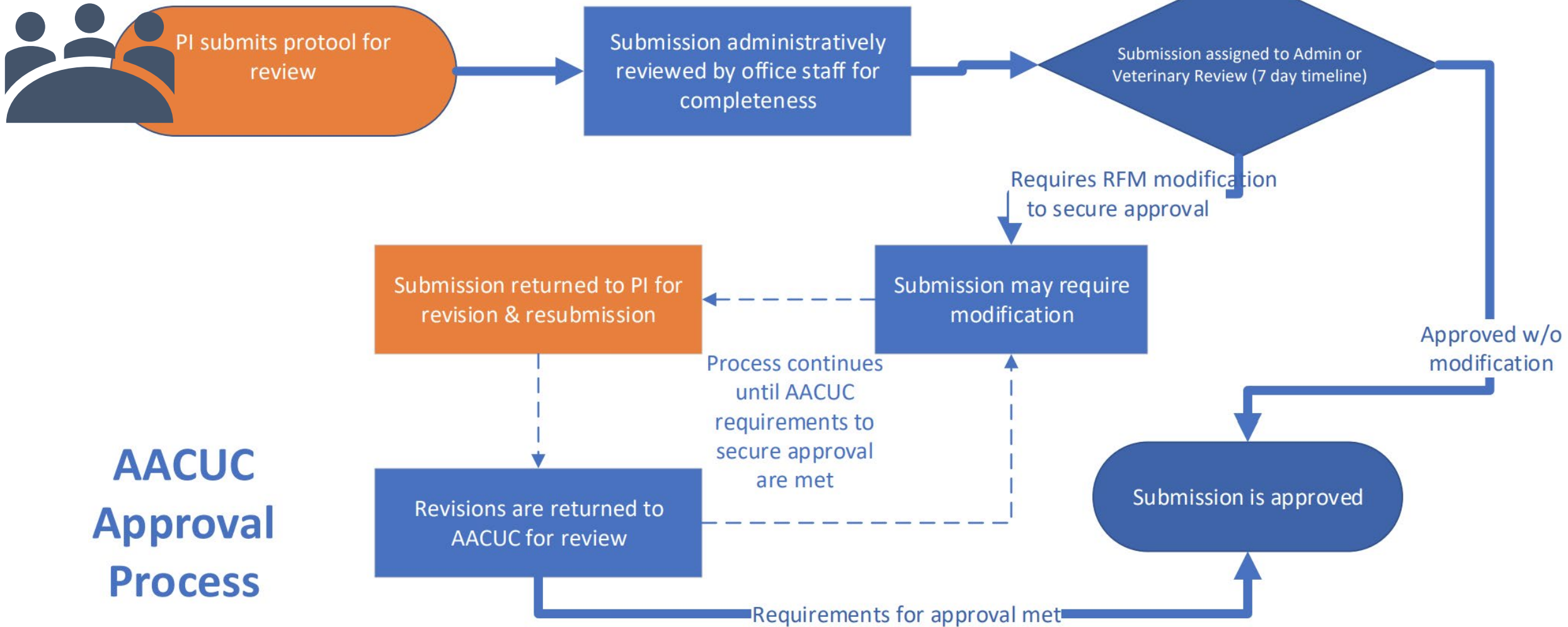
Committee Review





Expedited Level Submission





AACUC Approval Process



Committee Review Flow



Group Guidelines

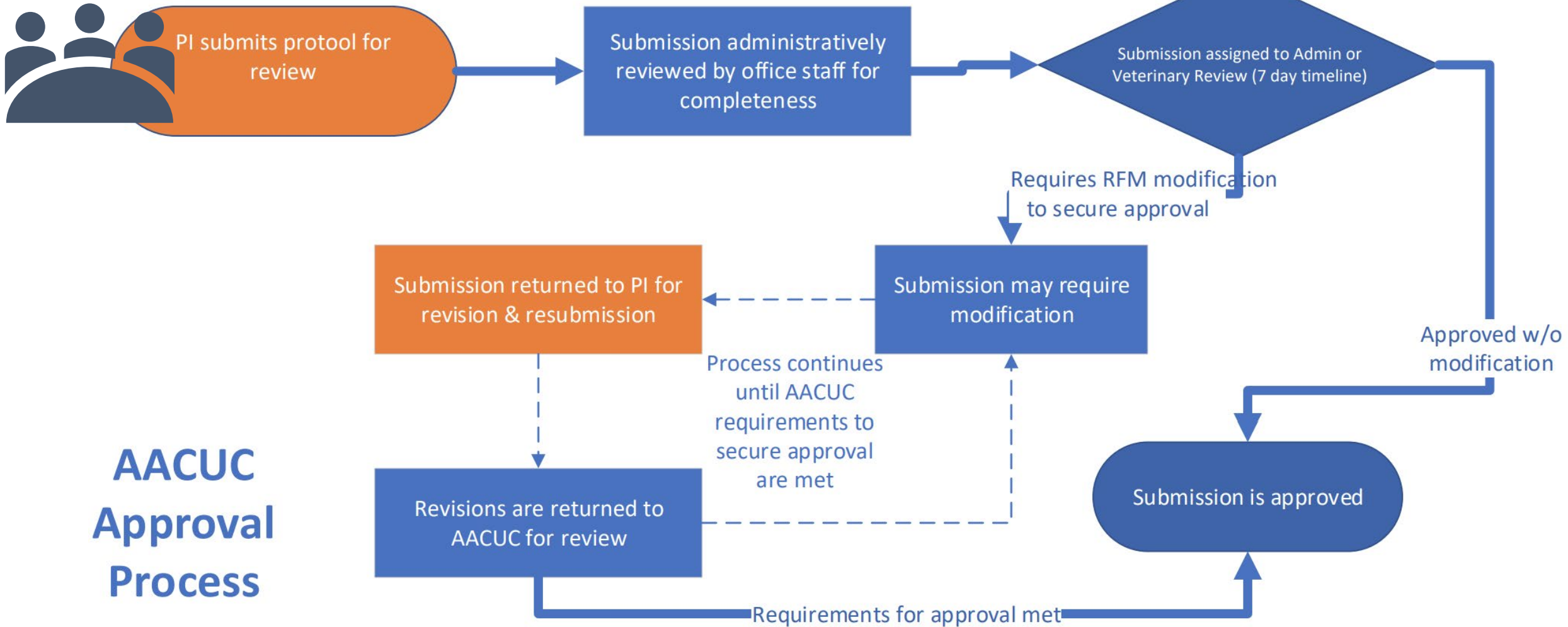


- Stories stay, lessons leave
- Make sure everyone is heard in your small group discussions
 - Limit your comments to a couple of sentences so that you don't dominate the discussion.
 - Three and me principle where you allow three people to speak before you speak again.
- Speak with the expectation you 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**



AACUC Approval Process



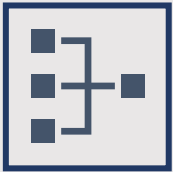
Committee Review Flow



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



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Protocols



Committee Review



Key Takeaways

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