

INSTITUTIONAL ANIMAL CARE AND USER COMMITTEE (IACUC)

POLICY ON REPORTING ANIMAL WELFARE CONCERNS

GENERAL POLICY

MGH institutional policy requires that animal care and use comply with all applicable federal, state, and local laws, regulations and policies including, but not limited to:

- [Animal Welfare Act and Regulations](#)
- [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#)
- [Guide for the Care and Use of Laboratory Animals](#), 8th edition
- [ACURO Regulations, Standards, & Requirements](#)

Principal Investigators (PIs) are responsible for ensuring that the members of their research team who are listed in approved protocols use proper procedures and techniques when performing animal experimentation. Certification of compliance with MGH policy is provided when the IACUC Protocol is signed by the PI and submitted to the IACUC for review and approval. The Attending Veterinarian, in his or her role as Director, Center for Comparative Medicine (CCM), is similarly responsible for ensuring that CCM animal care and veterinary staff use proper procedures and techniques in animal husbandry and veterinary care.

Any employee responsible for, aware of, or observing a deficiency in animal care or use, or who otherwise has concerns about care and use of animals at the institution, should report the deficiency or concern as outlined in this policy. A deficiency may include acts of perceived negligence, omission or non-compliance with approved protocols and IACUC policies, unintended accidental events with a negative impact on animal health and welfare, and intentional acts of cruelty towards laboratory animals. Retaliation against any employee reporting of a good faith issue or concern is prohibited. An employee's confidentiality will be maintained to the extent possible consistent with the need to conduct an investigation. An investigator who identifies an animal welfare-related incident, or a protocol or other non-compliance, within their own program, is also encouraged to self-report to the IACUC.

REPORTING PROCEDURES

Any employee who observes a deficiency in animal care or use should take the following steps:

- Note the date, time, building location, room number, and species of animal involved.
- Provide a complete description of the act, personnel involved, and observed circumstances. This description should contain sufficient details to allow proper assessment by the staff person receiving the report.

- Report the information either anonymously through the MGH/MGPO Compliance Helpline (617-726-1446), or by telephone, by mail, e-mail, or in person to members of the animal care and use program leadership identified in the animal welfare reporting poster ([Appendix 1](#)).

A poster with information on reporting animal welfare concerns is posted throughout all facilities and the IACUC policy on reporting is posted on the IACUC Website.

REVIEW PROCEDURES

All reports of deficiencies or concerns are reviewed by the IACUC compliance personnel for potential merit. This review may include a discussion with the reporting individual, research staff, veterinary personnel and/or a review of the approved protocol, medical records, or other documents. If no merit is found, a summary report is shared with the IACUC Compliance Subcommittee and a response is sent to the reporting individual. A summary of all reported concerns that were not investigated further due to lack of merit (based on the information provided), is provided to the IACUC at the next convened meeting.

If potential merit is found, the IACUC compliance officer convenes an investigative team to review the event. The team includes, at a minimum, the IACUC compliance officer or delegate, the facility veterinarian, and the PI or designee. Additional members will be included as appropriate, depending on the nature of the event.

The review of the event by the investigative team may include:

- Review of documentation such as the IACUC protocol, medical record, laboratory notebooks, security access logs, and/or submitted emails and reports by the research team or others.
- Interviews with pertinent personnel including the reporting individual (if not anonymous), research team members, facility staff or others.
- Review may also include a physical inspection of the animals and/or facilities involved. The facility or on-call veterinarian may take immediate action to protect animal welfare, as described in the [Policy on Adequate Veterinary Care](#) .

Violations of hospital policies outside of the IACUC's purview will be remanded to the appropriate hospital process.

The investigative findings will be presented by the IACUC compliance officer or delegate to the IACUC Compliance Subcommittee as a written report for discussion and review. The Compliance Subcommittee is comprised of the IACUC compliance officer, the IACUC Chairs, the Attending Veterinarian, the Director Animal Welfare Assurance (AWA), and a Scientist member of the IACUC, with the facility veterinarian as an ad hoc member. At a minimum, the IACUC Chair/Vice Chair or delegate or the Attending Veterinarian must be present for the subcommittee to meet. The Compliance Subcommittee may request further information or additional investigation as needed and may also make recommended revisions to the written

report for clarification purposes. The subcommittee will formulate proposed, recommended corrective actions for the IACUC's review, and will make a recommendation to the IACUC as to whether the event is reportable to the Federal agencies and AAALAC. The incident, and the recommendations from the subcommittee, will be presented to the IACUC by a member of the subcommittee at the next convened meeting. Following their review of the reported event, the IACUC may ask for additional information and/or further investigation. Once the committee agrees that they have the information needed to reach a decision, the IACUC will vote on whether the event is reportable, based on guidance and policy made available to the IACUC by the Federal and oversight agencies, and on institutional policy and procedure. The committee will also determine the appropriate corrective actions that must be put in place to prevent a recurrence of the event.

Corrective actions may include:

- Revisions to the approved protocol
- Reiteration of approved protocol practices and applicable IACUC policies
- Training/re-training of personnel
- Letter of notification/reprimand to personnel involved
- Temporary restriction on the use of animals in research by personnel involved
- Permanent prohibition of the use of animals in research by personnel involved
- Appropriate disciplinary action against personnel involved
- Remand to the appropriate MGH process if determined to be a case of misconduct in research or a serious violation of any other MGH policy
- Suspension or revocation of protocol(s).

The investigative findings and corrective action plan imposed will be reported in writing (email is acceptable) to the PI by an IACUC officer.

If there is a need for immediate action while the concern is being investigated, the investigative team, through the IACUC compliance officer, may convene a meeting of the IACUC Compliance Subcommittee to request immediate action to mitigate or correct a potential animal welfare concern. The meeting may be convened by teleconference. If a meeting cannot be convened within 24 hours, the IACUC compliance officer may notify any member of the IACUC Compliance Subcommittee to request immediate action. This action may include a request to the PI to stop the conduct of all animal research activity pertinent to the report, for whatever time is needed to complete the investigation. This action may also include the transfer of involved animals to a holding protocol or euthanasia of the animals involved. The IACUC Compliance Subcommittee member(s) may delegate this action to the IACUC compliance officer or facility veterinarian. The IACUC Compliance Subcommittee may also determine that a preliminary report to OLAW is appropriate at that time. Any such interim action will be included in the report to the IACUC Compliance Subcommittee and the IACUC.

APPEAL PROCESS

Once the IACUC has deliberated about a reported concern and decided on the corrective, and other, actions needed, any affected party may appeal such action by requesting to appear in person at the next regularly convened meeting of the IACUC, or by submitting a written request to the IACUC to reconsider their decision. A written request must be submitted to the IACUC compliance officer within 14 business days. This request will be reviewed by the convened IACUC at the next meeting.

INSTITUTIONAL REPORTING

The IACUC office will notify the PI of the committee's final determination, the corrective action plan and timeline, and whether the event was determined by the IACUC to be reportable to relevant regulatory agencies (i.e., OLAW, USDA, ACURO, funding agencies, etc.).

The outcome of reported concerns will be communicated to the concerned employee(s) when feasible, unless such concerns are reported anonymously.

The review and reporting process is summarized in [Appendix 2](#). The Standard Operating Procedure for reporting to OLAW is captured in [Appendix 3](#).

If, during the investigation, questions or concerns of interest to the institution and outside the direct purview of the IACUC are identified, they will be forwarded to the Institutional Official for further action. These may include human resource, research misconduct or other issues.

Reporting to OLAW

If the IACUC determines the event requires reporting to OLAW, the Director AWA submits a written report to the Director, Division of Compliance Oversight, OLAW on behalf of the Institutional Official. A verbal preliminary report will be provided to OLAW as appropriate.

Reporting to USDA

If the IACUC determines that an event involving a USDA-covered species warrants reporting to the USDA, the Attending Veterinarian with the Director AWA will make a verbal report to the USDA Veterinary Medical Officer (VMO).

Reporting to ACURO

If the convened IACUC determines that an event meets ACURO's definition of a significant deficiency, noncompliance, and/ or adverse event, the Director AWA will inform the investigator that the event must be reported to ACURO within 5 business days. In this case, either the investigator or the Director AWA will submit the report to ACURO. If the convened IACUC

suspends a DoD-supported or conducted research activity, if there is a change in the institution's AAALAC accreditation status, or if there is a socially-sensitive matter concerning, or potentially impacting, DoD-conducted or supported research activities, the Director AWA will notify ACURO within 5 business days. If USDA notifies the institution of an investigation related to a DoD conducted- or supported-study, the Director AWA will promptly notify ACURO within 5 business days of the initial notification. In any case, the Director AWA may make a preliminary inquiry regarding reporting to ACURO as needed.

Reporting to AAALAC

All reports to OLAW are forwarded to AAALAC for review. All other reporting to AAALAC follows AAALAC's reporting requirements.

RELATED POLICES

[Policy on Adequate Veterinary Care](#)

REFERENCES

National Research Council of the National Academies. [Guide for the Care and Use of Laboratory Animals, 8th edition](#). National Academies Press: Washington, D.C., 2011.

U.S. Department of Agriculture. [Animal Welfare Act and Regulations](#) (Animal Care Blue Book). Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1-4. 2020.

U.S. Department of Defense. [Institutional Notifications to the Animal Care and Use Review Office](#). U.S. Army Medical Research and Development Command, Animal Care and Use Review Office (ACURO): Fort Detrick, MD, 1 July 2020.

U.S. Department of Health and Human Services. [NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals](#). Office of Laboratory Animal Welfare, National Institutes of Health: Bethesda, MD, 2005.

U.S. Department of Health and Human Services. [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#). Office of Laboratory Animal Welfare, National Institutes of Health: Bethesda, MD, 2015.

v1.1, 16 February 2005
v1.2, 14 December 2011
v1.3, 16 January 2013
v2.1, 20 September 2017
v2.2, 20 June 2018
v2.3, 20 February 2018
v2.4, 16 June 2021
v2.5, 20 April 2022

Appendix 1. Animal Welfare Concerns Reporting Poster

Reporting Animal Welfare Concerns



Any MGH employee observing a deficiency in animal care or use is encouraged to report it as outlined below. A deficiency may include acts of perceived negligence, omission or non-compliance with approved protocols and IACUC policies, and intentional acts of cruelty towards laboratory animals.

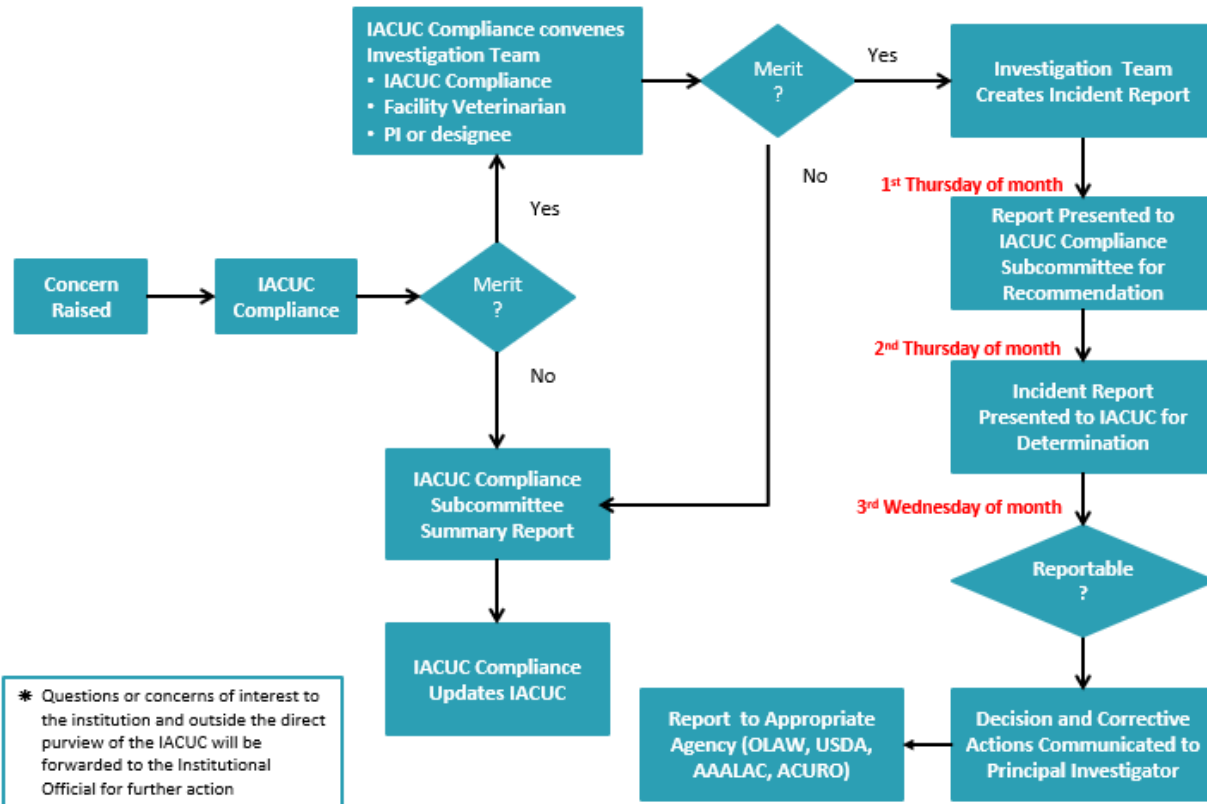
Hospital policy, as well as federal law, prohibits any discriminatory or reprisal measures being taken against any employee for reporting deficiencies in animal care or use.

MGH intends to protect, to the extent possible, the privacy of an individual who in good faith reports an apparent deficiency.

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Harry Orf, PhD Institutional Official & Senior Vice President for Research	BUL-2-240E	617-724-9079	horf@mgh.harvard.edu
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James S. Allan, MD, MBA IACUC Chair	FND-7	617-724-1103	jallan@mgh.harvard.edu
MGH IACUC Compliance mailbox			IACUCCompliance@mgh.harvard.edu
MGH/MGPO Compliance Helpline For Confidential & Anonymous Reporting		617-726-1446	

For more details, refer to the [IACUC Policy on Reporting Animal Welfare Concerns](#)

Appendix 2. Animal Welfare Concern Investigation Process Flowchart



Appendix 3. SOP for reporting animal welfare concerns to OLAW

1. Director Animal Welfare Assurance will draft a notification to OLAW summarizing the event, the species involved, and the corrective actions.
2. Director Animal Welfare Assurance will email the PI, IACUC contact, and Department Administrator (DA) a copy of the draft report. The email will include the IACUC protocol number and the dates of the event. The DA will be asked to provide a list of all funds charged for animal work during the period of non-compliance, including sponsored and sundry funds. Director Research Compliance MGH, Corporate Director Research Management Post-Award and Post-Award grant administrator will also be copied on the email to the PI.
3. The relevant funds identified by the DA will be listed on the report to OLAW. Director Animal Welfare Assurance will ask Director, Finance and Administration CCM for all animal invoice information for the protocol during the period of noncompliance as a cross-check for the information provided by the DA.
4. For events where no monetary adjustment is required (e.g., adverse event), the Director, Animal Welfare Assurance will email the draft report to the PI and IACUC contact as an FYI and will copy Director Research Compliance MGH and Corporate Director Research Management Post-Award as an FYI.
5. The IACUC Director forwards the report to the Institutional Official for review and signature and forwards the signed report to OLAW on behalf of the Institutional Official. The IO, Attending Veterinarian, IACUC Chair, Director Research Compliance MGH, and Corporate Director Research Management Post Award (as required) are copied on the email to OLAW.
6. Post-Award grant administrator will work with the DA to remove relevant charges from sponsored funds and will work with the PI to notify sponsor/prime awardee, as required.