

INSTRUCTIONS FOR COMPLETION OF THE
ACORP APPENDIX 9 -- DEPARTURES FROM “MUST” AND “SHOULD”
STANDARDS IN THE *GUIDE*
(ACORP APP. 9 INSTRUCTIONS)
VERSION 4

These instructions provide detailed guidance on completing Appendix 9 of the ACORP, and are referenced to the numbers of the items in Appendix 9. ONLY complete this appendix if it is relevant to the protocol being submitted for review. The PI may use the ACORP Appendix 9 template provided in the RAMS application by using the link available in question 17 of section M.

Regulatory documents mentioned in the instructions are abbreviated as follows:

Guide – Guide for the Care and Use of Laboratory Animals, 8th ed., 2011

OLAW FAQs – Frequently Asked Questions – PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/faqs.htm>)

PHS Policy – Public Health Service Policy on Humane Care and Use of Laboratory Animals

General Instructions:

Answer each question by completing the table provided or entering the requested information at the ►. Enter “N/A” for any item that does not apply to this protocol. The sections of the form will expand as needed.

To check an item, type “X” inside the () provided.

Define each abbreviation the first time it is used.

Header for Every Page. The header information for this appendix is pre-populated to match header for the Main Body of the ACORP to which it applies, to identify each page of this Appendix with that ACORP:

PI's last name: The PI's name is prepopulated

Protocol No. Assigned by the IACUC – This is a unique identifier for each protocol that is automatically generated by the system to the protocol as a whole

Official Date of Approval – This is the date of final and unequivocal approval by the IACUC, as defined in the PHS Assurance, which determines the due dates of the first annual continuing review and the triennial *de novo* review, as applicable. The IACUC committee will enter this date into the form when a decision is made.

PHS Policy (IV.B.3) requires that IACUC-approved departures from PHS Policy, including the provisions of the *Guide*, be reported to the Institutional Official in the report of each semiannual evaluation of the institutional animal care and use program. This appendix is to document the departures that have been approved by the IACUC for this protocol. The completed appendix may be copied for inclusion in semiannual reports.

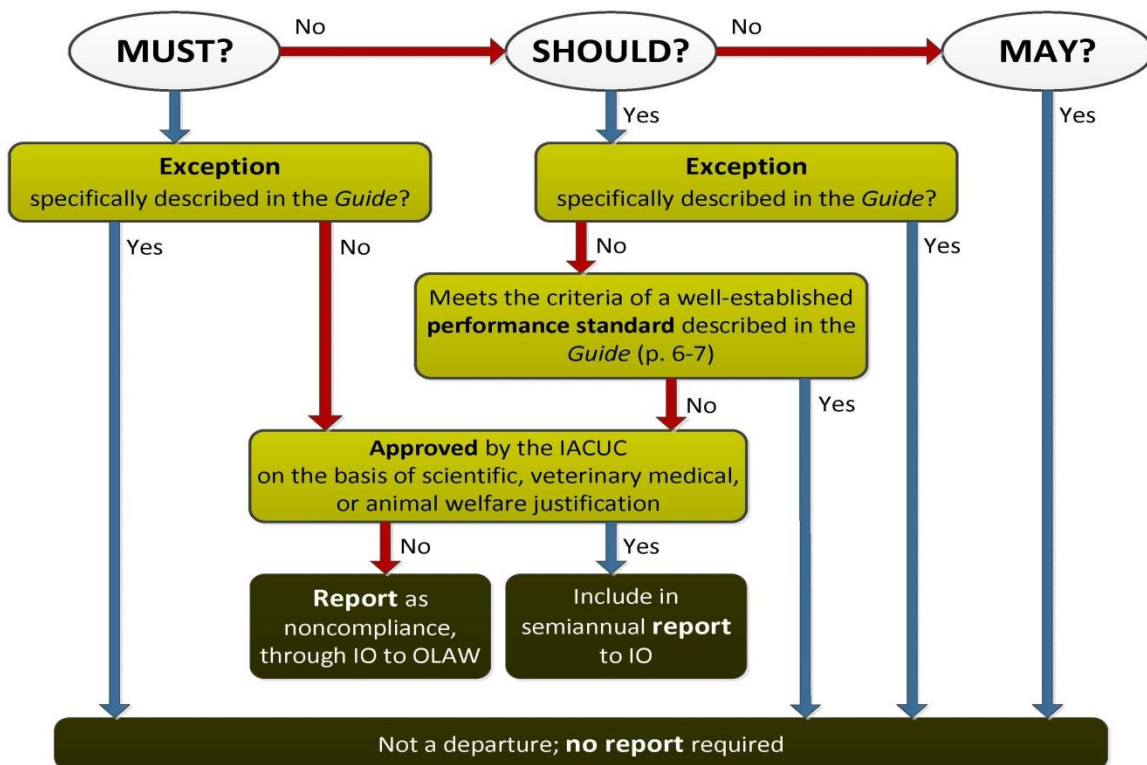
Consider each instance in this protocol that requires care or use of animals in a way that does not meet the general standards described in the *Guide*. These are all considered “deviations”, and most commonly appear in Items C.2.c, M, T, U, and V, and Appendices 2, 4, 5, 6, and 7 of the ACORP (procedures, husbandry, endpoint criteria, euthanasia, antibody production, antemortem specimen collection, surgery, transportation). Apply the series of test questions below to determine whether any of the “deviations” are considered “departures” and therefore must be documented in Appendix 9 (see also *OLAW FAQs* C.7):

1. Does the *Guide* describe the general standard as a “May” standard? If so, this is NOT a “departure”, and need not be documented in Appendix 9. Otherwise, for any “Should” or “Must” standard, proceed to the next question.

2. Does the *Guide* include an explicitly stated exception that allows for the “deviation”? If so, this is NOT a “departure”, and need not be documented in Appendix 9. Otherwise, proceed to the next question.

3. Does the “deviation” meet a well-established performance standard for a “Should” standard, according to locally-defined and continuously monitored performance measures? If so, this is NOT a “departure”, and need not be documented in Appendix 9. Otherwise, this IS a “departure”, and may be approved by the IACUC only if justified on scientific, veterinary medical, or animal welfare grounds.

The test questions above are summarized in the following flow chart:



For each IACUC-approved departure included in this protocol, provide the following information:

Briefly summarize the standard that is described in the *Guide* and reference the page numbers on which it appears.

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.

Provide the specific scientific, veterinary medical, or animal welfare considerations that justify this departure.