Comparison of Reporting Requirements for Deviations from the Provisions of the *Guide*

National Institutes of Health
Office of Laboratory Animal Welfare

Statement Type	Description	Example	Status	Report to IO?	Report to OLAW?	Guidance
A. Should or must with exceptions	Conduct of an activity according to a specifically described *Guide* exception.	Single housing animals with IACUC-reviewed scientific justification. [A.1.] IACUC-reviewed program SOP allowing deviation from housing policy for incompatible animals. [A.2.] Single housing arthritic dog for veterinary-related concern. [A.3.]	Not a departure	No	No	*Guide*
B. Must	Deviation from *Guide* must statement with IACUC-approved: • Scientific justification • Veterinary or animal welfare reason.	Housing animals in cages that do not allow natural postures to limit activity for scientific reasons. [B.1.]	Approved departure	Semiannual report	No	PHS Policy IV.B.3. PHS Policy IV.C.1.
B. Must	Deviation from *Guide* must statement without IACUC approval.	IACUC finds that satellite facility has no disaster plan. [B.2.]	Noncompliance	Promptly	Promptly	PHS Policy IV.F.3. NOT-OD-25-148
C. Should	Deviation from *Guide* should statement according to a locally established performance standard.	Trio breeding SOP with local performance measures to house mice in solid bottom cages with 71in^2 floor space. [C.1.]	Not a departure	No	No	NOT-OD-12-020
C. Should	Deviation from *Guide* should statement with IACUC-approved: • Scientific justification • Veterinary or animal welfare reason.	Not weighing animals weekly during food restriction study with IACUC-approved scientific justification. [C.2.]	Approved departure	Semiannual report	No	PHS Policy IV.B.3. PHS Policy IV.C.1.
C. Should	Deviation from *Guide* should statement without IACUC approval.	Post-approval monitoring determines that cage sanitation was not performed in accordance with the *Guide*. [C.3.]	Noncompliance	Promptly	Promptly	PHS Policy IV.F.3. NOT-OD-25-148

For more information, go to https://grants.nih.gov/policy-and-compliance/policy-topics/animal-welfare/compliance-topics/departures
References in [brackets] refer to examples below.

Examples

A. Conduct of an activity according to a specifically described exception listed in the *Guide*.

1. **Example:** In an animal study protocol, the PI requests single housing for her mice so that she can measure individual fluid consumption. After considering the specific details of the proposed experiment, the IACUC approves the protocol.
    i. *Guide: Social animals **should** be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility.* (page 51)
    ii. Discussion: This is a deviation from a should statement according to a specifically established exception in the *Guide* (experimental reasons). Exceptions are not departures from the *Guide*. It need not be reported to the IO in the semiannual report.
2. **Example:** Prior to implementing the *Guide* Eighth Edition, an institution had singly housed all rabbits. After trial attempts at social housing, the veterinarian determines that a current group of older male rabbits cannot be successfully socially housed. The facility manager and veterinarian prepare an SOP describing appropriate social housing of newly acquired rabbits which includes pairing of sibling does or neutered bucks. The IACUC approves an institution-wide SOP for social housing rabbits.
    i. *Guide: Social animals **should** be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility.* (page 51)
    ii. Discussion: The institution fulfilled the intent of the *Guide* should statement regarding social housing. Singly housing the older bucks is a deviation from a should statement according to a specifically established exception in the *Guide* (social incompatibility) and is not a departure from the *Guide*. It need not be reported to the IO in the semiannual report.
3. **Example:** The institution has previously housed all dogs in pairs. The veterinarian determines that one older dog can no longer be socially housed because of arthritis that requires specialized care and padded flooring. The veterinarian informs the IACUC of the circumstances for singly housing the dog based on veterinary medical and animal welfare issues.
    i. *Guide: Social animals **should** be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility.* (page 51) *Single housing of social species **should** be the exception and justified based on experimental requirements or veterinary-related concerns about animal well-being.* (page 64)
    ii. Discussion: This is a deviation from a should statement according to a specifically established exception in the *Guide* (veterinary-related concern) and is not a departure from the *Guide*. It need not be reported to the IO in the semiannual report.

B. Comparison of reporting requirements when deviating from a *Guide* must statement.

1. **Example:** PI proposes to confine dogs for 3 days in small cages to limit the dogs' ability to stand as part of a scientifically justified research requirement. IACUC reviews and approves the scientific justification and the protocol.
    i. *Guide: At a minimum, animals **must** have enough space to express their natural postures…* (page 56)

ii. Discussion: This is a deviation from a must statement of the *Guide* that has been scientifically justified by the PI and reviewed and approved by the IACUC. It is an approved departure and must be reported in the semiannual report to the IO.

2. **Example:** The IACUC learns that one of the satellite facilities has inadvertently been omitted from the disaster plan.

    i. *Guide: Facilities **must** therefore have a disaster plan.* (page 35)

    ii. Discussion: This is a noncompliance. The IACUC must develop a plan and schedule to correct this unapproved deviation from a must statement in the *Guide*.

C. Comparison of reporting requirements when deviating from a *Guide* should statement.

1. **Example:** The PI proposes to trio breed transgenic and inbred mice in solid bottom cages with 71 in^2 of floor space according to an SOP developed by animal facility personnel. The strains proposed are difficult to breed and generate small numbers of pups. The SOP addresses parameters of well-being and requires prompt weaning and separation of animals to avoid overcrowding. The SOP is based on local performance measures including growth rate, cage dimensions, and husbandry practices. The SOP has been reviewed and approved by the IACUC.

    i. *Guide: The space recommendations presented here are based on professional judgment and experience. They **should** be considered the minimum for animals housed under conditions commonly found in laboratory animal housing facilities. Recommended Minimum Space for Commonly Used Laboratory Rodents Housed in Groups. Female + litter, Floor Area/Animal in^2 = 51 in^2* (see Table 3.2, pages 56-57)

    ii. Discussion: This is a deviation from a should statement that follows a well-established performance standard, is not a departure from the *Guide*, and not reported in the semiannual report to the IO.

2. **Example:** In describing a food-restricted animal study, the PI stated that animals have to be anesthetized before weighing and cited data demonstrating the adverse effect of anesthesia on the animal's performance of behavioral tasks required in the proposed study. He cited other parameters of animal well-being that the research team will monitor and requested permission to weigh the animals monthly rather than weekly. IACUC reviewed and approved the request.

    i. *Guide: Regarding food-restricted diets, the Guide states: Body weights **should** be recorded at least weekly.* (page 31)

    ii. Discussion: This is a deviation from a should statement based on a scientific justification that has been reviewed and approved by the IACUC. It is an approved departure from the *Guide* and must be reported in the semiannual report to the IO.

3. **Example:** The PI's approved protocol includes having the research team sanitize solid bottom rodent cages in a satellite facility. The PI goes on sabbatical and the research team decides that sanitation every three weeks is sufficient. A post-approval monitor discovers the discrepancy and informs the IACUC.

    i. *Guide: In general, enclosures and accessories…**should** be sanitized at least once every 2 weeks. Solid-bottom caging…usually require[s] sanitation at least once a week.* (page 70)

    ii. Discussion: This is a noncompliance. The IACUC must develop a plan and schedule to correct this unapproved deviation from a should statement in the *Guide*