

Semiannual Program Review



OLAW Online Seminar
December 13, 2018

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Semiannual Program Review

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Throughout the Webinar

Dawn will describe the model used by the University of Michigan (U-M) to conduct program reviews on **white** slides.

Bill will discuss alternative processes for conducting program reviews that have been employed by other institutions across the country and the specific regulatory requirements they address on **grey** slides.

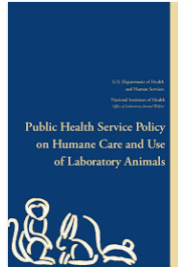
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Why do we Conduct Semiannual Program Reviews?

Federal Law

- Animal Welfare Act
- Health Research Extension Act of 1985

The federal law which provides the statutory mandate for implementing the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy)





Yes, Federal Law and Policy, but....

...the requirement can be used as an **opportunity** to:

1. Schedule regular IACUC reviews of program policies, guidelines and SOPs;
2. Confirm program supporting documents reflect program practices; and
3. Conduct ongoing training for the IACUC members.

Ensure the Program is Consistent with the Standards

1. *Guide for the Care and Use of Laboratory Animals (Guide)*
2. Animal Welfare Act Regulations (AWAR)
3. Guide for the Care and Use of Agricultural Animals in Research and Teaching
4. Occupational Health and Safety in the Care and Use of Animals



What Other Resource Documents may be Helpful?

1. For institutions with wildlife studies, some examples include:
 - a) Guidelines of the American Society of Mammologists;
 - b) Guidance from the Ornithological Council;
 - c) U.S. Fish and Wildlife Service Regulations; and
 - d) State and local regulations
2. AAALAC Position Statements (although not regulatory standards)
3. Performance standard data



NIH Guide Notices and OLAW FAQs

OLAW FAQ, Section D (Protocol Review), Question 9

“What is considered a significant change to a project that would require IACUC review?”

Guidance on Significant Changes to Animal Activities

Notice Number: NOT-OD-14-126

Key Dates

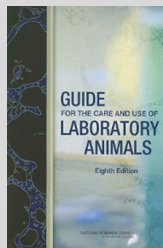
Release Date: August 26, 2014

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What are the Components of an Animal Care and Use Program (ACUP)?

Guide Chapters:

2. Animal Care and Use Program (e.g., oversight, resources, OHSP)
3. Environment, Housing and Management (e.g., husbandry)
4. Veterinary Care
5. Physical Plant



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Resources that may be Representative of the Program

1. OLAW semiannual program review checklist
2. A customized version of the OLAW checklist
3. A collection of polices, guidelines, and SOPs
4. The Program Description template that may be AAALAC accredited
5. The OLAW approved PHS Animal Welfare Assurance
6. Quality assurance/PAM reviews (ongoing ACUP review)
7. Program metrics



Does your Institution Conduct the Review by Just Checking the Boxes?

1. Include a copy of the OLAW checklist in the IACUC meeting packet
2. During the meeting, go through the checklist point by point, and ask IACUC members to confirm that the listed requirements are satisfied (questions when necessary)
3. Record the points of the discussion in the meeting minutes and the IO report
4. Repeat in 6 months!



What's the Dialogue during your Program Review?

Option 1

IACUC Administrator/Chair:

"Does anyone have any questions or concerns regarding Section 1 on the OLAW checklist?"

IACUC:

No comments

IACUC Administrator/Chair:

"Any questions on section 2?" ...



OR

What's the Dialogue During your Program Review?

This (Option 2)?

IACUC Administrator/Chair:

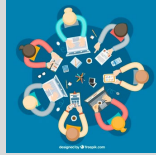
"Referencing the checklist, does the IO have the authority to allocate needed resources? The IO has a portion of the budget dedicated to the ACUP, and has and will continue to ensure we have the necessary resources"

IACUC:

"How much is allocated? Could you provide some examples of when allocations were made?"

IACUC Administrator/Chair:

"Referencing the checklist ..."



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Benefits of Checking the Box

1. Satisfies the requirement;
 - a. Option 1 – barely; **and**
 - b. Option 2 – much better
2. Minimal time commitment
3. Option 1 and 2 reminds the IACUC members of the general components of the animal care and use program, BUT
4. Option 2 also provides critical information on each component of the program



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Optimal Comprehensive Program Review

Capitalize on the Opportunities

1. IACUC member training opportunity
2. Keep the AAALAC accredited PD current
3. Keep the PHS Assurance current
4. Metrics review - maximize efficiencies



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What do we do at the University of Michigan (U-M)?



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Old U-M Program Review Model: Check the Boxes



Check Box Process:

1. ACUO prepared OLAW checklist and supporting documents, coordinating with Unit for Laboratory Animal Medicine
2. IACUC reviewed program according to checklist
3. Members of the ACUO updated the checklist and presented it at IACUC meeting

OLAW Semiannual Program Review and Facility Inspection Checklist
<https://olaw.nih.gov/resources/documents/checklist.htm>

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New U-M Program Review Model: Enhancement

Enhancement Model Process:

1. Communicate the strategy for conducting review
2. Select standard document for program review
 - Institutional program description (AAALAC accredited) (e.g., first semiannual program review)
 - OLAW checklist (e.g., second semiannual program review)
3. Review the program
 - IACUC subcommittees review designated sections
 - Subcommittees present findings to IACUC for discussion
 - ACUO staff updates standard document



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Step 1: Communicate the Strategy for Conducting Program Review

The key to success is to communicate a clear plan with expectations:



- Each Spring and Fall announce the review
- Announce subcommittee chair and member assignments
- Include documents necessary for the review
- Provide timeline for completion

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Step 2: Select Standard Document for Program Review

Program Description (AAALAC Template)

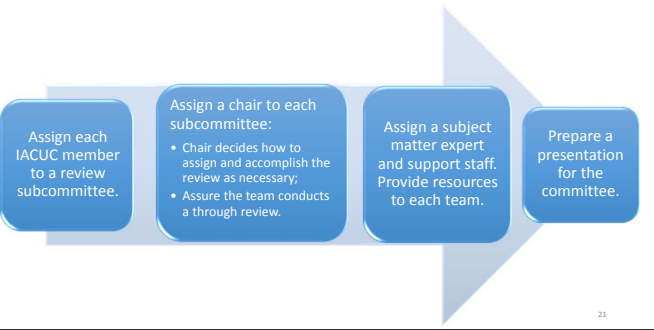
- I. Animal Care and Use Program
 - A. Program management
 - 1. Program Management and Responsibility
 - 2. Personnel Management
 - a. Training, Education, and Continuing Educational Opportunities
 - b. Occupational Health and Safety of Personnel
 - B. Program oversight
- II. Animal Environment, Housing & Management
 - A. Animal environment
 - B. Animal Housing
 - C. Animal facility Management
- III. Veterinary Care
 - A. Animal Procurement and Transportation
 - B. Preventive Medicine
 - C. Clinical care and management
 - D. Surgery
 - E. Pain and Distress
 - F. Analgesia and Anesthesia
 - G. Euthanasia
- IV. Physical Plant
 - A. Facilities Overview
 - B. Centralized (Centrally-managed) Animal Facility (ies)
 - C. Satellite Animal Housing Facilities
 - D. Emergency Power and Life Support Systems
 - E. Other facilities

OLAW Checklist (Guide)

- Animal Care and Use Program
- Disaster Planning and Emergency Preparedness
- IACUC
- Protocol Review (special considerations)
- Occupational Health and Safety
- IACUC Memberships and Functions
- IACUC Training
- IACUC Records and Reporting Requirements
- Veterinary Care
 - Clinical Care and Management
 - Animal Procurement and Transportation/Preventive Medicine
 - Surgery
 - Pain, Distress, Anesthesia and Analgesia
 - Euthanasia
 - Drug Storage and Control
- Personnel Security and Reporting Concerns
- Occupational Health and Safety of Personnel
- Personnel Security
- Investigating and Reporting Animal Welfare Concerns

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Step 3: Review the Program



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The Enhancement Program Review Model Provides IACUC Member Training Opportunities

For each section of the institution's PD or OLAW checklist:

- Subcommittee chairs present and confirm that practices are consistent with PD or checklist.
- Rotate members between subjects every 6 months.
- Inconsistencies with PD or checklist are communicated to the committee which suggests improvements.
- Discussions of the areas for improvement.
- Changes or actions are reflected in the meeting minutes.
- ACUO staff update the PD and follow through on actions items.

New vs. Old U-M Program Review Model

Pros of the Enhancement Process	Cons of Checking the Box
Facilitates in-depth engagement of IACUC members	IACUC not engaged
Provides IACUC member training opportunities	Inefficient use of members' time
Contributes to effective program management by increasing efficiency through interim updates of institution's PD and comparison to the <i>Guide</i> for the OLAW checklist	Missed opportunity for effective program management

Enhancements Through Program Review

- Committee engagement is key
- Team work to improve the program
- Accountability through responsibility

Results of the Enhancement Model

- Compassion fatigue in laboratory animal sciences
 - Initial program training for animal husbandry staff
 - Awareness and description
 - Symptoms of compassion fatigue
 - Departmental and university resources available
- Mirror imaged program soon to come for the U-M research community



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Are We Done Yet?

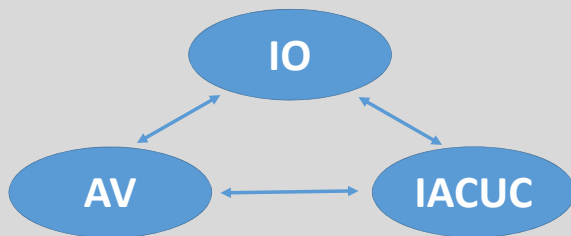
1. During the June 28, 2018 webinar, we discussed facilities inspections
2. Today we discussed the program review process



Anything Else?

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Let's Tell the Institutional Official (IO)



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Reporting to the IO

- 1. **AWAR:** "Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility;"
- 2. **PHS Policy:** "Prepare reports of the IACUC evaluations conducted as required by IV.B.1. and 2. of this Policy, and submit the reports to the Institutional Official."
- 3. **The Guide for the Care and Use of Laboratory Animals:** "After review and inspection, a written report (including any minority views) should be provided to the IO about the status of the Program."

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What Must the IO Report Include?

Generally Speaking:

- 1. Details from the semiannual facility inspections
- 2. Details from the program review.



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What Must the IO Report Include?

Specifically:

- 1. A description of the nature and extent of the institution's adherence to the *Guide*, PHS Policy and AWAR
- 2. A list of departures from the provisions of the *Guide*, PHS Policy and AWAR including the reason for each departure
- 3. Any deficiencies with each being identified as either significant or minor
- 4. Reasonable and specific plans and schedules for correcting each deficiency
- 5. Minority views of any committee members

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How about Some Definitions?

1. *Significant deficiency* (both PHS and USDA): is or may be a threat to the health or safety of the animals.
2. *Departure*: an activity related to animal care and use that is not consistent with *Guide*/AWAR expectations.
3. *Minority view*: a written opinion expressed by an IACUC member that may not be consistent with the majority view of the IACUC.

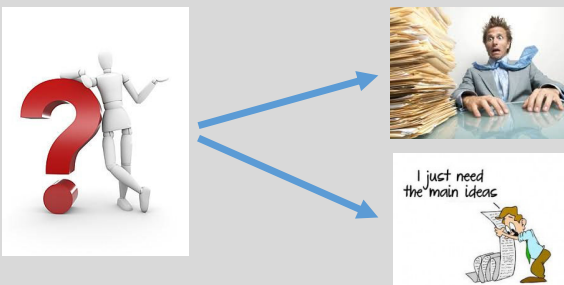


What Else do we Need to Know about the IO Report?

1. It must be prepared/updated and provided to the IO semiannually.
2. It must be signed by a majority of the IACUC members.
3. It must be maintained as an official document of the committee and made available to OLAW or USDA upon request.



What Should the Report Look Like?



Questions



Submit to the chat box in the GoToMeeting control panel

Question 1

Q: How much flexibility does OLAW allow in the conduct of semiannual program review?

If my institution performed its program review on January 15th, when does OLAW expect the next program review to occur?

Answer 1

Approximately 6 months later, and no later than 30 days after July 15th.

1 st Program Review Date	Ideal 2 nd Program Review Date	Permitted Program Review Date Range
January 15, 2018	July 15, 2018	As late as August 14, 2018

Question 2

Can institutions use the AAALAC site visit to satisfy their semiannual program review requirement?

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Answer 2

Yes, it is permitted. The provision to utilize *ad hoc* consultants may be invoked by IACUCs to use the AAALAC assessment for an IACUC semiannual program review.

Of course, the IACUC must ensure that PHS Policy provisions are met:

- (1) The IACUC semiannual report must comply with section IV.B.3.
- (2) The report must be endorsed by the IACUC and submitted to the IO.

See NIH Guide Notice OD-00-007
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-007.html>

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See NIH Guide Notice OD-00-007
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-007.html>

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Question 3

Does U-M routinely utilize *ad hoc* consultants for their semiannual program review?

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Question 4

Dawn explained that U-M rotates standard documents during the year, basing one review on the institutional Program Description and the next on the OLAW checklist.

Is use of the OLAW checklist mandatory?

Are all components that OLAW expects to be reviewed included in the institution's PD?

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Answer 4

No, there is no requirement for institutions to use the OLAW checklist. The checklist is an optional tool that OLAW developed to help IACUCs conduct thorough semiannual reviews. The OLAW checklist:

- covers the components that OLAW expects the institution to review: requirements of the PHS Policy and topics of the *Guide*.
- is linked to relevant descriptions in the *Guide*
- can be amended and updated, as necessary, to reflect institutional programs and ongoing practices.

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Question 5

Are the training opportunities, which are provided as part of the enhancement program review model, documented? If so, how?

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Question 6

Are all IACUC members provided the opportunity to review various components of the program review or are they allowed to specialize?

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Questions



Submit to the chat box in the GoToMeeting control panel

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Questions



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ICARE Workshop	2019 Date	Location
ICARE Academy	February 7-8	Dallas, TX
Advanced Train the Trainer Institute	April 1	Seattle, WA
ICARE Academy	May 7-9	Providence, RI
Train the Trainer Institute	June 4-7	Phoenix, AZ
ICARE Academy	September 10-11	Alexandria, VA

Register: <https://olaw.nih.gov/education/icare-interagency> Info: 301-402-4371

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Superstar Rats Teach Empathy to Researchers



OLAW Online Seminar
March 21, 2019

Catherine A. Schuppli, DVM, MSc, PhD, University of British Columbia

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