Self-Evaluation and Reporting:
Always Let the *Guide* Be Your Conscience
or
How to Encourage PIs and Their Staff to Self Report

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Objectives

- The PHS Policy and the *Guide* on reporting
- The *Guide* and self-evaluation
- Suggestions for self-evaluation
- Self-evaluation suggestions for the IACUC, veterinarians, veterinary technicians, animal care staff
- PI's self-reporting
- Dealing with noncompliance
- Perspectives on noncompliance
- Personal observation concerning PI's self-reporting

Reporting

- In a perfect world (or institution) where no protocol deviations or noncompliances occur, reporting is a moot point

- Unfortunately most institutions aren't perfect

- So it is the IACUC's responsibility to know what should be reported

Disclaimer

- Self-evaluation and reporting are a complex area and can be a major source of stress for IACUCs

- There is not one "best way" for an institution to address this area although there are wrong ways

- In this webinar, I will make suggestions that have been successful at my institution

- Personal experiences will also be discussed which may not apply to your institution

What Does the PHS Policy Say About Reporting?

- The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

  - Any serious or continuing noncompliance with this Policy

  - Any serious deviation from the provisions of the *Guide*

  - Any suspension of an activity by the IACUC

    PHS Policy, section IV.F.3.

What Does the *Guide* Say About Reporting?

- The *Guide* contains a section entitled "Investigating and Reporting Animals Welfare Concerns" (pp 23-24)

- The institution must develop methods for reporting and investigating animal welfare concerns.

- In the U.S. this responsibility rests with the IO and the IACUC.

- The IACUC must communicate such reports to the IO including the issue, findings, and corrective actions taken.

NOT-OD-05-034: Prompt Reporting to OLAW

"Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt."

More about NOT-OD-05-034

Provides excellent guidance on reporting including:

- Specific examples of issues which are and are not reportable, however, the list is not comprehensive

- The time frame for reporting

- The information which must be included in the reports

- Directions on where to send the report

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What Guides Your Conscience?

- Follow the *Guide,* or

- Don't report and keep the institution's reputation perfect!

  - Not recommended

What Does the *Guide* Say About Self-Evaluation?

- The *Guide* uses the term "Continuing Review" and states it must include oversight and evaluation by the IACUC of activities such as continuing protocol review, oversight and evaluation of facilities and animal use areas, regular review of the animal care and use program, and ongoing assessment of animal care and use.

- Program review and facilities inspections should occur at least annually per the *Guide* or more often as required (Animal Welfare Act, PHS Policy)

Self-Evaluation

Although continuing review of ongoing animal related activities by the IACUC is a requirement imposed by the Public Health Service Policy (PHS Policy) and United States Department of Agriculture (USDA) animal welfare regulations, there is lack of uniform understanding and application of these federal requirements.

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Self-Evaluation and Continuing Review

Model For Performing Institutional Animal Care and Use Committee: Continuing Review of Animal Research

GWENN S.F. OKI, MPH , ERNEST D. PRENTICE, PHD, NELSON L. GARNETT, DVM, DALE F. SCHWINDAMAN, DVM, and CAROL Y. WIGGLESWORTH

Contemporary Topics 35(5):53-56, 1996

Continuing Review (cont.)

The review process and report form described in this paper meet the requirements of the PHS Policy and the USDA regulations for continuing review. Use of this model for performing IACUC continuing review satisfies the PHS Policy requirement for triennial "de novo" continuing review, as well as the USDA annual review requirements.

How Does Your Institution Evaluate?

- Don't evaluate
  - Tremendous risk
- Let AAALAC or USDA evaluate your program for you
  - Not self-evaluation
  - May not give you the answer you want
- Meet the minimum requirements
- Develop a comprehensive program for self-evaluation

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Self-Evaluation Methods

Self-evaluation is more difficult than many think it is. We are often too harsh or too lenient.

- One method is to have many pairs of eyes and ears to get a representative opinion.

- It is suggested that people should come from all parts of the animal program including the outside member, attending veterinarian, principal investigators, and animal care staff, especially veterinary technicians.

Suggestions for Self-Evaluation

- Must meet the minimum OLAW and USDA requirements
- However, the minimum including semiannual reviews provides only a snap shot
- Make it a true team approach which includes:
  - IACUC committee and staff
  - Veterinarians
  - Laboratory animal staff
  - PI and the research staff

Suggestions for Self-Evaluation (cont.)

- By doing this the IACUC will foster a climate of trust, openness, and team work

- Stress that by being part of the team you are protecting both the animals and the institution

- Train all members of the team

- Develop a strong and transparent relationship with the IO

More Suggestions for Self-Evaluation

- Start with a positive attitude

- We are all humans, no one is perfect, no program is perfect

- The vast majority of the PIs and staff wish to do a good job, to reduce animal suffering, and to be proud of their work

- A major goal should be to develop a system devoted to continual learning and improvement of animal care, top to bottom and end to end

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Self-Evaluation (IACUC)

- Standardize approaches to inspections

- Have a common form that all use

- Pair newer members with more experienced members

- Encourage IACUC members to ask questions and discuss potential problems with staff members including laboratory animal staff and research staff

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Self-Evaluation (IACUC), cont.

- Try not to act as police

- Make Post Approval Monitoring (PAM) a friendly non-confrontational experience

- Use PAM as a training/teaching tool, not just as a way to uncover noncompliance

Self-Evaluation (Veterinarians)

- Need to develop a positive relationship not only with their own staff but with the PIs and the research staff

- Must have good rapport and transparency with other IACUC members

- Discuss protocols with veterinary technicians

- Participate in PAM, particularly as a trainer

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Self-Evaluation (Veterinary Technicians)

- Encourage Vet Techs to be part of the PAM program

- Vet Techs should become familiar with the animal protocols as they can often observe potential problems like protocol deviations

- Encourage Vet Techs to interact with the research staff and promote good laboratory animal practices and techniques

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Self-Evaluation (Lab Animal Staff)

- Seminars given by PIs to husbandry staff to promote understanding of research procedures performed on the animals

- Promote observation of procedures being performed in their work area

- Work with Vet Tech to understand possible problems

PI Self-Reporting

Encourage self-reporting!

When asked to self-report noncompliance, the typical response at our institution was:

"Why don't you just hit me again, IACUC?"

Quotes to Remember When Engaging PIs

"No one admits to an error if you punish them"

"The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes"

Lucian Leape, MD
Harvard School of Public Health

Gaining the PI's Trust and Cooperation

- Stress the importance of a compliant animal program to the PI

- Explain corrective actions ≠ punishment

- Use PAM to train PI's lab members in problem areas

- Encourage lab staff to be part of the program, including reporting

- Have some type of incentives that will increase the level of self-reporting

Dealing with Noncompliance

- An institution cannot just "forgive" because a PI self-reports

- Reported noncompliance must have a corrective action

- One approach is to make it more difficult for those that don't self-report, for example, have a stronger corrective action

I didn't mean to deviate from my animal protocol, I'm sorry I didn't self-report

Self-reporting should not alleviate corrective actions

Dealing with Noncompliance

Suggested corrective actions:

- Suspension of protocol
- Retraining in area of noncompliance
- Regular unannounced PAM visits
- Have lab members and the PI attend IACUC meeting separately
- Have staff members discuss the complete protocol with lab members

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Dealing with Noncompliance

Suggested corrective actions (cont.):

- Stress to lab members that loss of funding could mean loss of job

- Suggest the PI appoint a lab manager

- Regular visits by a Vet Tech at PI expense*

- Assign a Vet Tech to the laboratory at the PI expense*

- Require a Vet or Vet Tech to sit in on animal experiment planning meetings*

*options for those who don't self-report

Personal Perspective on Noncompliance (Why Some Lab Members Don't Follow the Rules)

- English is a second language
- Cultural differences relating to animal experimentation
- In times of tight funding, pressure by PIs to perform experiments quickly and economically (cut corners)
- Fear of retribution from the PI
- Not reading the protocol
- No communication with PI

Observations Following Our Experiences with PI Self-Reporting

- 80% of noncompliance reports now come from PIs increasing from a baseline of 0

- Total number of noncompliance reports have increased

- Communication between PIs and IACUC/vet staff has greatly increased

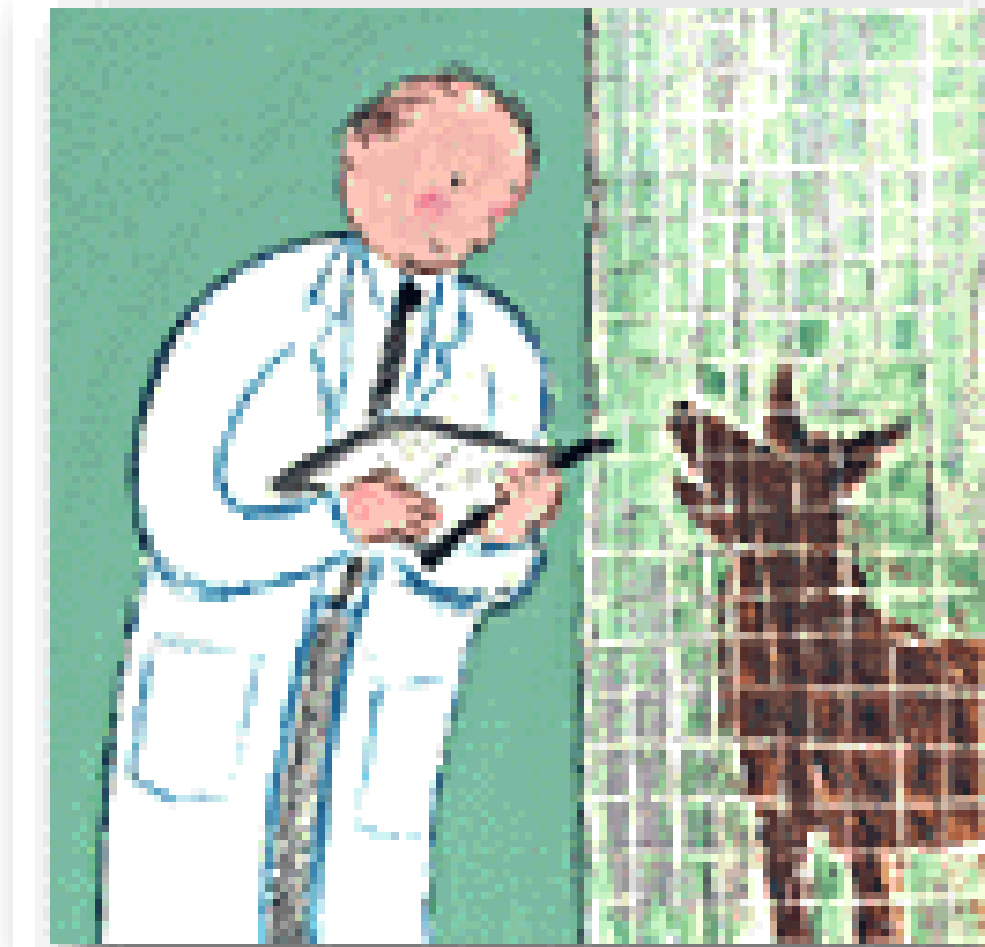- Request for training from the vet staff has increased

Observations (cont.)

- PIs who self-report rarely repeat the noncompliance

- Lab members are far more open to discuss problems including noncompliance

- PAM visits have become more collegial

- A small number of PIs are very resistant and now represent most of the noncompliance

Summary

- Use the *Guide* as your conscience for reporting

- Try a team approach for self-evaluation based on transparency, honest communication, and trust

- Use PAM as a non-confrontational teaching tool

- Include PIs and their staff as a major part of evaluation

- Train, train, train

Questions?

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Thank you