

Semiannual Program Review

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It's semiannual time!

- Again?... Already?... Really?....
- Didn't we just do that?



Overview – Program Review

- Requirements
- Define the "Program"
- Mechanisms for review
- Semiannual Report

Semi-annuals: Responsibility?



Requirements For Semiannuals

AWA/AWR's & PHS Policy –

- "Review, at least once every six months the research facility's program for humane care and use of animals....."
- "Inspect at least once every six months, all of the animal facilities, including study areas (satellite facilities)....." (study area > 12 hrs, satellite facilities >24 hrs)
- Use the AWR's and Guide as basis for evaluation

(at least 2 people; can't exclude a member who wants to participate)

Other reasons to do semiannuals

- IACUC has an obligation to provide program oversight (of everything related to animal use)
- "Management by walking around...."
- Keeps the IACUC in touch
- Assess "protocols in action"
- PAM



Program Review

• What is the "program"?

- ".....the policies, procedures, standards, organizational structure, staffing, facilities, and human resources that have a direct effect on the quality and safety of the program" (IACUC Guide - pg.11)

Everything related to animals.....



Animal Care & Use Program

- Regulations, Policies, and Principles
- Program Management/ Responsibility
 - The Institutional Official
 - The Attending Veterinarian
 - The Institutional Animal Care and Use Committee
 - Collaborations
- Personnel Management
 - Training and Education
 - Occupational Health and Safety of Personnel
 - Personnel Security
 - Investigating and Reporting Animal Welfare Concerns
- Program Oversight
 - The Role of the IACUC
 - IACUC Constitution and Function
 - Protocol Review
 - Special Considerations for IACUC Review
- Postapproval Monitoring
- Disaster Planning and Emergency Preparedness
- Program of Veterinary Care - Guide chapter 4
- + any "trend" issues identified on facility inspections

Animal Care & Use Program

- Regulations, Policies, and Principles
 - Animal Welfare Act/Regulations
 - PHS Policy
 - Guide
 - Institutional Policies (IACUC Policies)
 - US Government Principles

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Animal Care & Use Program

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Required Elements of Protocol Review

- Rationale and purpose of proposed use of animals
- Clear, concise, sequential description of procedures
- Availability of alternatives
- Justification for species and number of animals requested
- Unnecessary duplication
- Unusual housing and husbandry requirements
- Impact of proposed procedures on animal well-being
- Appropriate sedation, analgesia, anesthesia
- Surgical procedures
- Post-procedural care
- Description and rationale for selected endpoints
- Criteria for humane intervention
- Euthanasia/ disposition of long-lived species
- Adequacy of training/experience of personnel
- Personnel safety (hazards)
- Experimental & humane endpoints
- Unexpected outcomes
- Physical restraint
- Multiple survival surgeries
- Food and fluid restriction
- Non-pharmaceutical grade substances
- Agricultural animals
- Avoid or minimize discomfort, distress & pain
- Alternatives (for procedures that cause more than momentary or slight pain or distress *written narrative*)
- Assurance of no unnecessary duplication
- Procedures that may cause more than momentary or slight pain or distress
- Appropriate pain relief
- Humane euthanasia for animals that experience severe or chronic pain
- Living conditions appropriate for the species
- Medical care available and provided by a qualified veterinarian
- Personnel conducting procedures are appropriately trained/qualified
- Surgery
- No more than one major operative procedure with recovery – justification req'd
- Methods of euthanasia must adhere to the AWR definition of euthanasia

Animal Care & Use Program

- Post-approval Monitoring
- Disaster Planning and Emergency Preparedness
- Program of Veterinary Care – *Guide* chapter 4
- + any "trend" issues identified on facility inspections

Program Review – how to do it?

- Very little (no) guidance on how.....
- Usually done after inspections are complete
- Full committee or subcommittee (at least 2) meet and review
 - OLAW checklist <https://olaw.nih.gov/resources/documents/checklist.htm>
 - AAALAC program description
 - Review topics in *Guide* – chapters 2, & 4
 - AWR's Part 2 – Regulations
 - "Rolling" review

Method #1 - OLAW Checklist

- well-organized, topic-driven, *Guide* references
 - Beware of the "checklist mentality"
 - Animal Care and Use Program
 - Disaster Planning and Emergency Preparedness
 - IACUC
 - IACUC Protocol Review - Special Considerations
 - IACUC Membership and Functions
 - IACUC Training
 - IACUC Records and Reporting Requirements
 - Veterinary Care (veterinarian)
 - Personnel Qualifications and Training
 - Occupational Health and Safety of Personnel
 - Personnel Security
 - Investigating & Reporting Animal Welfare Concerns
 - Veterinary care (program)
 - Clinical Care and Management
 - Animal Procurement and Transportation/Preventive Medicine
 - Surgery
 - Pain, Distress, Anesthesia, Analgesia
 - Euthanasia
 - Drug Storage and Control
- A = acceptable
 M = minor deficiency
 S = significant deficiency
 C = change in program
 NA = not applicable

Method #2 - AAALAC Program Description

- Program management
 - Responsibility (i.e. AV, etc.)
 - Personnel management (training)
 - Occupational Health
- Program oversight
 - IACUC
 - Protocol review
 - Special considerations – protocol rev.
 - PAM
 - Investigating concerns
 - Disaster planning
- Animal Environment (I/H, vent, Etc.)
- Housing (social needs, enrichment)
- Facility management (feed/water, bedding, sanitation)
- Veterinary Care
 - Procurement/transport
 - Preventive medicine
 - Clinical care
 - Surgery
 - Pain & distress
 - Anesthesia/analgesia
 - Euthanasia
- Physical Plant
 - Centralized facilities & satellites
 - Support systems (MEP)

Method #3 - Review Chapters in the Guide (2,4)

Chapter 2 – Animal Care and Use Program

- Regulations, Policies, and Principles
- Program Management/ Responsibility
 - The Institutional Official
 - The Attending Veterinarian
 - The Institutional Animal Care and Use Committee
 - Collaborators
- Personnel Management
 - Training and Education
 - Occupational Health and Safety of Personnel
 - Personnel Security
 - Investigating and Reporting Animal Welfare Concerns
- Program Oversight
 - The Role of the IACUC
 - IACUC Composition and Function
 - Protocol Review
 - Special Considerations for IACUC Review
- Postapproval Monitoring
- Disaster Planning and Emergency Preparedness

Method #3 Review Chapters in the Guide (2,4)

Chapter 4 – Veterinary Care (the program of veterinary care)

- Procurement
- Transportation
- Preventive Medicine/Biosecurity
- Quarantine/ Stabilization
- Separation (health status/spp.)
- Disease (Dx, Tx, control)
- Clinical Care
- Medical Management
- Emergency care
- Recordkeeping
- Surgery (planning, facilities, asepsis monitoring, post-op care)
- Pain/Distress
- Anesthesia/ analgesia
- Euthanasia

Method #4 - Review the Animal Welfare Regulations – part 2.C.

- Registration
- IACUC (composition, structure, function)
- Personnel qualifications
- AV, and Veterinary care
- Recordkeeping
- Annual report

Note – the AWR's are silent on the topic of Occupational Health and safety – so you'll need to add this section to your semiannual review.

Method #5 – “Rolling review”

- Large institutions – do a portion of the semiannual every month
- PHS Assurance?
- Timely correction of deficiencies

Additional considerations

- Inspection results....
- Trend issues?
- Programmatic issues?
- "Big ticket" items?

The semiannual report

Report must include:

1. A description of the nature and extent of adherence to the Guide, PHS Policy & AWR's
2. Identify any departures (and the reasons for departures)
3. List of findings distinguishing "significant" from "minor" deficiencies
4. Reasonable and specific plan and schedule, with dates, for correction
5. Failure to correct a significant deficiency on schedule must be reported to USDA-APHIS within 15 days
6. Reviewed and signed by a majority of the IACUC – include minority views
7. Identify facilities accredited by AAALAC
8. Timely submission to the IO & follow up

Because.....

The investigators will seldom say it....

The public is unaware to say it....

The animals would say it if they could.....

Thank you for your service on the IACUC!

