Summary: The secondary review process, previously applied only to protocols for animal research funded by the Department of Veterans Affairs (VA), is now expanded to include all protocols for canine, feline, and non-human primate (NHP) research on VA property, regardless of funding source. Secondary 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 that require assignment of these species to United States Department of Agriculture (USDA) categories for greater potential pain or distress must now also be reported promptly to the CVMO’s office, but will not be routinely subject to 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 planned. The CVMO’s office will provide detailed consultation and support in preparing the necessary documents for review.
- Studies involving sensitive species, regardless of funding source, cannot begin until they have written Secretarial approval.
- It is illegal to spend VA funds on any studies involving sensitive species until written Secretarial approval has been obtained.

1. Background: IACUC review of animal research protocols has long 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. To address recent public and Congressional concerns about VA animal research, VA is expanding the secondary review mechanism to all canine, feline, and NHP (termed sensitive species) research performed in VA, as described in Section 3 below.

2. Issue: This guidance applies to canine, feline, and NHP protocols as follows:

   a. Each local program must ensure that work on any new proposed canine, feline, or NHP study to be conducted on VA property (any funding source) or funded by VA (any performance site), commences only after:
The project associated with the protocol has local Research and Development Committee approval;
The protocol has been reviewed and approved by the local IACUC, and the Office of the CVMO;
A VA Central Office ethics review has been completed;
The protocol has been reviewed and approved by the Chief Research and Development Officer;
Additional review and approval required by senior VHA managers, at their discretion, has been completed.

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 assigned USDA categories because of greater potential pain or distress 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 will change significantly.

e. Animal protocols approved using this guidance will need to be re-reviewed by the four-year anniversary of approval or earlier if the scope of the research will change 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 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.

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).
Revision History:
-December 15, 2017. Original release for canine research
-May 3, 2018, Revision 1. Feline and non-human primate protocols 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 include feline and non-humane primate research to reflect language in the FY2020 funding legislation.
-April 22, 2020, Revision 4. The Summary was expanded to further emphasize that studies using sensitive species could not start until they had obtained written Secretarial approval, and that it is illegal to use VA funds for such studies until such approval is obtained. The “sensitive species” rubric has been added multiple places, and item 5 was updated to reflect the FY2020 legislative mandate.