***Guide* Departures Checklist: Must Statements**

## About the checklist

The *Guide* Departures Checklist: Must Statements is provided to assist the Institutional Animal Care and Use Committee (IACUC) in identifying IACUC-approved departures from the *Guide for the Care and Use of Laboratory Animals: Eighth Edition* ([*Guide*](https://olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf))*.* The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](http://grants.nih.gov/grants/olaw/references/phspol.htm)), [IV.B.3](https://grants.nih.gov/grants/olaw/references/phspol.htm#FunctionsoftheInstitutionalAnimalCareandUseCommittee)., requires that the IACUC prepare reports of their semiannual program reviews and animal facility inspections and submit the reports to the Institutional Official (IO). Among other items, the reports must:

* contain a description of the nature and extent of the institution's adherence to the *Guide*
and the PHS Policy
* identify specifically any departures from the provisions of the *Guide* and the PHS Policy, and
* state the reasons for each departure.

The provisions of the *Guide* are stated in terms of standards that **must** be met, standards that **should** be met, and standards that **may** be met. IACUC approval of departures from the *Guide* must be based on scientific, veterinary medical, or animal welfare issues.

## How to use the checklist

This checklist is a tool to assist the IACUC in identifying IACUC-approved departures from the. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist.

 **The checklist covers the major topics of the *Guide* that may involve an IACUC-approved departure.**

***Must*** *statements are not presented in their entirety, and should be cross-referenced with the cited Guide page for complete detail.*

The checklist does not replace the *Guide* but should be utilized in conjunction with the *Guide* to determine if the departure is reportable in the semiannual report*.* Relevant references and links to the *Guide* are noted. A column to identify departures that have been approved by the IACUC since the last review is included.

## Reporting Requirements

OLAW defines **must** as a minimum standard required of all Assured institutions. Deviation from “**must**” standards with IACUC approval is a departure from the Guide and **must be reported** in the semiannual report. Deviation from a “**must**” statement without IACUC approval is a noncompliance that **must be reported** to OLAW through the IO.

**Questions or comments**? Suggestions or comments should be e-mailed to: olaw@mail.nih.gov.

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**Date:**

In the table below, columns indicate the following:

**E** = Existing IACUC-approved departure

**N** = New IACUC-approved departure (include in semiannual report to IO)

**NA** = Not applicable

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| **Musts in the Guide** | **E** | **N** | **NA** |
| “This edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*) strongly affirms the principle that all who care for, use, or produce animals for research, testing, or teaching **must** assume responsibility for their well-being.” ([p. 1](http://www.nap.edu/openbook.php?record_id=12910&page=1)) |  |  |  |
| “Veterinary consultation **must** occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control is not possible.” ([p. 5](https://www.nap.edu/read/12910/chapter/2#5)) |  |  |  |
| “The institution **must** provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care…there **must** be an individual with assigned responsibility for daily animal care and use and facility management.” ([p. 14](http://www.nap.edu/openbook.php?record_id=12910&page=14))  |  |  |  |
| “All personnel involved with the care and use of animals **must** be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being.” ([p. 15](http://www.nap.edu/openbook.php?record_id=12910&page=15)) |  |  |  |
| “Veterinarians providing clinical and/or Program oversight and support **must** have the experience, training, and expertise necessary to appropriately evaluate the health and wellbeing of the species used in the context of the animal use at the institution.” ([p. 15](http://www.nap.edu/openbook.php?record_id=12910&page=15)) |  |  |  |
| “Each institution **must** establish and maintain an occupational health and safety program (OHSP) as an essential part of the overall Program of animal care and use...The OHSP **must** be consistent with federal, state, and local regulations and should focus on maintaining a safe and healthy workplace” ([p. 17](http://www.nap.edu/openbook.php?record_id=12910&page=17)) |  |  |  |
| “Confidentiality and other medical and legal factors **must** be considered in the context of appropriate federal, state, and local regulations” ([p. 22](http://www.nap.edu/openbook.php?record_id=12910&page=22)) |  |  |  |
| “Preemployment or preexposure serum collection is advisable only in specific circumstances as determined by an occupational health and safety professional...the purpose for which the serum samples will be used **must** be consistent with applicable federal and state laws.” ([p. 22](http://www.nap.edu/openbook.php?record_id=12910&page=22)) |  |  |  |
| “The institution **must** develop methods for reporting and investigating animal welfare concerns” ([p. 23](http://www.nap.edu/openbook.php?record_id=12910&page=23)) |  |  |  |
| “The committee **must** meet as often as necessary to fulfill its responsibilities” ([p. 25](http://www.nap.edu/openbook.php?record_id=12910&page=25)) |  |  |  |
| “IACUC members named in protocols or who have other conflicts **must** recuse themselves from decisions concerning these protocols.” ([p. 26](http://www.nap.edu/openbook.php?record_id=12910&page=26)) |  |  |  |
| “Restraint devices…**must** be justified in the animal use protocol.” ([p. 29](http://www.nap.edu/openbook.php?record_id=12910&page=29)) |  |  |  |
| “Veterinary care **must** be provided if lesions or illnesses associated with restraint are observed.” ([p. 30](http://www.nap.edu/openbook.php?record_id=12910&page=30)) |  |  |  |
| “Facilities **must** therefore have a disaster plan.” ([p. 35](http://www.nap.edu/openbook.php?record_id=12910&page=35)) |  |  |  |
| “Animals that cannot be relocated or protected from the consequences of the disaster **must** be humanely euthanized.” ([p. 35](http://www.nap.edu/openbook.php?record_id=12910&page=35)) |  |  |  |
| “Animals maintained in outdoor runs, pens, or other large enclosures **must** have protection from extremes in temperature or other harsh weather conditions and adequate opportunities for retreat (for subordinate animals).” ([p. 54](http://www.nap.edu/openbook.php?record_id=12910&page=54)) |  |  |  |
| “At a minimum, animals **must** have enough space to express their natural postures and postural adjustments without touching the enclosure walls or ceiling, be able to turn around, and have ready access to food and water. In addition, there **must** be sufficient space to comfortably rest away from areas soiled by urine and feces.” ([p. 56](http://www.nap.edu/openbook.php?record_id=12910&page=56)) |  |  |  |
| “Hazardous wastes **must** be rendered safe by sterilization, containment, or other appropriate means before their removal from the facility” ([p. 73](http://www.nap.edu/openbook.php?record_id=12910&page=73)) |  |  |  |
| “Emergency veterinary care **must** be available after work hours, on weekends, and on holidays.” (p [74](https://www.nap.edu/read/12910/chapter/4#74)) |  |  |  |
| “Chlorine and chloramines used to disinfect water for human consumption or todisinfect equipment are toxic to fish and amphibians and **must** be removed or neutralized before use in aquatic systems” ([pp. 78](http://www.nap.edu/openbook.php?record_id=12910&page=78)-79) |  |  |  |
| “The biofilter **must** be of sufficient size (i.e., contain a sufficient quantity of bacteria) to be capable of processing the bioload (level of nitrogenous waste) entering the system.” ([p. 80](http://www.nap.edu/openbook.php?record_id=12910&page=80)) |  |  |  |
| “Chlorine and most chemical disinfectants are inappropriate for aquatic systemscontaining animals as they are toxic at low concentrations; when used to disinfect an entire system or system components, extreme care **must** be taken to ensure that residual chlorine, chemical, and reactive by products are neutralized or removed.” ([p. 86](http://www.nap.edu/openbook.php?record_id=12910&page=114)) |  |  |  |
| “The number, species, and use of animals housed in an institution may influence the complexity of the veterinary care program, but a veterinary program that offers a high quality of care and ethical standards **must** be provided, regardless of the number of animals or species maintained.” ([p. 105](http://www.nap.edu/openbook.php?record_id=12910&page=105)) |  |  |  |
| “All animals **must** be acquired lawfully” ([p. 106](http://www.nap.edu/openbook.php?record_id=12910&page=106)) |  |  |  |
| “compliance with any relevant statutes and other animal transportation requirements...**must** be met for animals” ([p. 107](http://www.nap.edu/openbook.php?record_id=12910&page=107)) |  |  |  |
| “Procedures **must** be in place to provide for emergency veterinary care both during and outside of regularly scheduled hours. Such procedures **must** enable animal care and research staff to make timely reports of animal injury, illness, or death.” ([p. 114](http://www.nap.edu/openbook.php?record_id=12910&page=114)) |  |  |  |
| “A veterinarian or the veterinarian’s designee **must** be available to expeditiously assess the animal’s condition, treat the animal, investigate an unexpected death, or advise on euthanasia.” ([p. 114](http://www.nap.edu/openbook.php?record_id=12910&page=114)) |  |  |  |

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| “In the case of a pressing health problem, if the responsible person (e.g., investigator) is not available or if the investigator and veterinary staff cannot reach consensus on treatment, the veterinarian **must** have the authority, delegated by senior administration...and the IACUC, to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary.” ([p. 114](http://www.nap.edu/openbook.php?record_id=12910&page=114)) |  |  |  |
| “All those involved in animal care and use **must** comply with federal laws and regulations regarding human and veterinary drugs and treatments.” ([p. 115](http://www.nap.edu/openbook.php?record_id=12910&page=115)) |  |  |  |
| “Researchers conducting surgical procedures **must** have appropriate training to ensure that good surgical technique is practiced...” ([p. 115](http://www.nap.edu/openbook.php?record_id=12910&page=115)) |  |  |  |
| “Antinociception occurs at a surgical plane of anesthesia and **must** be ascertained before surgery.” ([p. 122](http://www.nap.edu/openbook.php?record_id=12910&page=122)) |  |  |  |
| “Agents that provide anesthesia and analgesia **must** be used before their expiration dates” ([p. 122](http://www.nap.edu/openbook.php?record_id=12910&page=122)) |  |  |  |
| “Death **must** be confirmed by personnel trained to recognize cessation of vital signs in the species being euthanized.” ([p. 124](http://www.nap.edu/openbook.php?record_id=12910&page=124)) |  |  |  |
| “Because cryogen boil-off can lead to asphyxiation of both personnel and animals, rooms with MR scanners or in which cryogen gases are stored **must** be equipped with oxygen sensors and a method for increasing room ventilation to exhaust inert gases during cryogen filling...” ([p. 147](http://www.nap.edu/openbook.php?record_id=12910&page=147)) |  |  |  |
| “Biologic agents and toxins pose a threat to animal and plant health or public health and safety, and facilities in which they are used **must** adhere to APHIS, USDA, and CDC Select Agent Regulations...and/or other applicable federal, state, or local regulations.” ([p. 148](http://www.nap.edu/openbook.php?record_id=12910&page=148)) |  |  |  |