



**Duke University & Duke University Medical Center
Animal Care & Use Program
Policy**



IACUC SEMI-ANNUAL INSPECTION PROCESS

PERFORMANCE STANDARD: IACUC Semiannual facility inspections will be performed in an efficient and comprehensive manner; deficiencies will be resolved appropriately and within the time frame defined by the IACUC.

BACKGROUND: Both the Animal Welfare Act (AWA) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals mandate that the IACUC perform semi-annual reviews of animal facilities and animal study areas. These regulations state that reports must contain any identified deficiencies, distinguish between significant and minor deficiencies, and contain a reasonable and specific plan and schedule for correcting each deficiency. Any failure to resolve a significant deficiency by the scheduled date set forth shall be reported to the Office of Laboratory Animal Welfare (NIH) and, if applicable, to the Animal and Plant Health Inspection Service (USDA).

PROTECTIVE POSTURES REQUIRED: N/A

ROLES:

1. The PI (or designee who is knowledgeable about the animal care & use) is responsible for:
 - a. Being present at the IACUC semiannual inspection;
 - b. Insuring that all records (e.g. controlled substance, environmental monitoring, etc) pertaining to the animal care or use are available for inspection; and
 - c. Responding to the notification of deficiencies memo describing the resolution of the deficiency (s).
2. The IACUC Vice Chairman is responsible for assigning IACUC members to the inspection team.
3. The OAWA is responsible for:
 - a. Coordinating the date of the inspection with the inspection team and the lab leader;
 - b. Consolidating the deficiencies post-visit;
 - c. Communicating the inspection team concerns with the laboratory;
 - d. Posting citations and responses in the database, and reporting to the IACUC outstanding items / laboratories.
4. The IACUC inspection team is responsible for recording deficiencies observed during IACUC Semiannual inspection.
5. The IACUC inspection team leader is responsible for relaying clear, accurate, and complete descriptions of inspection observations.

POLICY:

1) INSPECTION PROCESS:

- a) The OAWA Compliance Liaison will contact the PI (or designee who is knowledgeable about the PI's animal care & use laboratory) and coordinate the date and time of the IACUC inspection. The initial contact will generally occur 2 or more weeks prior to the scheduled inspection.
- b) The OAWA Compliance Liaison will prepare the necessary formwork (or laptop) for the visit and coordinate with the team leader necessary inspection details. <The OAWA will provide familiarization for the inspection team>
- c) The IACUC semiannual inspection team will inspect facilities and review procedures using the Animal Welfare Act (USDA regulations), The Guide for the Care and Use of Laboratory Animals, and the Public Health Service Policy, Duke IACUC Policies, Duke IACUC Guidelines, and DLAR SOPs as the reference documents.
- d) Deficiencies will be assessed as to 'Significant' or 'Minor.'
 - i) Significant: Those situations where there exists a direct threat to the health or safety of the animals (unrelated to the research objectives and/or not approved by the IACUC).
 - ii) Minor: Those situations that are not consistent with the references above and could impact the health or wellbeing Duke animals.
- e) During the inspection, the inspection team will observe and record any situation that is inconsistent with the above references.

2) IMMEDIATE ACTIONS FOR SIGNIFICANT CONCERNS: For observations that are classified as significant, the team will contact the Director, DLAR and / or the Director, OAWA as soon as practical. This direction and appropriate contact numbers are provided on the cover sheet that accompanies each team. DLAR and / or OAWA senior management will provide the necessary immediate steps to terminate animal distress and protect animal well being.

3) FOLLOW-UP ACTIONS POST-IACUC SEMI-ANNUAL COMMITTEE INSPECTION:

- a) The IACUC semiannual inspection subcommittee will record their observations and report these to the OAWA.
- b) The inspection team will determine which of the deficiency observations will be listed as 'significant' or 'minor.'
- c) The team will provide the Compliance Liaison, OAWA with a list of inspection results by individual room inspected.
- d) The Compliance Liaison, OAWA will forward to the PI (or designee):
 - i) All minor deficiencies.
 - ii) Any significant deficiencies: The Director, DLAR and/or Director, OAWA will likely have already resolved the significant issue, but within 3 business days of the inspection a notification email will be sent to the PI (or designee)
 - iii) All official reports will be sent to the PI (or designee) within 15 business days of receipt of complete information from the Subcommittee team.
- e) The PI (or designee) will reply with their response within 15 business days of the OAWA advisement.
- f) Failure to meet the timelines described above, will be reported to the IACUC for consideration of the appropriate disposition.

Appendix A

Site Visit Instruction Sheet
<Name of Building> BUILDING
IACUC SEMI-ANNUAL SITE VISIT
<Date of Inspection>

IF ANY ANIMAL WELFARE OR SIGNIFICANT CONCERNS ARE NOTED, PLEASE NOTIFY DR. RON BANKS (919-684-4744) OR DR. NORTON (919-681-6792) IMMEDIATELY

Site Visitors:

The tentative plan is for the two of you to meet at * beforehand so that you will be able to start the scheduled visit of the ** Building at 1PM.

Instructions:

1. Included you will find a set of forms to be used for inspection of laboratories and procedure rooms. You can list each room at the top of the column and mark any deficiencies that you find. Five rooms can be listed on each form.
2. You will also find a set of forms that can be used to take additional notes if specific deficiencies from the laboratories/procedure rooms need further explanation or clarification. These forms should also be used for any animal facility that is inspected as well.
3. Included is a list of the deficiencies from the previous visit. Please check to make sure that these have been corrected.
4. We have also provided labels for you to place on any CO2 chambers that you may find during your visit. One note of clarification when you do find CO2 chambers: The chambers should have a portion that is transparent so that the animals within the chamber can be visualized during euthanasia. The entire chamber does not have to be transparent, but a portion must be in order to allow for observation of the animals.
5. Please return the paperwork and clip board back to the Office of Animal Welfare Assurance at your earliest convenience. We need to know if you were not able to inspect any rooms during this visit, so that we can have a team go back before the end of the month to catch any of these rooms. Please sign all forms (both inspectors).

Thank you for all of your help with these visits and dedication to the IACUC,

Ron E. Banks, DVM, Dipl. ACVPM, Dipl. ACLAM, CPIA
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