

Common IACUC Issues in Pacific Rim Region



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Flow of Presentation & Discussion

- References
 - *The Guide* (NRC 2011)
 - Reference Resources
- AAALAC Expectation, Position Statements and FAQs
- List of Common Issues
- Case Scenarios – Kahoot and discussion

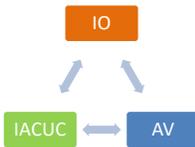


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IO-AV-IACUC's Communication



- Chapter 2, Page 13
- **Program needs should be clearly and regularly communicated to the IO by the AV, the IACUC, and others associated with the Program.**




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Case scenario 1

<p>IACUC Composition</p> <ul style="list-style-type: none"> ▪ The IO was the principal investigator for the four out of a total of 9 approved protocols. ▪ He was an IACUC member and also one of its Vice Chairman (PD Appendix 7). 	<p>Question?</p> <ul style="list-style-type: none"> ▪ Not an issue ▪ Mandatory issue ▪ SFI
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Case Scenario – Why?

<p>Why?</p> <ul style="list-style-type: none"> ▪ The Guide (page 13) describes three primary parties directing the animal care and use program – the IO, IACUC and AV. The implication is clear that these three are separate agents acting on behalf of the institution. The Guide goes so far as to say 'The Program direction should be a shared responsibility among the IO, AV and IACUC.' For reasons of conflict of interest, the IO must not be an IACUC member. 	<p>What?</p> <ul style="list-style-type: none"> ▪ IACUC composition must be re-evaluated to ensure the IO does not have any conflict of interest with it.
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The IACUC decided that the IO would no longer be an IACUC member. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially Addressed?
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PROGRAM OVERSIGHT
The Role of the IACUC
 IACUC Function (page 24)



The responsibility of the IACUC is to oversee and **routinely** evaluate the Program.



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IACUC's Responsibilities



- Chapter 2, Pages 14 – 15
- The IACUC is responsible for assessment and oversight of the institution's Program components and facilities.
- It should have sufficient authority and resources to fulfill this responsibility.
- Pages 24 – 34: Detailed information on the role and function of the IACUC.



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Collaborations (Page 15)

- Inter-institutional collaboration has the potential to create ambiguities regarding responsibility for animal care and use.
- In cases of collaborations between institutions that involves animal use, institutions should have a formal written understanding (contracts, MOU, or agreement..) between the institutions.
- The written agreement should address:
 - the responsibility for offsite animal care and use
 - animal ownership
 - IACUC review and oversight.



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Myth or Fact?

2

We will sign an agreement with a university to provide services for an experiment in monkeys that cannot be done at our institution. Since all animal housing and procedures will be handled by the university, this is not the business of our IACUC.



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Case scenario

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IACUC - Collaborations

There was no formal written understanding that addressed responsibility for animal care and use, animal ownership, and IACUC review and oversight for the collaborative research efforts with another university, Protocols 6-01 and 6-02.

Question

- Mandatory?
- SFI?



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Case scenario – Why?

Why?

- Interinstitutional collaboration has the potential to create ambiguities about responsibility for animal care and use. According to the recommendations of the *Guide* (p. 15), a formal written understanding (e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight should be implemented.

What?

- The responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight should be implemented.



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Unit's Action & Council's Consideration

Unit's Action

- The unit has instigated a policy that all new collaborations with other institutions that a MOU be signed.
- The proposed MOU covers the responsibility of IACUC review, states that the IACUC is empowered to visit, if needed. However it also states that ownership remains with the PI and the offsite institution oversees the program.

Council's Consideration

- Fully Addressed?
- Partially addressed?



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IACUC Constitution and Membership

1. A certified DVM or with training and experience in laboratory animal science and medicine or in the use of the species...
2. At least one practicing scientist experienced in research involving animals
3. At least one member from a nonscientific background drawn from inside or outside the institution
4. At least one public member (nonaffiliated and should not be laboratory animal users)

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IACUC Composition Issues

- All IACUC members have scientific background or education
- An IACUC public member was affiliated with the institution, i.e. former employee
- The public member is a research scientist and also uses animals



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Case scenario

<p>IACUC/OB Composition</p> <ul style="list-style-type: none"> ▪ Although “non-scientist” IACUC member had been serving as administrator in the last 10 years, she graduated with degree in biochemistry, held PhD degree in molecular biology and agricultural science. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

Why?

- The Guide (p. 24) indicated committee membership includes at least one member from non-scientist background, drawn from inside or outside institution. Although the "non-scientist" member did not work with animal, her education/degree background may pose a bias as "non-scientist".

What?

- Unit should review IACUC membership to ensure non-scientist component in the IACUC membership is represented properly and in accordance with the *Guide*.



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Unit's Action & Council's Consideration

Unit's Action

- Unit appointed a new member, an administrative assistance with economic background to serve in a role as non-scientist member.
- The official appointment letter and supporting documents were provided.

Council's Consideration

- Fully Addressed?
- Partially addressed?



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Case scenario

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IACUC Composition

- Although there was a non-scientist member (who was affiliated with the unit) who served on the IACUC, all of the public members of the IACUC were laboratory animal users or veterinarians working in a biomedical research institution.

Question

- Mandatory?
- SFI?
- At deliberation Council may determine differently?



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Case scenario – Why?

Why?

- The Guide, NRC 2011 (p. 24) recommends that at least one public member to represent general community in the proper care and use of animals be a part of the IACUC.
- The public members should not be laboratory animal users, affiliated in any way with the institution, or members of the immediate family of a person who is affiliated with the institution.

What?

- A member who is not a laboratory animal user, affiliated in any way with the institution, or a member of the immediate family of a person who is affiliated with the institution should be appointed.



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Unit's Action & Council's Consideration

Unit's Action

- The unit will recruit appropriate public members, but not at this term of current committee.
- When a new committee is formed (in 12 months), the unit would include a new public member.

Council's Consideration

- Fully Addressed?
- Partially addressed and retain as a mandatory issue?
- Partially addressed and retain as a SFI?



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Case scenario

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IACUC Composition/Participation

- There was no non-scientific background member in IACUC and the participation of public member (a librarian) was not enough (absent from all IACUC meetings and inspections since he joined IACUC in the past 12 months).

Question

- Mandatory?
- SFI?
- At deliberation, Council may decide differently?



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Unit's Action & Council's Consideration

Unit's Action

- A new public member (a lawyer) has been appointed by the IO.

Council's Consideration

- Fully Addressed?
- Partially addressed and retain as an SFI since no response regarding the participation of the public member?



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IACUC and Personnel Management (Pages 15, 17 and 24)



- Institutions are responsible for providing appropriate resources to support personnel training, and the **IACUC is responsible for providing oversight and for evaluating the effectiveness of the training program.**
- All program personnel training should be documented.



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Case scenario 7

<p>Training - IACUC</p> <ul style="list-style-type: none"> ▪ Despite several years of serving on the IACUC, the nonaffiliated member had not been included in the general IACUC training, nor did he have the opportunity to participate in semi-annual facility inspections. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ Training record for the nonaffiliated IACUC member was provided. Training topics covered include animal management system, quality control department management system, and occupational health and safety. ▪ In addition, IACUC management SOP had been updated to include all members in semi-annual facility inspections and encourage members to attend training opportunities. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Training for All Research Groups
(Page 17)

- All research groups should receive training in:
 - animal care and use legislation
 - IACUC function
 - ethics of animal use and the concepts of the Three Rs
 - methods of reporting concerns about animal use
 - occupational health and safety issues pertaining to animal use
 - animal handling, aseptic surgical technique
 - anesthesia and analgesia, euthanasia and other subjects as required by statute

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Myth or Fact

Our research scientists have extensive experience and they are very competent in what they are doing; therefore, they do not need any additional training. This is not IACUC business.

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Program Review and Facility Inspection

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At least annually or more often as required

- National or regional regulations, policies and guidelines, as well as conditions of funding, may set a minimum frequency for such reviews, of greater importance to AAALAC

AAALAC's Expectation

- AAALAC International encourages Committees to carefully **consider the frequency of their evaluations in order to ensure quality** animal care and science.
- In certain programs and circumstances, self-assessments at **frequencies greater than minimally required may be prudent.**

See FAQ: http://www.aaalac.org/accreditation/faq_landing.cfm

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Program Review/Facility Inspection Issues

- Program review has not been done
- Facility inspection did not cover all areas
 - Satellite animal rooms
 - Laboratories where procedures are performed
- Public member has never entered the animal facilities
- IACUC did not inspect investigator laboratories used for rodent survival surgeries
- The animal transportation vehicle was not inspected by the IACUC
- The report of the review was not submitted to the IO

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Case scenario

Program Review/Facilities Inspections

- There was no facility inspection and program review report conducted by the IACUC been submitted to the Institutional Official (IO), and the Program Description Appendix 10 was not provided.
- The facility inspection was conducted annually by the Quality Assurance staff (IACUC secretary, non-voting member) and did not include other IACUC members. The inspection and report followed the OECD GLP requirements only.

Question

- Mandatory?
- SFI?

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Unit's Action & Council's Consideration

Unit's Action

- Program review and facility inspection was conducted and reviewed by IACUC member.
- The report was submitted to the IO and also provided.
- The unit will conduct the facility inspection and program review annually.

Council's Consideration

- Fully Addressed?
- Partially addressed and retain as an SFI?
- Partially addressed and retain as a mandatory issue for the program review and facility inspection to be conducted?



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Case scenario

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Facility inspection

- In PD (p. 22-23) described that the unit owned a transportation vehicle. The driver was educated about the risk of animal transport; however, this transportation vehicle was not in the scope of semi-annual facility inspection.

Question

- Mandatory?
- SFI?



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Unit's Action & Council's Consideration

Unit's Action

- The new transportation vehicle was bought 30 days ago. The institution has revised the check list of semi-annual facility inspection in which vehicle inspection was included. The vehicle was inspected, and the inspection report was enclosed.

Council's Consideration

- Fully Addressed?
- Partially addressed?



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**Protocol Preparation and Protocol Review
Topics Pages 25-26**

- Rationale & purpose of the use of animals
- **Sequential procedures**
- Alternative availability
- Justification of animal species and numbers (and **experimental group sizes**)
- Adequacy of Personnel training and experience , **role and responsibilities**....
- **Nonstandard** housing and husbandry requirements
- **Impact of the procedures on the animals' well-being**
- Appropriate sedation, analgesia, and anesthesia
- Unnecessary duplication of experiments
- Conduct of surgeries
- **Description and rationale for anticipated endpoints**
- Early endpoint criteria for euthanasia
- Postoperative care and **observation**
- Method of euthanasia and **plan for care of long-lived species**
- Use of **hazardous materials** and provision of safe working environment



Page 26
IACUC members named in protocols or have other conflicts must recuse themselves from decision concerning these protocols.



Protocol Review Procedures and Process Issues

- Many errors in the approved protocols
- Procedures did not follow the IACUC SOPs
- Lack of potential biological hazard information in the protocol
- Fail to mention non-standard housing or standard practices or exception to the *Guide*, and its justifications in the protocols
- The IACUC member (PI or co-PI) did not recuse him/herself from voting of his/her protocol approval
- The IACUC meeting minutes lack important protocol review discussion and voting information



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Case scenario

Documentation - Protocol review	Question
<ul style="list-style-type: none"> ▪ The Program Description described the use of rodents for 'anesthetic practice' of an imaging study. However, there was no protocol or other document that had been reviewed and approved by the IACUC describing the use of rodents for those procedures. 	<ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?



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Case scenario – Why?

Why?	What?
<ul style="list-style-type: none"> ▪ To ensure proper care, all animal use within the institution must be reviewed and approved by the IACUC. 	<ul style="list-style-type: none"> ▪ The IACUC must review and approve all animals, including rodents for training purposes, used at the institution.



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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ A protocol for using animals in training programs had been approved by the IACUC. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Case scenario 12

<p>Protocol Review Considerations</p> <ul style="list-style-type: none"> ▪ The IACUC protocol template did not include some animal welfare concern topics: prolonged restraint, exceptions for social housing and scientific justification, use of non-pharmaceutical drugs, humane endpoints, qualification of visiting scientists for conducting animal work, etc. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The IACUC protocol template was revised and provided. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Case scenario

<p>Protocol Review Considerations</p> <ul style="list-style-type: none"> ▪ Protocol review was not adequately conducted for the following examples: 1. Protocols were approved without justification of the animal number. Additionally, any change in animal number was considered "minor amendment" and was approved without the IACUC review. 2. The approved protocol No. 304, tumor transplantation in mice had death as an endpoint without consideration or application of humane endpoints. 3. The protocol No. 264 was approved without details on surgical procedures and wound clips removal and post-operative analgesics. During the AAALAC site visit, the PI confirmed that the clips were never removed. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

<p>Why?</p> <ul style="list-style-type: none"> ▪ The Guide defines one of the responsibilities of the IACUC as protocol review, and that the membership of such committee includes at least one member from a nonscientific background (p. 24). ▪ The Guide also states that the "IACUC members named in protocols or who have other conflicts must recuse themselves from decisions concerning these protocols" (p. 26). ▪ Additionally, all protocols, and amendments that involve significant changes to an animal research protocol or change in animal number need to be reviewed and approved by the IACUC before animal studies begin (Guide pp. 14, 25-28). 	<p>What?</p> <ul style="list-style-type: none"> ▪ The institution must modify the protocol review process to comply with the recommendations in the <i>Guide</i>.
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ol style="list-style-type: none"> 1. A new public member/non-scientist and the existing member of the IACUC were added to the protocol review. 2. Protocol review process was modified to avoid the COI. 3. Protocol format was revised to add more detail on experiments including animal number justification and perioperative care. The new protocol format was provided. Protocol revision and IACUC review would be required for increasing animal number. The revised protocol No. 264 was included in the PSYC. 4. The protocol No. 304, which used death as an experimental endpoint, was discontinued. 5. The protocol review process was modified to evaluate humane endpoints and animal care. 6. A new "procedure record" form was added for record keeping. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Case scenario

Protocol Review Considerations – Pain/Distress

- Although there were 4 pain categories defined under SOP 0003, pain categorization of animal activities was not mentioned in the IACUC protocol template, resulting in inconsistent pain management expectations post manipulation.
- In protocol 0004 which involved gastric bypass surgery in mice, IACUC approved the protocol even though there was no mention of administration of analgesics as part of post-surgical care, and there was no specific justification on why analgesics was withheld.
- In protocol 0007 which involved coronary vessel ligation surgery in mice, the frequency and duration of pain medication was not specified in the protocol.
- During the pre-review process, although comments were made by the Attending Veterinarian regarding clarification of surgical procedures and medication usage, it was unclear how the comments were incorporated into the final approved document.
- These observations demonstrated insufficiencies in the process of animal pain/distress review by the IACUC.

Question

- Mandatory?
- SFI?

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Case scenario – Why?

Why?

- The proper use of anesthetics and analgesics is an ethical and scientific imperative, and unless the contrary is established, researchers should consider that procedures which cause pain in human beings may also cause pain in animals.

What?

- During the protocol review process, the IACUC must ensure that the use of analgesics has been appropriately addressed.

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Unit's Action & Council's Consideration

Unit's Action

- The IACUC meeting minute indicated that the IACUC voted to suspend the two animal use protocols and will require the PIs to re-apply using the new protocol template.
- Two SOPs were provided: on classification of pain category, and listed examples of procedures that would require the use of anesthesia, analgesia, or sedatives; and pain management, listing actions to be taken for typical clinical signs associated with mild, moderate, and severe pain in rodents.
- IACUC will strengthen the inspection of the use of anesthetics and analgesics.

Council's Consideration

- Fully Addressed?
- Partially addressed?

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Case scenario 15

<p>Wire-bottom caging for rodents</p> <ul style="list-style-type: none"> ▪ The SOP required only long term study (more than 9 months) should be housed in solid bottom cages or provide solid resting area in wire bottom cages. The IACUC did not require justification for housing rodents in wire bottom cages in each research project. ▪ For studies shorter than 9 months, rodents were housed in solid and wire bottom cages. Study director selected the cage type based on the sponsors requirement. If wire bottom cages were selected for studies shorter than 9 months, no resting board were provided. ▪ At the SV, no foot lesion was observed. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

<p>Why?</p> <ul style="list-style-type: none"> ▪ As stated in the <i>Guide</i> (P51), if wire-mesh flooring is used, a solid resting area may be beneficial, as this floor type can induce foot lesions in rodents. Pressure neuropathy may result when animals are housed on wire-bottom cages for extended periods of time. 	<p>What?</p> <ul style="list-style-type: none"> ▪ The IACUC should review the duration in SOP for use of wire-bottom caging for rodents and ensure that caging enhances animal well-being consistent.
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ Policy on wire-bottom caging use was approved. ▪ Solid bottom cages will be used for rodent as default method. ▪ Wire bottom cage usage need be to approved by IACUC. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Case scenario 16

<p>Protocol Review Process</p> <ul style="list-style-type: none"> ▪ Review of protocols 201811, 201801, 201861, and 201841 and associated IACUC minutes showed that the <u>PIs on these protocols, who were also IACUC members,</u> participated in the review and approval of their own protocols. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

<p>Why?</p> <ul style="list-style-type: none"> ▪ Page 26 of the <i>Guide</i> stated that "IACUC members named in protocols or who have other conflicts must recuse themselves from decisions concerning these protocols. 	<p>What?</p> <ul style="list-style-type: none"> ▪ To avoid conflict of interest, unit must ensure that the animal use proposal evaluation process effectively identifies and excludes PI from voting on their own protocols.
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ IACUC members will pay attention and exclude PIs in the protocol deliberation process moving forward. This was also reflected in the revised IACUC SOP. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Reporting animal welfare concerns
http://www.aaalac.org/accreditation/faq_landing.cfm
 Pages 23-24

AAALAC's expectation

- The institution **must** develop methods for reporting and investigating animal welfare concerns
- Employees should be aware of the importance of and mechanisms for reporting animal welfare concerns
- Reported concerns and any corrective actions taken should be documented
- Mechanisms for reporting concerns should be posted in prominent locations in the facility and on applicable institutional website
- Multiple points of contact are recommended
- The process should include a mechanism for anonymity...., protection from reprisals
- Training and regular communication with employee

- The reports will be investigated by IACUC and any necessary corrective actions will be taken.
- AAALAC International should be informed of the results of the investigation and any subsequent corrective measures.

Animal Welfare Reporting Issues

- No mechanism for reporting and investigating animal welfare concerns
- Personnel were not trained in how to report an animal welfare concern
- Instructions for reporting an animal welfare concern was not posted in prominent locations or on the institutional website

Case scenario 17

<p>Animal Welfare Concern Reporting</p> <ul style="list-style-type: none"> ▪ There was no mechanism for receipt and review of concerns involving the care and use of animals at the institution. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The unit provided a photo of posted signage for reporting animal welfare concerns and the draft of "Policy and Code of Practice for the Care and Use for Scientific Purposes". However, the policy have not been approved and no training was provided to the staff. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Retain as a mandatory issue? ▪ Retain as an SFI?
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Case scenario 18

<p>Animal Welfare Concern Reporting</p> <ul style="list-style-type: none"> ▪ The institute provided a drop box for reporting animal welfare concerns. IACUC chair was the only person who can access to open the box monthly. However, IACUC chair was also principle investigator of several studies. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

Why?

- The *Guide* (p 24) states “The process should include a mechanism for anonymity, compliance with applicable whistleblower policies.

What?

- The institute should provide adequate mechanism regarding personnel accessing the box for avoiding potential conflict of interest.



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Unit’s Action & Council’s Consideration

Unit’s Action

- The institute revised the IACUC policy that the drop box should be checked by an administrative staff who has received training on animal welfare and ethics, appointed by the IACUC Chair and approved by the IO. The policy was authorized by the IACUC, however multiple points of contact was not mentioned.

Council’s Consideration

- Fully Addressed?
- Partially addressed and retain as an SFI?
- Partially addressed and retain as a mandatory issue?



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Case scenario

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Animal Welfare Concern Reporting
Finding Description:

- Although there was description of animal welfare concern reporting in the SOP, however the SOP did not include a mechanism for anonymity, compliance with applicable whistleblower policies and protection from reprisals.

Question

- Mandatory?
- SFI?



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Case scenario 20

<p>Animal Welfare Concern Reporting</p> <ul style="list-style-type: none"> ▪ Mechanisms for reporting and investigating animal welfare concerns were established but personnel were not trained and no signage was posted in the facility or displayed on institutional websites. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Use of Non-Pharmaceutical-Grade Chemicals and other Substances

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AAALAC's expectation

- Whenever possible, pharmaceutical grade drugs must be used for clinical purposes
- If available and suitable, pharmaceutical grade compounds are preferred for experimental purposes
- **Several factors should be considered** by the IACUC when the use of non-pharmaceutical-grade compounds is proposed for a study.

- should be described and justified in the animal use protocol and be approved by the IACUC
- consideration should be given to the grade, purity, sterility, pH, pyrogenicity,, and animal welfare and scientific issues relating to its use

http://www.aaalac.org/accreditation/faq_landing.cfm

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Recent NPG Issues

- Non-pharmaceutical-grade (NPG) pentobarbital was used for euthanasia. The IACUC did not review or consider the *Guide's* recommendations for NPGs. The IACUC did not consider other anesthetic options.
- Non-pharmaceutical-grade pentobarbital was used as an anesthetic agent for invasive procedures, survival surgery, etc.

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Case scenario 21

<p>Non-Pharmaceutical-Grade Drugs</p> <ul style="list-style-type: none"> ▪ The availability of pharmaceutical-grade Ketamine, Xylazine, and Sodium Pentobarbital were limited, or not available. Tribromoethanol (TBE), urethane were used for rodent anesthesia, and NPG Sodium Pentobarbital for euthanasia. ▪ These drugs were listed in the SOP for animal users based on the recommendation of veterinarians. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The use of urethane for rodents was for terminal procedure - electrophysiological study, and was approved by IACUC. Researcher indicated gas anesthesia cannot be used in the electrophysiological equipment as it affected the signal. ▪ The unit is seeking new approach to acquire pharmaceutical grade alternative anesthetics. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed and retain as a mandatory issue? ▪ Partially addressed and retain as an SFI?
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Case scenario

<p>IACUC</p> <ul style="list-style-type: none"> ▪ NPG Pentobarbital sodium was used for anesthesia, analgesia, and euthanasia. PG Pentobarbital was <u>un</u>available. ▪ There was no IACUC consideration given to NPG and no evaluating the formulations for purity, sterility and/or other physical properties that could cause pain or distress to the animals. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Post-Approval Monitoring (PAM)

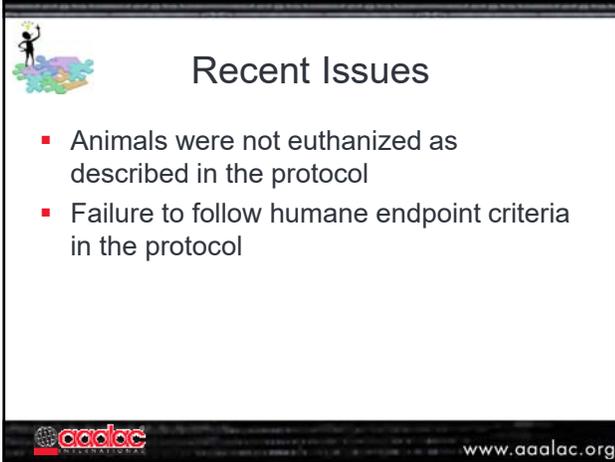
- **Methods stated in the *Guide*:**
 - Continuing protocol review: annual update or review
 - Laboratory inspection
 - Veterinary or IACUC observation of selected procedures
 - Observation of animals by animal care, veterinary and IACUC
 - External inspections and assessment

Pages 33-34

AAALAC expects that there will be a **system** for ensuring animal procedures conform with the approved protocol.

http://www.aaalac.org/accreditation/faq_landing.cfm

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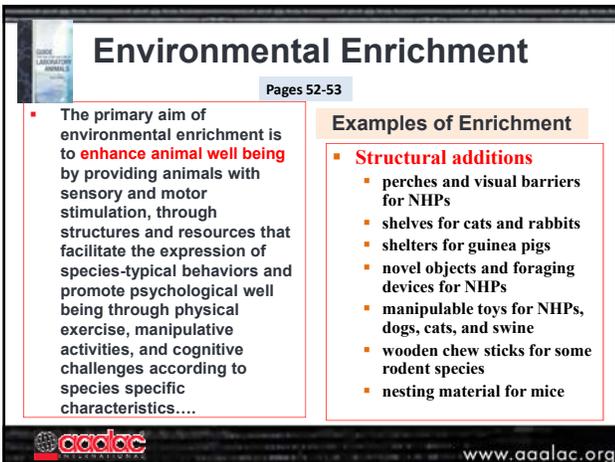
Recent Issues

- Animals were not euthanized as described in the protocol
- Failure to follow humane endpoint criteria in the protocol

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Environmental Enrichment

Pages 52-53

- The primary aim of environmental enrichment is to **enhance animal well being** by providing animals with sensory and motor stimulation, through structures and resources that facilitate the expression of species-typical behaviors and promote psychological well being through physical exercise, manipulative activities, and cognitive challenges according to species specific characteristics....

Examples of Enrichment

- **Structural additions**
 - perches and visual barriers for NHPs
 - shelves for cats and rabbits
 - shelters for guinea pigs
 - novel objects and foraging devices for NHPs
 - manipulable toys for NHPs, dogs, cats, and swine
 - wooden chew sticks for some rodent species
 - nesting material for mice

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Environmental Enrichment

Page 53

- Novelty of enrichment through rotation or replacement of items should be a consideration; however changing animals' enrichment too frequently may be stressful.
- Not every item added to the animals' environment benefits their well-being...
- Enrichment should be reviewed by the IACUC, researchers and veterinarian on a regular basis to ensure that they are beneficial to animal well being
- They should be updated as needed..
- Personnel ..should receive training in behavioral biology...

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Environmental Enrichment

AAALAC's expectation

- AAALAC expects that the enrichment program will be reviewed regularly by the IACUC, and that the IACUC adequately represents the research community and veterinarian(s) at the institution in the review of enrichment program.
- Environmental enrichment should be provided in a consistent manner across the animal program, with due attention to personnel and animal safety.
- Program implementation properly by adequate training of personnel.
- Personnel responsible for daily care should be adequately familiar with normal animal behavior such that abnormal behavior may be recognized and reported.

http://www.aaalac.org/accreditation/faq_landing.cfm

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Recent Issues

Environmental Enrichment (EE)

- No (EE) items
- Lack of nesting material for rodents
- Inconsistent provision of EE
- Inappropriate structural enrichment for rabbits, macaques
- EE procedures - lack of IACUC approval
- Lack of structural environment, i.e. resting area for rabbit, perches for macaques

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Case scenario 23

<p>Environmental Enrichment</p> <ul style="list-style-type: none"> ▪ Throughout the animal facilities, there was variable use of environmental enrichment devices and practices. All rodents had environmental enrichment while other species such as dogs and rabbits had no enrichment items. ▪ The nonaffiliated IACUC member had highlighted these deficiencies during the semiannual review; however, additional enrichment items had still not been provided. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

<p>Why?</p> <ul style="list-style-type: none"> ▪ The lack of a uniform environmental enrichment program may not effectively promote the well-being for all animals. ▪ The <i>Guide</i> emphasizes the importance of environmental enrichment, as one component of an IACUC approved behavioral management program that should be provided in a consistent manner across the animal program. 	<p>What?</p> <ul style="list-style-type: none"> ▪ The IACUC, in collaboration with the Attending Veterinarian and investigators, should establish a uniformly implemented program of environmental enrichment that promotes the expression of species-typical behavior and overall animal well-being, recognizing that in some cases, the application of environmental enrichment may not be appropriate for some studies.
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ Environmental enrichment plan will be updated. ▪ IACUC will review the plan and ensure full implementation. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Case scenario 24

<p>Environmental Enrichment</p> <ul style="list-style-type: none"> ▪ While most of rodents cages in the facility provided with enrichment items, in Room 30, <u>all singly housed mice cages were not provided with any enrichment.</u> There was no rationale for the exemption. Additionally in Room 41, 11 socially housed rodents cages did not have any enrichment. There was no justification in the approved protocol. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The enrichment SOP has been revised and implemented. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed? ▪ Retain as an SFI?
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Case scenario 25

<p>Environmental Enrichment</p> <ul style="list-style-type: none"> ▪ The implementation of enrichment program was inconsistently carried out, evidenced by lack of enrichment for cages of animals in room 1A (mice), R24 (rats), R34 (rats), and Room 2B (mice). ▪ The husbandry staff decided what combination of products to use. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

Unit's Action

- The AV revised the environmental enrichment SOP and clarified the standard practice for enrichment provision. Exemption from the program will require scientific justification and be approved by the IACUC.
- The revisions was approved by the IACUC.

Council's Consideration

- Fully Addressed?
- Partially addressed?



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AAALAC International's Application of Performance Standards - Rabbit Cage Height

Engineering Standard

- The 2011 *Guide* states that the recommended minimum cage height for rabbits is **16"** (40.5 cm)



Performance Standard

- The *Guide* states that animals must have enough space to express their **natural postures and postural adjustments without touching enclosure walls or ceiling**

AAALAC site visitors consider the health, welfare and species-typical behavior of the animal than small differences in cage height or size.

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Case scenario

<p>Microenvironment - Space</p> <ul style="list-style-type: none"> ▪ The rats housed in Room 5 were housed in cages that were of insufficient height. The cage height, excluding bedding, was less than 16 cm and animals were unable to make normal postural adjustments without contacting the cage ceiling. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The unit attached a purchase order for new caging that would meet the minimum Guide recommendations for cage height for rats. ▪ The cages had not been delivered. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed and retain as a mandatory issue? ▪ Partially addressed and retain as an SFI?
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Social Housing

- **Social housing will be the default method of housing unless otherwise justified** based on social incompatibility resulting from inappropriate behavior, veterinary concerns regarding animal well-being, or scientific necessity approved by the IACUC.
- When necessary, single housing of social animals should be limited to the minimum period necessary, and where possible, visual, auditory, olfactory and, depending on the species, protected tactile contact with compatible conspecifics should be provided.

<http://www.aaalac.org/accreditation/positionstatements.cfm>



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Social Housing AAALAC's Expectation

- **In the absence of other animals, additional enrichment should be offered**, such as safe and positive interaction with the animal care staff, as appropriate to the species of concern; periodic release into larger enclosures; supplemental enrichment items; and/or the addition of a companion animal in the room or housing area.
- **The institution's policy and exceptions for single housing should be reviewed on a regular basis and approved** by the IACUC and/or veterinarian.

<http://www.aaalac.org/accreditation/positionstatements.cfm>



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Social Housing & Social Experience

- When pair or group housing is not possible because of social incompatibility, veterinary concerns or scientific necessity, **AAALAC recognizes that there is a spectrum of possible degrees of social experience that can be made available** to an animal based on the species, health, and use of the animal.
- Examples include continuous access to full contact with conspecifics; part time access (e.g., overnight, when the animal is between studies, defined periods of time during the day, etc.) to **full contact** with conspecifics; and **protected contact** that allows interaction through a mesh panel, grooming bars or other type of perforated barrier on either a part or full time basis.

http://www.aaalac.org/accreditation/faq_landing.cfm



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Social Housing & Social Experience

- The staff responsible for the day-to-day management and oversight of the social experience of the research animals **should be well versed in recognizing aggressive and affiliative behaviors** of the various species in their care to provide for rapid identification and any necessary intervention.
- The Institutional Animal Care and Use Committee and veterinarian **should periodically review the strategies for providing social housing and social experience** of the animals at the institution to ensure conformance with the *Guide*.

http://www.aaalac.org/accreditation/faq_landing.cfm



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Recent Issues

Single Housing of Social Species

- Single housing of social species of animals without suitable reasons
- Single housing was allowed without any justification in the protocol
- Lack of suitable animal caging for pair or social housing
- Social housing policy was well written but not fully implemented



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Case scenario

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Social Housing

- Dogs not currently on study were singly housed, without evidence of IACUC review and approval, though it was described in the PD (page 35) that "monkeys and dogs are housed in pair".

Question

- Mandatory?
- SFI?



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Case scenario – Why?

Why?

- The Guide states that single housing of social species should be the exception.
- Social housing will be considered by AAALAC International as the default method of housing unless otherwise justified based on social incompatibility resulting from inappropriate behavior, veterinary concerns regarding animal well-being, or scientific necessity approved by the IACUC (or comparable oversight body). <https://www.aaalac.org/accreditation/positionstatements.cfm#social>

What?

- The unit must ensure compliance to its policy on social housing and exceptions for single housing must be reviewed and approved by the IACUC.



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Unit's Action & Council's Consideration

Unit's Action

- Social housing had been discussed in the IACUC meeting. It was emphasized that dogs must be housed in pair, and singly housed dogs must be reviewed and approved by IACUC.
- A new social housing policy was implemented and all dogs were housed in pairs.

Council's Consideration

- Fully Addressed?
- Partially addressed?



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Case scenario

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Social Housing

- Rabbits on multiple protocols 131, 130, 122 were singly housed in rabbit Rooms 3, 4 and 5. There was no evidence or veterinary approval that single housing was as a result of aggression or incompatibility, nor clear evidence or documentation for the experimental animals that the Institutional Animal Care and Use Committee (IACUC) reviewed and approved the exception to social housing based on scientific necessity. In addition, cages with individually housed animals lacked environmental enrichment. No cages available for social housing.

Question

- Mandatory?
- SFI?



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Unit's Action & Council's Consideration

Unit's Action

- the rabbits will be immediately moved to larger cages, and provided enrichment and rest areas, as well as the plans to purchase cages capable to accommodate social housing of rabbits.

Council's Consideration

- Fully Addressed?
- Partially addressed and retain as a mandatory issue?
- Partially addressed and retain as an SFI?



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Case scenario

29

Social Housing

- There was a written policy regarding social housing of animals, (Husbandry of Canine, which stated that all animals should be socially housed). However, all of the dogs housed on site, whether on or off study, were singly-housed. Also, Protocol 018 (PK Studies in Beagle dogs) did not indicate the possibility of single housing animals. There were no caging for Social housing of dogs.

Question

- Mandatory?
- SFI?



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Unit's Action & Council's Consideration

Unit's Action

- Unit revised the policy indicating that single housing will be performed based on study requirement.
- The details will be listed in study protocols, but the document does not get reviewed by the full IACUC.
- Budget will be sought to purchase new caging.

Council's Consideration

- Fully Addressed?
- Partially addressed and retain as a mandatory issue?
- Partially addressed and retain as an SFI?



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Case scenario

<p>Social Housing</p> <ul style="list-style-type: none"> ▪ All guinea pigs and rabbits were singly-housed because there were no cages suitable for group housing. ▪ The Institutional Animal Care and Use Committee (IACUC) did not consider single housing in terms of scientific justification. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The institution ordered new cages, which meet the recommendation of the Guide and anticipated to install them within the next 3 months. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed and retain as a mandatory issue? ▪ Partially addressed and retain as an SFI?
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Case scenario

<p>Social Housing</p> <ul style="list-style-type: none"> ▪ Social housing was considered as the default method, but there were deficiencies in the IACUC oversight of the animal care and use program as follows: <ol style="list-style-type: none"> 1. In the animal used protocol G11 which have been approved by IACUC stated social housing applied for this study, but in the study protocol, single housing was used for male mice. During the animal facility tour, male mice on this study (13 weeks repeat dose toxicity study with 4 weeks recovery period) were all singly housed without IACUC approval. 2. Nearly 200 NHPs for study B21 were single housed during acclimation period since Jan 16 this year. The approved protocol stated that social housing applied for this study. During the facility tour, the single housing NHPs were aggressive and angry, while the social housed NHPs in playground were all very calm. 3. Dogs on study G11 were single housed in pens. In the AUP the scientific rationale given by study director was potential cross contamination. Actually it was two connected pens, staff need to cross one pen to access the other dog for feeding, watering, dosing and observation. No detailed information been stated in the protocol on what kind of potential cross contamination was the concern. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ Social housing in the IACUC approved protocol G11 was limitation of the software design, so they can't give more detailed information. As in the approved policy, male mice is the exception for social housing, so the IACUC deemed to approved the protocol with single housing male mice. The software will be modified to give exact housing status. ▪ All NHPs were socially housed. ▪ The policy was revised and approved. The policy removed the conditions for single housing. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Case scenario 32

<p>Social Housing</p> <ul style="list-style-type: none"> ▪ Most nonhuman primates (NHP) and dogs were singly-housed. There was no evidence or veterinary approval that single housing was a result of aggression or incompatibility, nor clear evidence or documentation for the experimental animals that the IACUC had reviewed and approved the exception to social housing based on scientific necessity. ▪ Cages with individually housed animals lacked additional environmental enrichment, and although an exercise regimen for a 10 minute daily social experience in dogs was mentioned; however, there was no evidence of this activity taking place. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ A section on single housing was added to the protocol form. ▪ A policy of pair-housing would be the default for animals both on-study (experimental) and off-study (stock) but the approved policy was not provided. ▪ No information was provided as to the fate of currently single housed NHP and dogs, whether experimental or stock animals, whether they were now socially housed, nor whether the IACUC had reviewed these exceptions. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed and retain as a mandatory issue? ▪ Partially addressed and retain as an SFI?
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Case scenario

<p>Social Housing</p> <ul style="list-style-type: none"> ▪ A policy indicating social housing of rodents as the default, however the policy did not cover other social species including NHPs, rabbit, and zebrafish. ▪ Most of NHPs and all rabbits were singly housed. There were NHP protocols that justified singly housed and approved by IACUC, including after surgery (cranial implants) and fighting. However, the justification was general, and/or not all animals exempted had history of incompatibility/fighting/ aggression; nor underwent surgery. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ IACUC revised the policy to include NHP, rabbits, and zebrafish. ▪ The current housing was evaluated. Some of the monkey was approved for singly housing for metabolic study and related to their dominance; and some had history of incompatibility. It was clarified that the singly housing were approved by IACUC. ▪ Six (6) NHP was social housed; and 116 were singly housed (88 assigned under metabolic study; and 28 for neuroscience). ▪ Larger new rabbit cages that allowed social housing had been purchased and trial of social housing in the new cages had been started. ▪ The justification in the protocol was re-examined and considered adequate. ▪ Unit planned to constantly evaluated the policy and monitor the implementation. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Trio Breeding



- The *Guide* now states that 51 in² (330 cm²) are recommended for a dam with a litter.
- ETS 123 also states that 51 in² (330 cm²) is acceptable for a monogamous pair (outbred/inbred) or a trio (inbred).

http://www.aaalac.org/accreditation/faq_landing.cfm

AAALAC's expectation

- **Performance based criteria** for establishing and evaluating cage densities will continue to be considered paramount to determinations of appropriate cage size.


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Trio Breeding

AAALAC's expectation

- Cages that might be acceptable when litters are born may have insufficient space as pups grow, again depending on other factors.
- **The IACUC should consider many factors**, including national or regional regulations, policies and guidelines, as well as conditions of funding, and critically evaluate objective measures of outcome-based performance standards.

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Case scenario

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<p>Microenvironment – Cage Density</p> <ul style="list-style-type: none"> ▪ Overall animals are healthy. In Animal Room 1, Building C, at least four mouse cages containing two females with their pups and one male were observed to be overcrowded. The pups ranged from neonates to 13 days of age and came from different litters, mostly the same age per cage. The floor space of the housing cage was 575.64 cm². 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

Unit's Action

- The overcrowded cages had been weaned.
- IACUC discussed further and the revised the SOP. Based on the IVC cage size, to only use breeding configuration of 1:1 in both rats and mice, and requiring weaning on time. SOP had been modified and approved in the IACUC meeting.

Council's Consideration

- Fully Addressed?
- Partially addressed?



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Surgery in Investigator Laboratories



Page 144

AAALAC's expectation

- "For most **survival surgery performed on rodents and other small species** such as aquatics and birds, **an animal procedure laboratory, dedicated to surgery and related activities** when used for this purpose and managed to minimize contamination from other activities conducted within the room at other times, is recommended."
- The surgical area **should be dedicated** for that purpose while surgery is performed.
- For complex or long procedures, or if the layout of the laboratory does not permit a suitable dedicated surgical space, it may be advisable to temporarily stop other laboratory activities, thereby dedicating the laboratory to surgery in order to maximize the potential for a good surgical outcome.
- The investigator, IACUC (or comparable oversight body) and veterinarian **should evaluate** surgical areas to ensure they are appropriate.



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Case scenario

<p>Surgical Facilities</p> <ul style="list-style-type: none"> ▪ Numerous investigator laboratories were used for recovery major and minor surgical procedures in rabbits and rodents. The same areas also served as laboratories. ▪ The areas for conducting surgery were not sufficiently isolated from foot traffic and other activities in the laboratory and there were many contained cluttered and dirty benches or benches. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ Laboratory areas for rodent survival surgery was modified, and the dedicated area for performing rabbit survival surgery was established. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Disaster Planning and Emergency Preparedness

(facilities, humans and animals)

- Facilities **must** have a disaster plan
- Define the actions necessary to prevent animal pain, distress, and death due to loss of systems (power, HVAC, water, etc.)
- Describe how the facility will preserve animals in critical studies or irreplaceable
- Animals that cannot be relocated or protected from consequences of the disaster **must** be humanely euthanized.



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Disaster Planning and Emergency Preparedness

- Disaster plan should be approved by the institution and be part of the overall institutional disaster response plan



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Recent Disaster Plan Issues

- Disaster plan had no information regarding animals
- Disaster plan was not approved by the IACUC and/or was not implemented



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Case scenario 36

<p>Disaster Plan</p> <ul style="list-style-type: none"> ▪ The SOP "Disaster Plan" was reviewed, which included the measures and action plans for different kinds of emergencies. However, animals were not mentioned in the SOP. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

<p>Why?</p> <ul style="list-style-type: none"> ▪ Facilities must have a disaster plan which should define the actions necessary to prevent animal pain, distress and death, and preserve animals as necessary during disasters. If possible the plan should describe how the facility will preserve animals that are necessary for critical research activities or are irreplaceable. 	<p>What?</p> <ul style="list-style-type: none"> ▪ Animals that cannot be relocated or protected from the consequences of disasters must be humanely euthanized (<i>Guide</i>, p. 35). The IACUC must ensure animals are incorporated/covered in the disaster plan.
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The "Disaster Plan SOP" was revised, reviewed and approved by IACUC. Animal had been added in the Disaster Plan. Animals cannot be saved should be euthanized after veterinarian's evaluation. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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Case scenario 37

<p>Disaster Plan</p> <ul style="list-style-type: none"> ▪ Although the disaster plan was in place, but there was no information related to the animals that cannot be relocated or protected from consequences of the disaster must be humanely euthanized. 	<p>Question</p> <ul style="list-style-type: none"> ▪ Mandatory? ▪ SFI?
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Case scenario – Why?

<p>Why?</p> <ul style="list-style-type: none"> ▪ The <i>Guide</i> states (p.35) that Disaster plans should be established in conjunction with the responsible investigator(s), taking into consideration both the priorities for triaging animal populations and the institutional needs and resources. Animals that cannot be relocated or protected from the consequences of the disaster must be humanely euthanized. 	<p>What?</p> <ul style="list-style-type: none"> ▪ The disaster plan must be revised to meet Guide recommendations that animal must be euthanized when animals that cannot be relocated or protected from the consequences of the disaster.
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Unit's Action & Council's Consideration

<p>Unit's Action</p> <ul style="list-style-type: none"> ▪ The institution has modified Policy of "Disaster response plan for animal facilities" and animal treatments at the disaster were added to plan. ▪ The new policy became effective, and training was provided to relevant technical staff and husbandry staff. The new policy and training record also provided. 	<p>Council's Consideration</p> <ul style="list-style-type: none"> ▪ Fully Addressed? ▪ Partially addressed?
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