

**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

Canine, Feline and Non-Human Primate (Sensitive Species) Research Protocols

Original Release Date: 12/15/2017

Guidance Document: AR2017-001 (Rev 5)

Revised: May 3 and October 25, 2018, and January 29, April 22, and July 16, 2020

For questions on this guidance, email the Office of the Chief Veterinary Medical Officer: Dr. Alice Huang (alice.huang@va.gov) or Dr. Michael Fallon, CVMO (michael.fallon@va.gov)

Summary: The secondary review process, previously applied specifically to research funded by the Department of Veterans Affairs (VA) involving research with animals, and involving just secondary veterinary review, is now expanded to include all protocols for research with canines, felines, or non- human primates (NHPs) on VA property, regardless of funding source, or funded by VA ,at any performance site, and involves several more levels of review. Secondary veterinary review is performed by the office of the Chief Veterinary Medical Officer (CVMO), after protocol approval by the station's Institutional Care and Use Committee (IACUC), and then additional reviews will be performed by senior Veterans Health Administration (VHA) managers, depending on the species involved. Changes in approved protocols will not be routinely subject to further review, but those that require assignment of these species to United States Department of Agriculture (USDA) categories for greater potential pain or distress must be reported promptly to the CVMO's office, for evaluation of the need for further review.

Note:

- ***It is critically important to contact the CVMO's office as soon as possible when a new project subject to this guidance is being planned. The CVMO's office will provide detailed consultation and support in preparing the documents necessary for review.***
- ***Work with sensitive species, regardless of funding source, is not permitted to begin until Secretarial approval has been documented in writing.***
- ***It is illegal to spend VA funds on any studies involving sensitive species until written Secretarial approval has been granted.***
- ***Details of how the reviews are conducted are found in a separate ORD SOP. Contact the CVMO's office (below) for a copy of this document.***

1. **Background:** IACUC review of animal research protocols, long standard for publicly funded research in the United States, has consistently included evaluation of whether the use of animals and the choice of species are scientifically necessary, and whether the welfare of the animals is appropriately safeguarded. VA has for over 15 years provided a secondary Central Office veterinary review after IACUC review, to continually guide and improve the local IACUC process. To address recent public and Congressional concerns, VA has expanded the secondary review mechanism further, to apply to all research performed in VA involving canines, felines, or NHPs (termed “sensitive species”), as described in Section 3 below.
2. **Issue:** This guidance applies to protocols for research with canines, felines, or NHPs, as follows:
 - a. Each local program must ensure that work on any new proposed research with canines, felines, or NHPs to be conducted on VA property (with any funding source) or funded by VA (at any performance site), commences only after:
 - The project associated with the protocol has local Research and Development Committee approval;
 - The protocol has been reviewed, revised as needed, and approved by the local IACUC, and the Office of the CVMO;
 - A veterinary ethics review has been completed, with results provided to the Chief Research and Development Officer;
 - The protocol has been approved by the Chief Research and Development Officer, after review of the protocol and the results of the veterinary ethics review;
 - Additional review and approval required by senior VHA managers, at their discretion, has been completed.
 - Written Secretarial approval of the work has been documented in writing.
 - b. Each local program must disclose to the office of the CVMO any IACUC-approved change in a previously approved protocol that requires assignment of animals to a new USDA category because of greater potential pain or distress, within one week of IACUC approval of the change.
 - c. Annual reviews and triennial renewals of previously approved protocols that do not involve changes in potential pain or distress, as reflected in the assigned USDA categories, need not be routinely reported to the CVMO’s office.

- d. All animal protocols already underway at the release of this guidance will be subject to re-review by March 27, 2022, or earlier if the scope of the research changes significantly.
 - e. Animal protocols approved according to this guidance will have to be re-reviewed at intervals of no more than four years (shorter if the scope of the research changes significantly).
3. **Requirements:** The local program must provide the IACUC-approved protocol to the office of the CVMO and respond as instructed to the secondary veterinary review comments.
 4. **FY2020 Legislative Update.** Consistent with earlier legislative mandates, no new research studies involving sensitive species may begin after October 1, 2019 until reviewed and approved by the VA Secretary per the FY2020 VA funding legislation (“Further Consolidated Appropriations Act, 2020”, PL 116-94, 12/20/2019, Section 249). Section 249 has additional restrictions placed upon sensitive species research that must be met, such as a requirement that studies address a combat-related condition or illness.
 5. **Reporting:** Unless documents will be uploaded into the JIT system for a VA-funded project, they are to be sent as attachments by email to Dr. Alice Huang (alice.huang@va.gov) and Dr. Michael Fallon, CVMO (michael.fallon@va.gov).
6. **Revision History.**

- December 15, 2017. Original release for research with canines
- May 3, 2018, Revision 1. Protocols for work with felines and non-human primates added; existing VA Secretary’s review of canine protocols documented as new Section 5.
- October 25, 2018, Revision 2. Language in paragraphs 3.d and 3.e was revised to clarify when re-review of approved protocols must occur.
- January 29, 2020, Revision 3. Paragraph 5 was updated to reflect language in the FY2020 funding legislation, including feline and non-humane primate research.
- April 22, 2020, Revision 4. The Summary was expanded to further emphasize that studies using sensitive species may not start until Secretarial approval is granted in writing, and that it is illegal to use VA funds for such studies until such approval is granted. The “sensitive species” rubric has been added multiple places, and item 5 was updated to reflect the FY2020 legislative mandate.
- July 16, 2020, Revision 5. A note was added to the Summary to clarify that the details of the secondary and higher level reviews are found in an ORD SOP, which is available from the CVMO’s office. Item 4 was expanded to not only note that the Secretary’s approval is needed, but that other restrictions are found in the FY2020 funding legislation.