

<b>IACUC Policy #:</b>	<b>320</b>
<b>Policy Title:</b>	<b><i>Progressive Action for Noncompliance with IACUC Deficiencies</i></b>
<b>Date Approved:</b>	<b>December 16, 2020</b>
<b>Date Reviewed:</b>	

**Purpose:** This policy establishes a standard procedure for progressive action for repeated noncompliance with deficiencies noted by IACUC during any facilities inspection. This policy does not apply to deficiencies which apply to animal welfare; the IACUC is empowered to suspend protocols for noncompliance with animal welfare issues.

**Rationale:** The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals Section IV.B.1. – 2.1<sup>1</sup> requires IACUC to inspect all of the institution’s animal facilities at least once every six months using the Office of Laboratory Animal Welfare (OLAW) Guide for the Care and Use of Laboratory Animals (The Guide) most recent edition as a basis for evaluation.

Additionally, the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) enforces the Animal Welfare Act (AWA) and requires the IACUC to inspect all the institution’s animal facilities at least once every six months using the Guide for the Care and Use of Agricultural Animals in Research and Teaching (The Ag Guide)<sup>2</sup>.

Deficiencies noted in semiannual facilities inspections are deemed to be either “minor” or “significant.” Minor deficiencies do not pose an immediate threat to the health and safety of animals, while significant deficiencies do. However, “ongoing inattention to a minor deficiency may result in a chronic problem indicative of a programmatic failure and may constitute a significant deficiency.<sup>3</sup>” Thus, repeated incidents of minor deficiencies, such as lack of training, husbandry or surgery records, cluttered labs, and so on, while not posing an immediate threat to the health and safety of animals, may themselves be an indication of a significant programmatic failure. Repeated minor deficiencies in the same laboratory are elevated to a significant deficiency, and must be treated in the same way as a significant deficiency, by progressive action and listed below for second and/or third communication and re-inspection.

**Policy:** The IACUC may conduct inspections of animal care and use facilities at any time, both announced and unannounced.

Following an inspection, the IACUC will communicate with the person responsible for the care and use of animals for that facility; this may include the Principal Investigator and the facility manager. This communication will be written, and will include a list of deficiencies identified by the IACUC, with a list of required remediation(s), and a date for re-inspection of the facility to ensure compliance.

Following re-inspection, if the deficiencies have not been adequately remediated, the IACUC will issue a second written communication to the responsible persons, listing the items still in noncompliance, and include another date for re-inspection. This second communication will be copied to the responsible persons' immediate supervisor, which may include the program director or dean- level of authority. The IACUC or the responsible persons may request a meeting to discuss the findings; such meeting must be held within a week of the date of the second communication, regardless of the supervisor's availability to attend such meeting.

Following the second re-inspection, if the deficiencies have not been adequately remediated, the IACUC will issue a third written communication to the responsible persons, listing the items still in noncompliance, and include another date for re-inspection. This third communication will be copied to the appropriate Vice Chancellor level. The IACUC or the responsible persons may request a meeting with the appropriate Vice Chancellor or equivalent authority to discuss the matters, if such meeting can be held within a week of the third communication. Re-inspection will not be delayed if the Vice Chancellor or other authority is unavailable during the specified time period.

If the re-inspection following the third communication continues to find deficiency, the IACUC may take enforcement action against the responsible persons. Such actions may include suspension of protocol, removal of one or more persons' permission to work with animals, or other actions deemed appropriate by the IACUC.

### References

1. National Institutes of Health Office of Laboratory Animal Welfare, <https://olaw.nih.gov/policies-laws/phs-policy.htm#FunctionsoftheInstitutionalAnimalCareandUseCommittee>
2. United States Department of Agriculture Animal and Plant Health Inspection Service Guide to the Care and Use of Agricultural Animals in Research and Teaching, [https://www.adsa.org/Portals/\\_default/SiteContent/docs/AgGuide3rd/Ag\\_Guide\\_3rd\\_ed.pdf](https://www.adsa.org/Portals/_default/SiteContent/docs/AgGuide3rd/Ag_Guide_3rd_ed.pdf)
3. PHS Policy on the Humane Care and Use of Laboratory Animals, Program Review and Inspections of Facilities, <https://olaw.nih.gov/guidance/faqs>