Policy 4439
Reporting Animal Care and Use Concerns Policy and Procedure

Responsible Entity: IACUC  
Responsible Official: IACUC Chair  
Effective Date: 10/10/12  
Last Revision: 9/14/16

4439.1 Background
Yale University is committed to the humane care and use of animals involved in research and teaching activities, which are integral to the fulfillment of the University’s mission to advance scientific knowledge for the betterment of society. The University takes seriously its responsibility to ensure that animals are treated humanely at all times.

Furthermore, Yale University is committed to conducting business ethically and complying with applicable federal, state and local laws and regulations, and University policies and procedures. Such behavior is expected of all Yale faculty and staff.

4439.2 Regulation
The regulations issued pursuant to the Animal Welfare Act (AWA) [9 CFR §2.31(c)(4)] (AWA) and the Public Health Service Policy, Section IV.B.4, (PHS Policy) require that the IACUC review, and, if warranted, investigate concerns involving the care and use of animals at the research facility (Institution) that result from received public complaints or reports of noncompliance from laboratory or research facility personnel or employees.

In accordance with the AWA, [(9 CFR Ch. 1), Part 2-Subpart C, 2.32 (c)(4)]: training and instruction shall inform how any employee of the facility can report deficiencies in animal care and use. “No facility employee, committee member or laboratory personnel shall be discriminated against or subject to any reprisal for reporting violations of any regulation or standards under the Act”.

The 8th edition of the Guide (the Guide) for the Care and Use of Laboratory Animals lists among the IACUC’s oversight functions the “establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution” (Program Oversight, Role of the IACUC, pg 25).
4439.3 Policy

Any individual having a concern about the care and/or use of laboratory animals at Yale University can (and should) report that concern. The concern will be investigated appropriately, and, if requested, the concerned individual will be notified of the progress/outcome of the investigation.

- Yale University ensures that no individual shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standard pertaining to an animal cared for or used under the Yale Animal Program.

- A concern or report can be made anonymously through the University Hotline. Whether or not made anonymously, all reviews and investigations will be dealt with confidentially to the extent reasonably possible.

4439.4 Guidance for Individuals with Concerns

- Any individual with concerns regarding animal care and use, animal handlers, adherence to approved protocols, or related matters can bring their concerns to the attention of the University by contacting any of the individuals or offices listed at the end of this policy document.

- If the individual is not sure a situation warrants official reporting, he/she is encouraged to seek guidance and additional information about the situation from a program representative, such as the University’s Attending Veterinarian, Veterinary Clinical Services, the Institutional Animal Care and Use Committee (IACUC) Chair or any Committee member, Office of Animal Research Support (OARS) staff, or a Yale Animal Resource Center (YARC) senior manager.

- When a program representative (e.g., Veterinarian, IACUC member, OARS staff) is contacted by an individual wishing to make informal or anonymous inquiries, the discussion should begin with the representative clearly disclosing the following:
  
  o The individual has the option of stopping the discussion and reporting their concerns themselves at any point via appropriate official channels.

  o If in the course of discussion, the individual determines the matter should be reported, if requested to do so by the individual, the representative can make the report on behalf of the individual to maintain the individual’s anonymity.

  o If the representative determines that the matter should be reported, but the individual disagrees, the representative is required to inform the IACUC Chair (who in turn may decide to take action) of the matter, without disclosing the individual’s identity.

4439.5 Procedure

The recipient of a report about a concern must notify the IACUC Chair/Designee as soon as possible. If the Chair is associated with the reported concern, the Vice Chair will assume the Chair’s responsibilities for the process. The IACUC Chair/Designee will:
1. **Initial Steps:**

   - If the reported activity, situation and/or condition is occurring and potentially involves an animal welfare concern, the Chair/Designee will request that the Attending Veterinarian (AV)/Designee initiate an immediate on-site assessment of the animal(s) and/or condition(s) and address any animal welfare issues under their authority.

   - If the reported activity, situation and/or condition is either not currently occurring or does not potentially involve an imminent animal welfare concern, the Chair/designee will notify the Institutional Official (IO), AV and IACUC Office Director of the reported concern. If any of these individuals are associated with the concern, they will not be notified at this point.

2. **IACUC Notification:**

   - The IACUC must consider all allegations of noncompliance of animal care and use, or animal welfare, and determine if there is sufficient reason to warrant further investigation based on regulatory requirements.

   - If the nature of the reported concern is such that the IACUC should discuss the situation before the next scheduled convened meeting, the Chair/Designee will call for a committee meeting to discuss the reported concern; business will not be conducted unless a quorum is present.

   - If notification prior to the next convened IACUC meeting is not required, the Chair/Designee will report on the reported concern and review and/or investigation process initiated at the next convened IACUC meeting. The IACUC can either accept the plan initiated or request a modification to the plan. The Chair/Designee will oversee any IACUC requested changes to the plan.

3. **Review/Investigation Team:**

   - The Chair/Designee, in consultation with the IO, AV, IACUC Vice Chair and/or the OARS IACUC Office Director, plus one committee member not holding a leadership title will determine the initial process for review of the reported concern. The specific approach to be taken will be determined on a case-by-case basis, and may include:

     - A review conducted by the OARS designee

     - Establishment of an IACUC subcommittee to conduct a more thorough review and/or investigation

       - When establishing an IACUC subcommittee, the Chair/Designee in consultation with some or all of the individuals listed in the first bullet under #3 above will select and then invite Committee members and, if appropriate, outside expertise to conduct the review and/or investigation. An OARS staff member will serve on the subcommittee to assist subcommittee members with process, scheduling information gathering sessions, obtaining records, record keeping and/or other administrative tasks as necessary.
Another approach agreed to by all individuals participating in the discussion.

- More thorough investigations are likely needed when:
  - it is not clear or there is a difference of opinion as to whether the allegation warrants investigation
  - it is clear that gross mistreatment of an animal has occurred
  - the initial approach to resolution did not result in a satisfactory conclusion, such that the report was made a second time
  - the reported concern involves repeated minor instances of noncompliance or mistreatment of an animal(s) by the same person(s)

- Once the subcommittee is formed, the Chair/Desigee will provide the group with expected deliverables.

4. Outcome of Review/Investigation:

- If during the initial phase of the review/investigation, the subcommittee thinks that the reported concern is reportable to OLAW, the office staff member supporting the subcommittee should notify the Chair/Desigee and the IACUC Office Director/Designee.

- Following completion of the review/investigative process, a report will be presented to the IACUC at a convened meeting. This report should include:
  - An introduction that includes a summary of the report
  - Members of the review/investigative group
  - A description of activities conducted as part of the review/investigation
  - Findings from the review/investigation
  - Conclusions from the review/investigation
  - Recommendations for addressing the concern and minimizing the chance of re-occurrence

5. IACUC Actions

IACUC response to the report may include, but are not limited to the following:

- Acceptance of the report and recommendations
- Acceptance of the report, but revision of the recommendations
- Rejection of either the report or recommendations, in which case the IACUC will determine appropriate resolution and/or corrective actions
- If protocol suspension is included in the IACUC approved resolution or corrective actions to the situation, the IO will be informed.

6. Reportable to Regulatory Agencies

- If the nature of the reported concern is such that OLAW should be immediately notified, the Chair/designee will contact OLAW by phone.
• If the review/investigation determines that the reported concern involves non-compliance or an animal welfare issue that is reportable to OLAW, but did not require an immediate notification (see above) the IACUC Office Director/designee and IACUC Chair/designee will jointly send an email to OLAW with the initial report.

• If an initial report to OLAW was filed, following IACUC acceptance of the subcommittee report and the recommendation(s), the OARS Office will draft the final report to OLAW. After approval by the IACUC Chair/designee and review and approval by the IO, the final report will be sent to OLAW by the IO on behalf of the IACUC.

• If the outcome of the review/investigation results in IACUC suspension of an approved activity, reporting is required to OLAW and/or the USDA.

7. Records of the Reported Concern

• The OARS designee and the IACUC Chair/designee will ensure that all documents related to the reported concern are retained by the OARS in a location dedicated to such reports for the required retention period.

• The OARS and the IACUC Chair/Designee will ensure that an up-to-date list of activities related to the review and/or investigation is maintained and that it includes the date, description of the activity and status of the process. This information will be retained by the IACUC Office for the required retention period.

• All documentation will follow the office business rules for redacting personal information in official reports while maintaining the details supporting the report.

• If the individual that reported the concern wishes to be notified of the outcome of the review/investigation and/or the recommendations of the reviewing/investigating body/IACUC, the IACUC Chair/designee will work with University officials to draft a response to the reporting individual.

4439.6 Training

Training and instruction shall be made available on how deficiencies in animal care and use can be reported by any individual.

To comply, the following training programs and information venues are used:

• A section about reporting animal care and use concerns is included in the IACUC on-line regulatory training course taken by all research staff and YARC personnel.

• The IACUC will review the Reporting Animal Care and Use Concerns Policy and Procedure on an annual basis at a convened meeting with a quorum present.
  o The IACUC Reporting Animal Care and Use Concerns Policy and Procedure documents will be reviewed as part of new IACUC member orientation and training.

Reporting instructions will be posted in prominent locations within the institution and reviewed during post-approval monitoring activities.
### Contacts

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<th>Individual/Office</th>
<th>Contact</th>
<th>Phone</th>
<th>E-mail/website</th>
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<tbody>
<tr>
<td>Attending Veterinarian</td>
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<td>University Hotline</td>
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<td>1-877-360-YALE (1-877-360-9253)</td>
<td><a href="http://www.mycompliancereport.com/yale">www.mycompliancereport.com/yale</a></td>
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### Revision History

6/17/02; 10/10/12; 11/13/13; 9/9/15; 9/14/16

### References

1. *Guide for the Care and Use of Laboratory Animals*, NRC, 2011;
2. IACUC Handbook, 2nd edition, 10-4-2006; J. Silverman
3. Public Health Service Policy on Humane Care and Use of Laboratory Animals, August 2002.
4. AWAR’s 9CFR Ch.1 2.31(c)(4); 2.31(d)(6)(7);2.32(b)(4)

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