

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

Signatures Required for VA Protocols for Research with Animals
(Clarification by the Office of the CVMO)

DATE: November 23, 2020

Guidance Document: AR2020-001

(Rev. 1, May 24, 2022, to clarify the timing of the signatures required)

(Rev. 2, April 7, 2023, to update the circumstances under which signed certification statements are required.)

(Rev. 3, May 15, 2023, to clarify the discretion that the IACUC has with regard to the signatures.)

1. **Summary.** The applicable certification statements in the ACORP form (https://www.research.va.gov/programs/animal_research/documents.cfm#docs-c) must be signed for any protocol submitted for JIT processing.
2. **Background.** The instructions about signatures in the ACORP form (Item Z) say, “The typed names and dated signatures certify agreement with the terms of the ACORP, and are required as shown below for the Main Body and each of the attached Appendices for any ACORP that is to be submitted to VA Central Office for Just-In-Time approval prior to release of VA funding to support the work. Do not include signatures for any Appendices that do not apply, and which therefore should not be attached.” The guidance originally released in November, 2020, explicitly expanded this to ACORPs that will not be submitted for Just-In-Time (JIT) review.
3. **Issue.** Because it has become apparent that requiring the certification statements in the ACORP to be signed for all protocols adds burden but does not meaningfully impact compliance with regulatory requirements, this guidance is being updated to rescind the general expansion of the requirement to protocols not being submitted for secondary review. It is still important for the certification statements to be signed for each protocol that is submitted for secondary review, as this documents that the version of the protocol submitted is the version recognized by all relevant local personnel as the version in effect.
4. **Practical Implications.**
 - a. Effective immediately, signature of the applicable certification statements is required only for any protocol that is to be submitted for secondary review, but regardless of whether the protocol is documented on the ACORP form, or on the form of an affiliate whose IACUC is formally designated as the VA IACUC of record.
 - b. Protocols documented on the form of an affiliate IACUC serving as the VA IACUC of record must contain all of the information requested in the ACORP for IACUC review. Information not already collected on the affiliate’s form may be added within the form or in an appendix that is included in the IACUC’s review and approval. VA does not

- require the signed certification statements in Item Z of the ACORP to be reviewed by the IACUC, but they must be submitted along with the approved protocol for secondary review, and apply to the contents of the protocol on the affiliate's form, as long as the pages of the protocol and of the pages showing the certification statements and signatures are each labeled as in the header of the ACORP (PI name, local IACUC protocol ID, official date of IACUC approval).
- c. The signatures required for the applicable Appendices must be in place before the protocol is submitted for secondary review, but may be dated after the IACUC grants approval for the protocol. IACUC approval of the protocol includes approval by the IACUC of the information provided in the Appendices, but it is left to the discretion of the IACUC whether to require the certification statements for the Appendices to be signed before it grants approval.
 - d. The signatures of the Chair and Attending Veterinarian, required on every ACORP that is to be submitted for secondary review, certify the review and approval of the IACUC, so they must be dated on or after the date of that approval.
 - e. The signature of the PI is needed on the final version of the ACORP that is approved by the IACUC and submitted for secondary review. The PI may sign at the time of initial submission of the ACORP to the IACUC for review and approval, but if modifications are required by the IACUC before approval is granted, the PI must sign the modified version as well.
 - f. VA accepts either "wet" or digital signatures that are individually applied to each signature block. "Wet" signatures must be handwritten by the signer directly on a hard copy of the page being signed; pasted images of the signature are not acceptable. VA considers digital signatures valid only when they meet the criteria of VA Handbook 6510, "A digital signature is a specific electronic signature technology that allows the recipient to prove the origin of the document and to protect against forgery." Most commonly, this is accomplished with the "certificates" function of Adobe Acrobat, or by DocuSign. Documents with digital signatures must be submitted without being "flattened", so that the signature validation functions are active.