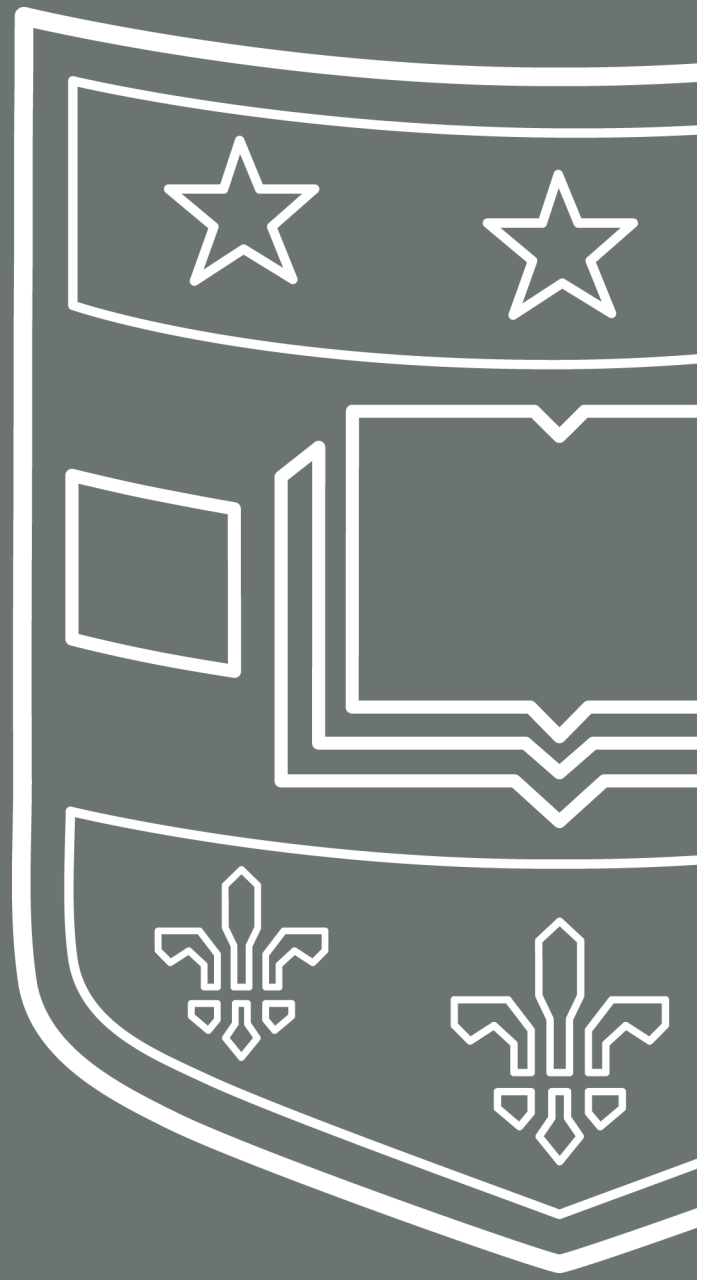
Why Does My Protocol Take So Long to Be Approved?

Understanding the Protocol Review Process and Tips to Expedite



Washington University in St. Louis

Welcome to the IACUC Brown Bag

- Why do I need a Protocol?
- Types of Reviews
- The Process
- Speed Bumps
- Speed Bump Removal Tips
- Direct Questions to Chat Feature

Why the Protocol Requirement?

- Animals are utilized for research, training, or testing is conducted under authority or directive of the university, regardless of funding sources

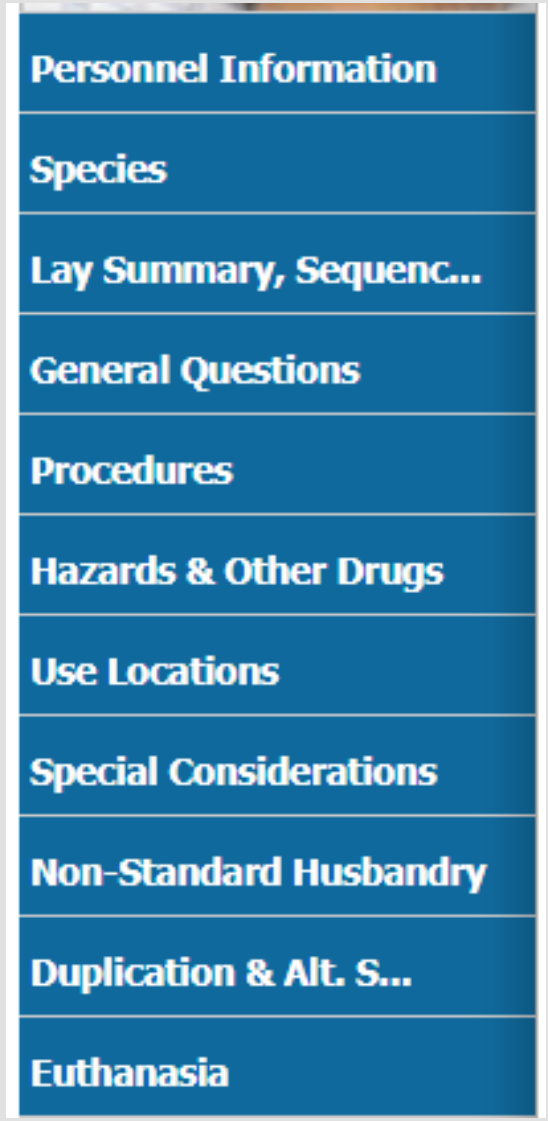
- IACUC review and approve animal use

What does the IACUC look for in the Protocol?

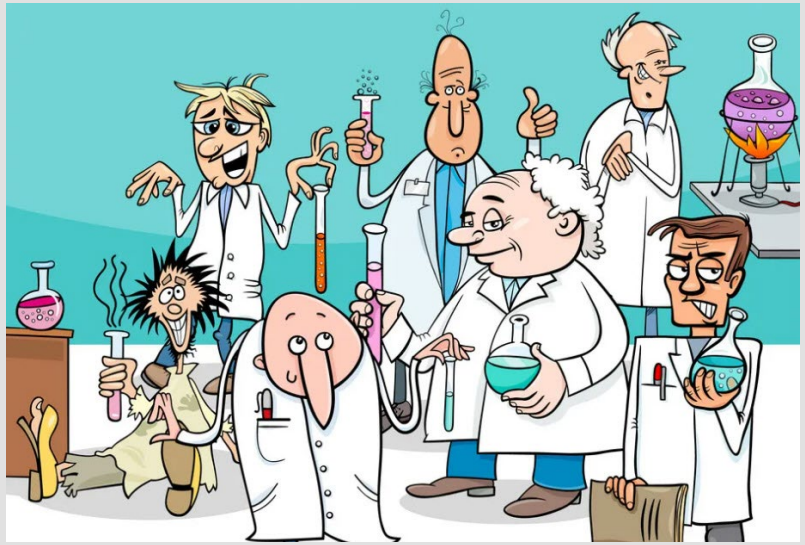
- IACUC looks to ensure that the protocol is consistent with Washington University policy and upholds the highest animal welfare standards
  - Animal Welfare Act
  - Public Health Policy
  - *Guide for the Care and Use of Laboratory Animals*

Some of the Specific Stuff

- Justification and rationale for proposed animal use and numbers
- Training and experience of personnel performing procedures
- Detailed descriptions of procedures
- Appropriate perioperative care
- Search for alternatives
- Clear endpoints and humane methods of euthanasia
- Consider the impact to the animals' well-being vs scientific benefit



Who are these Reviewer People?



WASH U FACULTY

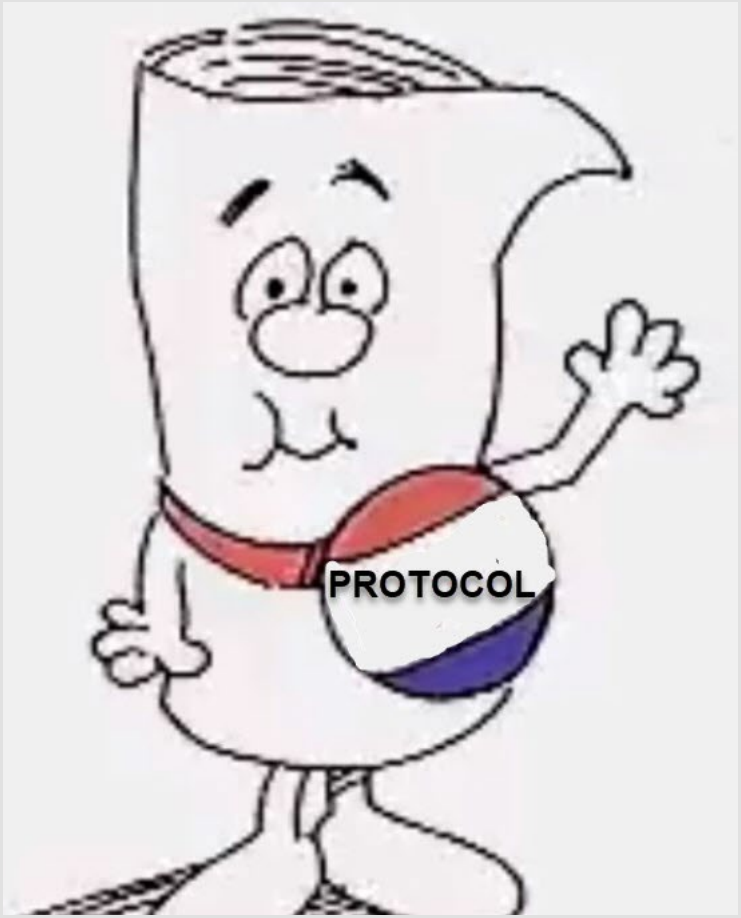
NON-AFFILIATED MEMBERS

DCM VETERINARIANS

IACUC STAFF

The Reviews we can do for you

- Administrative
- Veterinary Verification and Consultation (VVC)
- Designated Member Review
- Full Committee Review



Administrative Review

- Personnel Changes
  - Non-USDA covered personnel
  - Non-PI changes
- Existing Use Location Changes
- Funding Changes
- Numbers Increase
  - Non-USDA covered species
  - 30% increase limit
  - One-Time

IACUC STAFF

Veterinary Verification and Consultation(VVC)

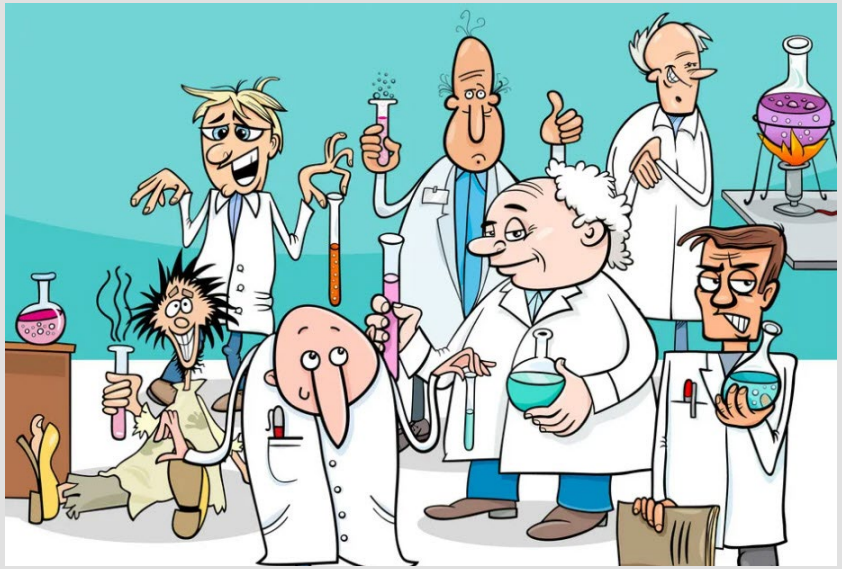
- Anesthesia, analgesia, or sedation, related changes
- USDA Covered Species Administrative Changes
- Experimental substance administration route changes and concentrations
- Duration, frequency, type of procedural changes as described in the policy
- Euthanasia Methods

DCM VETERINARIANS

The Committee Reviews

- Designated Member Review (DMR)
  - New Protocols
  - Renewals
  - Any non-administrative or VVC amendments

- Full Committee Review (FCR)
  - Asked for by any committee member



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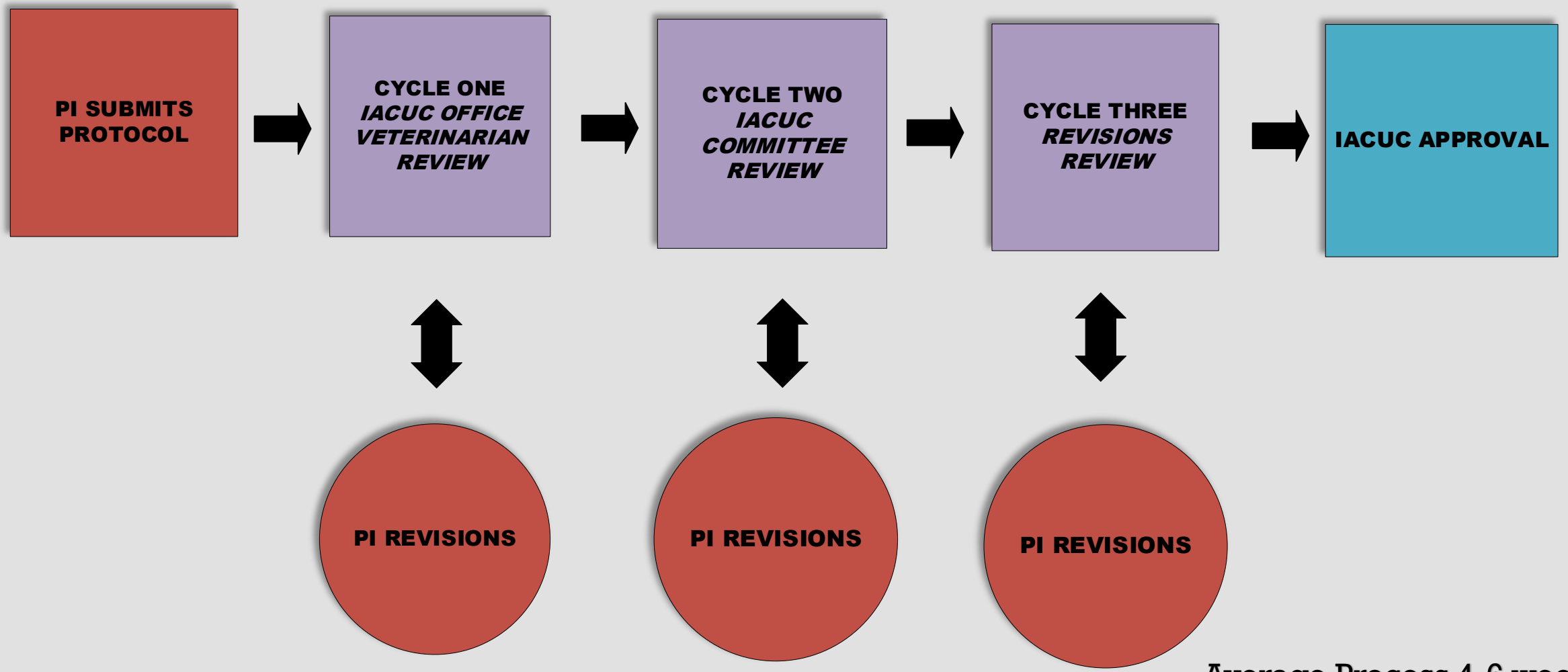
NON-AFFILIATED MEMBERS

The DMR Process



Average Process 4-6 weeks

Cycle One-Administrative and Veterinarian Review

- IACUC Office Staff
  - Completeness
  - Training Requirements
- Veterinarian Review
  - Proper Procedure Descriptions
  - Pain Intervention
  - Endpoint Criteria
  - Drug Appropriateness and Dosages

Training Requirements Incomplete
Emergency Contacts
Personnel Experience Section
Hazards Not Approved
Alternative Search Update

Improper Drug Dosages
Incomplete Perioperative Care
Missed Procedural Tabs

Cycle 2- Designated Member Review (DMR)

- Option for to call For FCR
- Primary Reviewers
  - Ask for Revisions
  - Can approve
- Secondary Reviewers
  - Ask for Revisions
  - Call for FCR

Flow Chart Not Updated
Incomplete Fields
Undefined Endpoints
Plan Clarity
Number Incongruities

Cycle 3- Addressing Member Comments

- Committee Member Review
  - More Comments
  - Recommend Approval
  - Office Approval and Letter

Not Actually Updating
Clarifications
The PI Response Time

- PI Response
  - Address Committee Comments
  - Consultation call the IACUC

Full Committee Review (FCR)

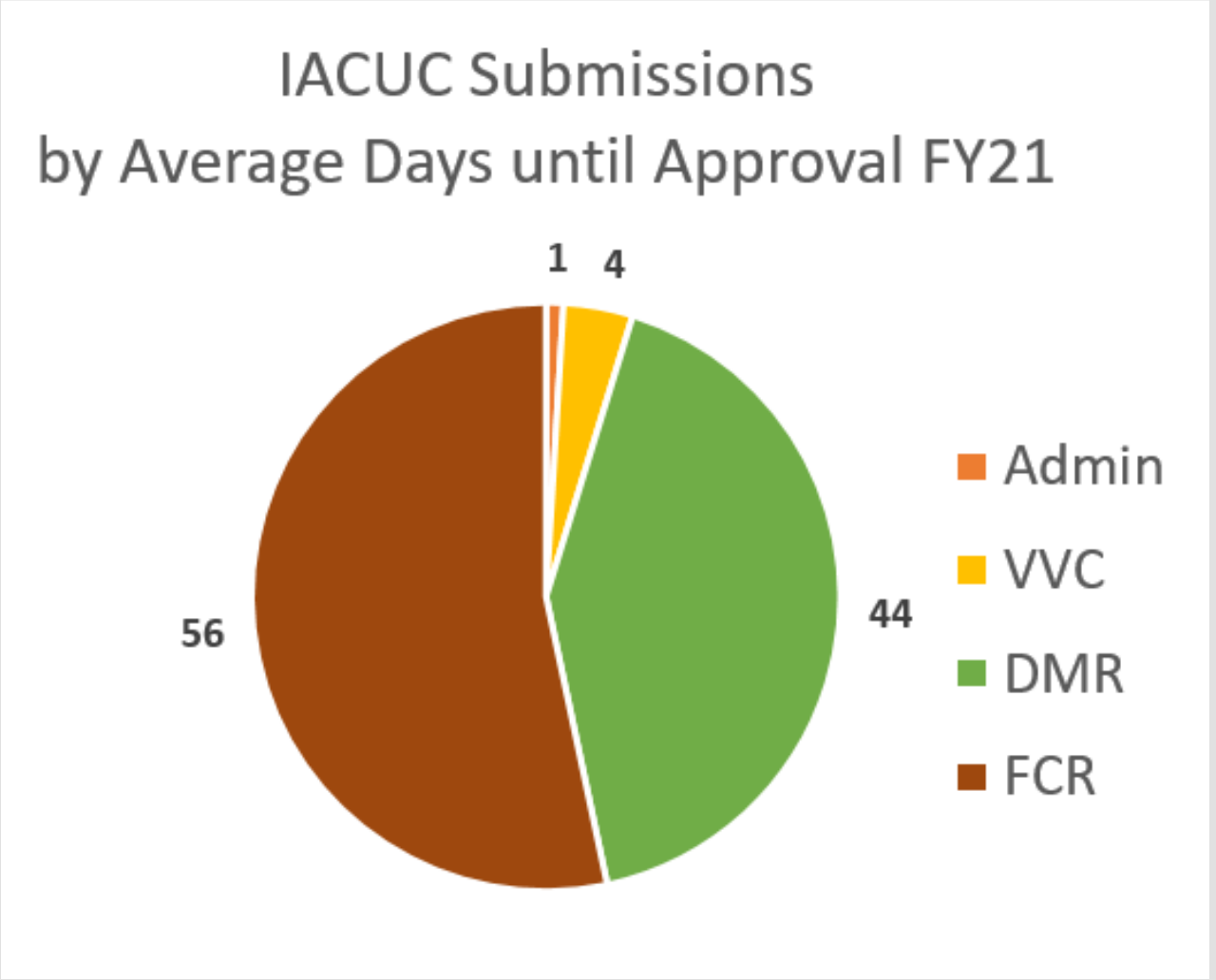
- Full Committee Review (FCR)
  - Meets Monthly
  - Multiple survival surgeries
  - Novel experimental models
  - Death as an end point
  - Animal welfare concerns

Just a Little Bit Longer…

- Department of Defense (DOD) Funding
  - ACURO Review
- Institutional Biological and Chemical (IBC) Safety Committee
  - Meets Monthly

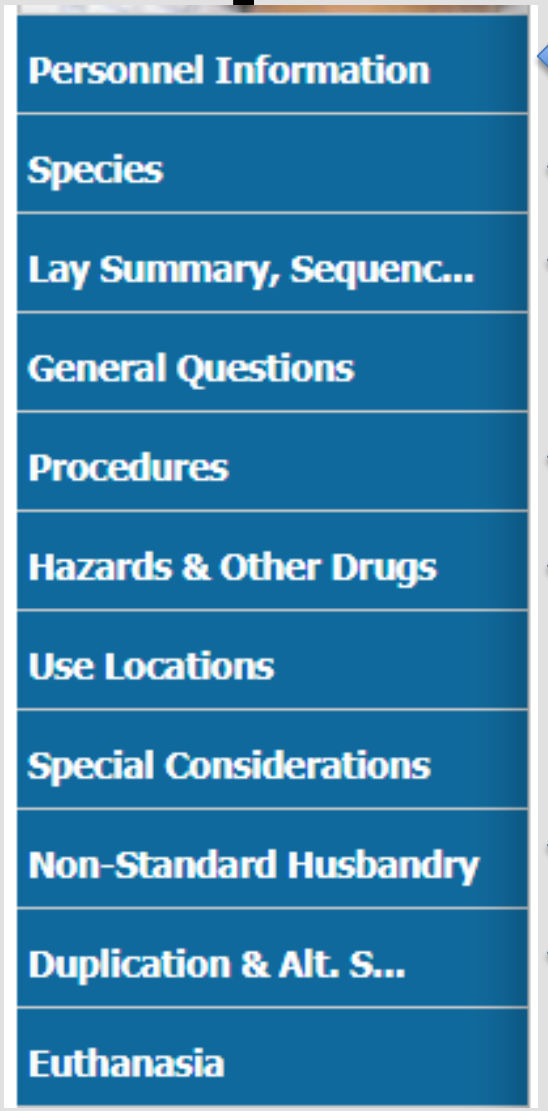
IACUC Speedbumps

- Submission Volume
  - Fiscal Year 20-1514
  - Fiscal Year 21-1978
- LAMPS
- Member Conflicts



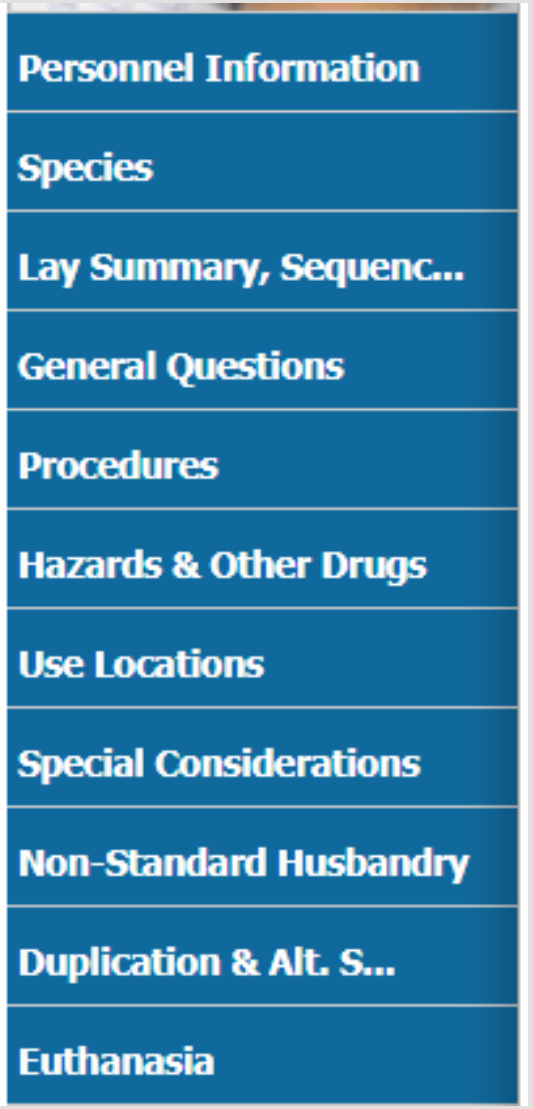
Protocol APPROVAL!!!

Amendment Example: Dr. PI is adding a new behavioral procedure with experimental drug X



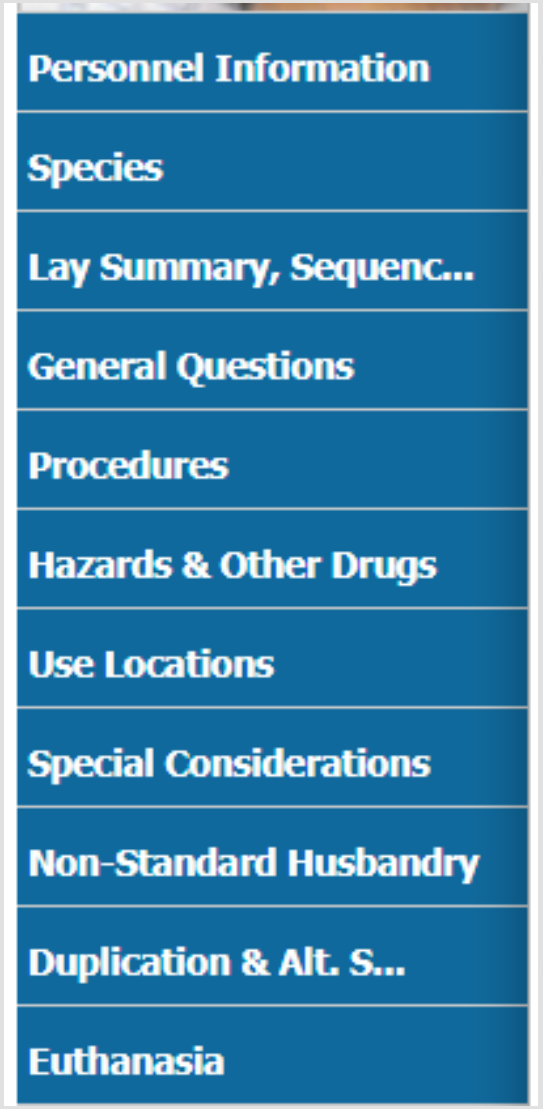
- Personnel Information ← Personnel Training Review
- Species ← Increase in Animal Numbers
- Lay Summary, Sequenc... ← Flow Chart Update and Numbers Justification
- General Questions
- Procedures ← Procedure Addition
- Hazards & Other Drugs ← Drug X addition and Possible IBC Amendment
- Use Locations
- Special Considerations
- Non-Standard Husbandry ← Possible new housing for Behavioral Studies
- Duplication & Alt. S... ← Update for any New Pain Class D or E Procedures
- Euthanasia

Amendment Example: Dr. PI is adding a new collaborator and High Fat Diet



- **Personnel Training Review**
- **Increase in Animal Numbers**
- **Flow Chart Update and Numbers Justification**
- **Addition of Collaborator and Activities**
- **Addition of Collaborator Procedure**
- **New Collaborator Location if outside DCM Facilities**
- **Description of new diet feeding regimen**

Amendment Example: Dr. PI is adding a new survival surgery



- Personnel Training Review
- Increase in Animal Numbers
- Flow Chart Update and Numbers Justification
- Addition and Description of Surgical Procedure
- New Alternative Search for Pain Category D

Protocol Check List for Speed Bump Reductions

- Plan Ahead
- Know the Fields and Up Front Assistance
- Training and IBC
- Be Descriptive in Amendment Field
- Need additional animals?
- Check for Completeness
- Ask the IACUC

Help Wanted

- Your Input
  - Suggestions
  - Outreach
  - What's working and What's not
- Your Time
  - Sign up today!
  - Interested?
  - Contact Allison Overmyer or Dr. John Cirrito

Helping you… The IACUC Resources

- **Web Site:** Find policy answers and forms at the IACUC website https://research.wustl.edu/topics/animal-care-use/
- **Call or Email:** Staff happy to answer questions and direct you to resources iacuc@wustl.edu 314-362-3229
- **IACUC Training Coordinator-** Nicholas Benshoff benshoffn@wustl.edu
- **Newsletter:** Keeping you updated on changing policy and events

Thank you! Any Questions?