

Beyond Protocol Review and Facilities Inspection

Susan S. Silk, M.S.

Director, Division of Policy and Education,
NIH OLAW

J.G. (Jerry) Collins, Ph.D

Professor of Anesthesiology, Yale University School
of Medicine

Consultant, Division of Policy and Education, NIH
OLAW

Why Were IACUC's Developed?

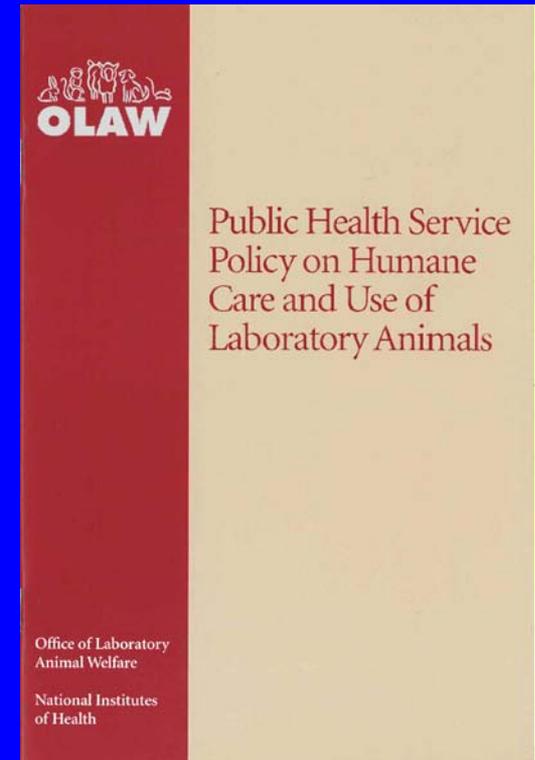
“The requirement to establish animal care committees is intended to provide the most constructive assurance that NIH guidelines for the care and treatment of animals are met. It is far preferable to place primary responsibility for assuring compliance with NIH guidelines on committees within institutions rather than relying on intrusive Federal inspections.”

IACUC Functions

The PHS Policy on Humane Care and Use of Laboratory Animals defines the following eight functions of an IACUC:

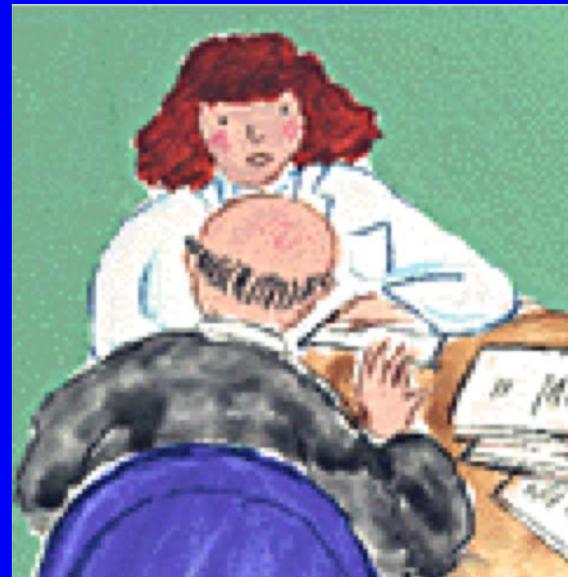
1. Review animal program.*
2. Inspect animal facilities.*
3. Report results of 1 and 2 to IO.

* Semiannual Evaluation



IACUC Functions

4. Review animal care and use concerns.
5. Make recommendations to IO about any aspect of animal program, facilities, or personnel training.



IACUC Functions

6. Review and approve, require modifications in (to secure approval), or withhold approval of proposed animal activities.*
7. Review, require modifications to approve, or withhold approval of proposed significant changes to ongoing animal activities.*

* Protocol Review

IACUC Functions

8. Suspend an activity involving animals.



Not on the List but Essential to Success

- The PHS Policy states: “...the IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this policy at appropriate intervals as determined by the IACUC, including complete review... at least once every three years.”

Continuing Review

- Conduct continuing review of each previously approved ongoing activity.
 - Don't confuse this review with the current trend to hire post-approval monitoring (PAM) personnel.
 - The PHS Policy requires IACUCs to conduct continuing review.
 - The PHS Policy does not require a formal PAM program; it is one way for your institution to achieve compliance.

Post-approval Monitoring

Does your IACUC:

- Conduct annual protocol reviews,
- Track unexpected animal death or disease,
- Keep an eye on problem labs,
- Receive veterinary reports,
- Report noncompliance to OLAW?

If yes to any of these examples, you are conducting PAM!

1. Review Animal Program

- Program review makes an IACUC responsible for assessing the effectiveness of other institutional components.
- An IACUC must ensure that **institutional responsibilities** are being met as part of program review, for example:
 - Adequate veterinary care and animal housing.
 - Animal-program relevant occupational health and safety program.
 - Comprehensive emergency/disaster plan.

1. Review Animal Program

- PHS Policy defines IO as “An individual who signs, and has the authority to sign the institution’s Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.”

2. Inspect Animal Facilities

- PHS Policy directs IACUCs to inspect, at least once every six months, all of the institution's animal facilities using the Guide as a basis for evaluation.

3. Report Semiannual Review Results to the IO

- Are your semiannual reports
 - Reviewed and signed by a majority of the IACUC?
 - Do they reflect minority opinions?
- Does your IO get an accurate sense of your program from the semiannual report?
- How does your IO follow up on questions or concerns raised in the report?

3. Report Semiannual Review Results to the IO

- Do the reports distinguish significant from minor deficiencies?
 - Significant deficiency, in the judgment of the IACUC and the IO, is or may be a threat to the health or safety of animals or humans.
 - Does your IACUC involve your IO in this determination?
- If deficiencies are noted, is a reasonable and specific plan and schedule for correcting each deficiency included in the report?

3. Report Semiannual Review Results to the IO

- The report must:
 - Contain a description of the nature and extent of the institution's adherence to the *Guide* and the PHS Policy,
 - Identify any departures from the *Guide* and the PHS Policy,
 - State the reasons for each departure.
- Departures are not deficiencies.

4. Review Animal Care and Use Concerns

- Is your general counsel aware of this federally-mandated IACUC function?
- How do you maintain anonymity and protect whistleblowers?
- What will you do if there are:
 - Human resource issues?
 - Public relation issues?

4. Review Animal Care and Use Concerns

- Do you have a policy that encourages everyone to report concerns and identifies individuals to whom concerns should be reported?
- Do persons to whom a report is to be made represent all levels in your organization?

5. Make Recommendations to IO About any Aspect of Animal Program, Facilities, or Personnel Training

- Usually the semiannual report focuses on short-term problems.
- The IACUC is also charged with providing the IO with a long-range view.
 - e.g., When will the institution run out of rodent housing space?

6 and 7. Protocol Review

- Great place for ongoing review!

8. Suspend an Activity Involving Animals

- If an IACUC suspends an animal activity or denies approval of an animal activity, the decision can not be reversed by an institutional authority.
- Institutional leadership may say no to an animal activity that was approved by an IACUC.

8. Suspend an Activity Involving Animals

- The IACUC may suspend an activity only:
 - After review at a convened meeting of a quorum of the IACUC.
 - And with a majority of the quorum present voting for suspension.

8. Suspend an Activity Involving Animals

- If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC:
 - Shall review the reasons for the suspension,
 - Take appropriate corrective action,
 - And report the action with a full explanation to OLAW.
- The institution must also inform the funding agency.

IACUC's are Important Because:

- “...their presence will create an ongoing discussion within the nation’s research institutions of sensitivity to the care and treatment of research animals. This ongoing process recognizes that such sensitivity cannot be captured in any set of rules, that standards of care will change in the future as science advances, and that the value of medical research requires such judgments to be professionally and scientifically sound.”

Thank You!

- For participating in this webinar.
- For overseeing essential work that contributes to human and animal health.
- For helping your institution ensure that self regulation promotes ethical treatment of animals used in research, teaching and testing.

Questions? Please Ask!



Upcoming Seminars:

June 9, 2011: Writing a Good Assurance

September 8, 2011: Occupational Health and Safety Programs

December 9, 2011: Grants Policy and Congruence

