



Institutional Animal Care and Use Committee (IACUC)

Guidance for IACUC Semiannual Inspections

Date of IACUC Review and Approval: June 2, 2017

- I. Purpose:** The intent of this guidance document is to define the requirements and process for the conduct of the Brown University IACUC's semiannual inspections of animal facilities and laboratories in an effort to increase transparency and ensure consistency. This guidance is intended for use by the members of the IACUC, the Animal Research Protection Program (ARPP), Principal Investigators (PIs), and facility managers responsible for the management and operation of animal research labs. The Brown IACUC strives to maintain a spirit of collegiality in its approach to semiannual inspections, and aims to leverage its face-to-face interactions with Principal Investigators, lab members and facility managers to provide education and increase awareness of policies and regulatory requirements.
- II. Definitions:**
- **Minor deficiency:** An identified problem for which an immediate solution is not necessary to protect life or prevent distress (e.g., peeling or chipped paint). Ongoing inattention to a minor deficiency may result in a chronic problem indicative of a programmatic failure and may constitute a significant deficiency (*Public Health Service [PHS] Policy on Humane Care and Use of Laboratory Animals*)
 - **Significant deficiency:** An identified problem that is or may be a threat to the health or safety of animals or personnel. Significant program deficiencies can result from an institution's failure to fully understand or implement some aspect of its animal care and use program required by the PHS Policy, or failure to function according to commitments made in its Assurance, and may reach the level of reportable noncompliance (*PHS Policy on Humane Care and Use of Laboratory Animals*)
 - **Satellite facility:** A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours
- III. Background:**
- a. All animal facilities housing live, vertebrate animals for research, testing or teaching purposes must be inspected by the IACUC semiannually¹ (no less frequently than once every six months). An animal facility includes buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, procedures or experiments.

¹ In accordance with the Animal Welfare Act Regulations, Sec. 2.31 Institutional Animal Care and Use Committee.

- b. Every IACUC member is expected to participate in semiannual inspections. IACUC members may not be excluded from an inspection if they wish to participate.
- c. The IACUC must have access to all approved Brown University animal facilities 24 hours/day, 7 days a week. Access is defined as the ability to enter an approved animal facility immediately for a pre-scheduled inspection and within two hours of an unannounced inspection. Any exceptions must be mutually agreed upon by the individual responsible for the facility and the inspection team.
- d. In accordance with PHS Policy, the inspection will be conducted using [*The Guide for the Care and Use of Laboratory Animals, 8th edition*](#) as a basis for evaluation. Any deficiency identified in the inspection report must be categorized as “minor” or “significant” and an appropriate time frame and a specific date for correction must be included.
- e. The inspectors may request the implementation of immediate corrective actions during the inspection or directly following the inspection, particularly for deficiencies that may have a substantial impact on animal health or human safety.
- f. Each inspection report must be submitted to the IACUC for review/approval and a summary of all findings must be included in the semiannual report to the Institutional Official (IO).
- g. PIs and/or facility managers must ensure that all deficiencies identified during the inspection are corrected within the time frame assigned by the IACUC, and confirmation of correction submitted in writing.
- h. Inspection of facilities used only for a short duration will be done, when possible, at a time when the animals are housed there.

IV. Procedures:

- a. **Scheduling of Inspections:** Routine, semiannual inspections are scheduled in advance. Although not required, the facility manager and/or PI is typically notified of the date and time of the inspections, as well as the rooms to be inspected. It is the responsibility of the facility manager / PI to ensure that the room numbers identified are accurate and that the list of rooms is complete. The facility manager/investigator or a designated alternate serves as a point-of-contact during the inspection of that facility. Random, unannounced inspections may also occur and will be organized by the Animal Research Protection Program (ARPP), the Post-Approval Monitoring Administrator, or the IACUC.
- b. **Inspection Team:** Inspection teams are comprised of the individuals necessary to maintain compliance with all applicable regulations. The inspection team will ordinarily include a minimum of two IACUC members, one of whom will be an Animal Care veterinarian. [PHS policy](#) allows the option of including *ad hoc* consultants to assist during inspections, in consultation with the IACUC or the IACUC Chair. IACUC members may not be excluded from an inspection if they wish to participate. In some facilities, special entry requirements for non-essential personnel are required because of controlled environments (e.g., specific pathogen free facilities) or special occupational health issues (e.g., Biosafety Level 3 facility). In an effort to minimize administrative burden on PIs and disruption of labs, Brown’s IACUC tries to coordinate its inspections with other groups within the University that also need to conduct inspections (e.g., Environmental Health and Safety).
- c. **Scope of Inspections:** The IACUC evaluates all aspects of the animal facility during the inspection including, but not limited to:
 - 1. Housing
 - 2. Environmental conditions
 - 3. Feed

4. Bedding
 5. Water
 6. Cleaning/sanitation
 7. Specialized space
 8. Animal care, including review of medical, procedural and post-operational records
 9. Personnel
 10. Occupational health and safety
 11. Infrastructure/construction
 12. Brown-owned vehicles used to transport animals
 13. Expiration dates, storage and proper labelling of substances administered to animals
- d. **Conduct of Inspections:** During the inspection, the IACUC assesses different aspects of the animal care and use program, as required by the [Office of Laboratory Animal Welfare \(OLAW\)](#) and the [USDA](#). Minor and significant deficiencies and any comments related to the inspected areas are documented. The inspection team will attempt to highlight all noted deficiencies to the PI/facility manager at the time of inspection; however, some deficiencies (i.e., protocol deviations) may not be known at the time of inspection, and will be determined only after the inspection team conducts a post-hoc review of its notes.
- e. **Corrective Actions:** Following the inspection, the ARPP sends a copy of the inspection report to the facility manager and/or the PI and assigns correct-by dates and preliminary categorizations (e.g., minor vs. significant²) for any noted deficiencies. The IACUC ultimately makes the final determination regarding the categorization of any identified deficiencies. It is the responsibility of the facility manager/PI to correct the deficiencies by the deadlines cited and to inform the ARPP when the corrective actions are completed.

The PI or facility manager may submit a written request for an extension, with appropriate justification, if the timeline for corrective actions is unattainable. The IACUC Chair or his/her designee will determine if the proposed extension may be granted. The ARPP documents these corrections.

Any significant deficiency that is not corrected by the assigned deadline (and for which an extension has not been granted) is reported to the Institutional Official (IO) and any appropriate regulatory agencies are notified.³ A minor deficiency that is not corrected by the specified date is reviewed by the IACUC and follow up action is determined on a case-by-case basis.

- f. **Reporting to the IACUC:** The semiannual inspection reports are provided to the IACUC for review and approval at its next convened committee meeting.⁴ The IACUC may require further actions, request an explanation of any finding, and/or request to modify the correct-by deadlines. The ARPP documents all meeting decisions, communicates additional requirements or requests to the responsible individuals, and coordinates appropriate resolution.

² Distinguishing deficiencies as “minor” or “significant” is required by the Animal Welfare Act Regulations.

³ As required by the Animal Welfare Act Regulations, program or facility deficiencies that are not rectified by the correct-by date will be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity.

⁴ In accordance with the Animal Welfare Act Regulations, the report must be reviewed and signed by a majority of the IACUC members and must include any minority views.

- g. **Reporting of inspections to the IO:** The semiannual program report to the IO includes a complete list of all facilities where inspections were conducted during the reporting period, dates of inspections, any deficiencies identified, corrective actions and timelines for completion of the corrective actions. Any delays or other issues related to the inspections are documented in this report.

V. Regulatory Reporting Requirements:

The IACUC adheres to the [Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals](#) and [AAALAC reporting requirements](#) when evaluating whether a deficiency identified during the semiannual inspection process requires reporting to an external agency. If the IACUC determines that a report to an external agency is required, the PI and/or facility manager will be sent a draft of the report to confirm accuracy before it is submitted to the outside agency.

VI. References:

1. Institute for Laboratory Animal Research, National Research Council. 2011. [The Guide for the Care and Use of Laboratory Animals, 8th edition](#). Washington, DC: National Academies Press.
2. Federation of Animal Science Societies. 2010. [Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd edition](#). Champlain, IL: FASS.
3. National Research Council. 2003. [Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research](#). Washington, DC: National Academies Press.
4. [Animal Welfare Act](#). United States Department of Agriculture Animal and Plant Health Inspection Service. November 2013. USDA-APHIS
5. <https://grants.nih.gov/grants/olaw/faqs.htm#649>
6. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>