

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

Preliminary Pre-Decisional Notifications about Potentially Reportable Matters

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- 1. Summary.** It is important to provide preliminary pre-decisional notifications to the VA Office of Research Oversight (ORO), the VHA office of the Chief Veterinary Medical Officer (CVMO), and the NIH Office of Laboratory Animal Welfare (OLAW), even before the IACUC makes a formal determination of reportability, but OLAW's expectations differ in important ways from those of ORO and the office of the CVMO.
- 2. Background.** Preliminary pre-decisional notifications demonstrate attention to prompt reporting, and make it possible for the oversight entities to provide guidance and support to ensure that reporting meets regulatory requirements.
- 3. Issue.** We understand that there is some uncertainty in the field about the timing of preliminary pre-decisional notifications, and about what information is to be included. This is guidance for field personnel responsible for preparing and sending these notifications.

 - For ORO and the office of the CVMO, preliminary pre-decisional notification is to be provided as soon as possible after a matter comes to the attention of the IACUC that requires investigation as potentially reportable. It is understood that the circumstances of the matter may not yet be clear, and the notification does not imply any presumption about the outcome of the investigation. The notification nonetheless allows ORO and the office of the CVMO to be prepared to respond to any inquiries from the public. For this, it is sufficient to provide just enough information to characterize the matter (which species was involved, the general nature of the concern raised, whether there are known impacts on animal health or welfare), and to convey the current status of the investigation.
 - For OLAW, the focus is on supporting institutions to demonstrate prompt reporting, rather than being able to respond as ORO and the office of the CVMO do to inquiries about events at individual institutions. OLAW also oversees a much larger number of institutions than do ORO and the office of the CVMO, so it is important, when possible, to focus specifically on matters that are most likely to be reportable. Therefore, OLAW encourages programs to wait until someone with regulatory expertise (examples include the Chair and the Attending Veterinarian) believes that the matter will be found by the IACUC to be reportable, before providing OLAW with a preliminary pre-decisional notification. Personnel investigating the incident should be encouraged to consult with the

office of the CVMO and OLAW, as needed. OLAW will then open a case in preparation for receiving the formal report. The information to be provided about the actual matter in a preliminary pre-decisional notification to OLAW is the same as for ORO and the office of the CVMO. Additional information to include in reports to OLAW is the role(s) of those who evaluated the available information and reached the conclusion that it is highly likely that the matter will be reportable. It is still possible at this point that new information may emerge in the investigation that changes what is understood about the matter, and the IACUC may determine that it is not reportable. OLAW recognizes this and accepts that on occasion, cases opened on the basis of preliminary notifications may wind up getting closed with no report. Programs should make every effort to avoid providing notification to OLAW of matters that turn out not to be reportable.

- In any case, for ORO, the office of the CVMO, and OLAW, a follow-up communication about the final determination of the IACUC is important. If the final determination is that the matter is reportable, the formal report is the follow-up communication. If the final determination is that the matter is not reportable, follow-up communication is to confirm that that is the case. It's valuable to include a brief explanation of the basis of the determination (e.g., PAM inspector misread the protocol). Such follow-up is best communicated in the same way as the preliminary pre-decisional notification was provided.