**IACUC Training Exercise #3 – 2020 (Responding to a Level 2 score)**

The following exercise may be useful in stimulating discussion regarding compliance with PHS Policy and VA Handbook 1200.07. To facilitate discussion, page 1 of the exercise may be distributed to the IACUC members prior to a meeting. After a few minutes of discussion about the exercise during the meeting, the remainder of the exercise may be distributed to provide ideas for the committee’s consideration.

Dr. Lucy Pettigrew is one of the Hometown VAMC’s most prominent and well-funded physician scientists; she has a large research laboratory with a multitude of post-doctoral fellows and graduate students. The ACORP associated with her most recent VA-funded MERIT application received a Level 2 score. Dr. Pettigrew relies heavily on her lab manager and senior post-doctoral fellow to handle IACUC related issues; they promptly made the revisions that were needed to address the concerns that the IACUC office had communicated to them and submitted the response to the IACUC office. After the IACUC reviewed and approved the revised ACORP, Dr. Pettigrew, the IACUC Chair, and the Attending Veterinarian each signed and dated it. Soon after the response to the secondary review was uploaded in JIT, the ORD reviewer uploaded a note into JIT. Ann Marie, the IACUC Manager, was surprised to see that the JIT area had not been approved and wondered whether the ORD reviewer was having difficulty opening the file but found that the ORD reviewer had uploaded a note. The ORD reviewer’s note indicated several issues had been identified in the response to the L2 secondary review.

What issues with the response documents would cause the ORD reviewer to send a JIT note instead of a review of the response?

An ACORP that receives a Level 2 score contains concerns that are sufficiently serious that they must be addressed by the investigator and the local IACUC before funding can be released (see the table below).

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|  | **Score** | **Description** | **Action Needed by IACUC** |
| • | 2 | Concerns are noted that must be addressed by the local IACUC and PI before funding can occur, but work described in the ACORP(s) may continue. | *A response to each of the* ***level 2*** *concerns noted below must be reviewed and cleared by the CVMO* before funding can be released. Upload the following at <https://vaww.gateway.research.va.gov>:(1) a memo addressing the concerns, dated and signed by the PI, veterinarian, and IACUC Chair; and (2) (a) revised ACORP(s) approved by the IACUC.*The IACUC must review each of the* ***level 1*** *concerns listed and* *decide what response is needed. This action must be documented in the IACUC minutes* *and the changes required by the IACUC must be incorporated into the ACORP(s). All new information/text in the revised ACORP must be clearly indicated (**italics, bold font, underlined text, etc.)* |

Most responses to Level 2 concerns satisfactorily address the concerns that gave rise to the Level 2 score so the review of the revised ACORP results in a revised score of 1 or 0, and the JIT area is approved. When the response is not satisfactory, a note is provided to the station, generally for reasons such as those below, starting with the most serious reasons:

1. The response does not address the reviewers concerns because the investigator never received the actual secondary veterinary review detailing the Level 2 and Level 1 concerns to be addressed. Instead, the IACUC office has provided the investigator with a summary of the comments, perhaps with the intention of making the process more efficient for the investigator. Unfortunately, this can result in loss of important specifics, context, and/or explanations provided by the ORD reviewer, which makes it much harder for the investigator to satisfactorily address what the reviewer intended. Unfortunately, this has occurred at more than one VA station. A much better approach is for the IACUC office to simply forward the ORD reviewer’s comment sheet directly to the investigator.
2. The IACUC office provided the secondary veterinary review uploaded in the VA JIT Document Manager to the investigator, but the investigator did not adequately address some or all of the Level 2 concerns. When the IACUC reviewed the revised ACORP, the committee did not carefully evaluate whether the changes addressed the concerns indicated in the secondary review. The IACUC has a responsibility to review the comments of the ORD reviewer in terms of guiding the investigator to make the changes needed to secure approval in JIT, as well as for improving the quality of its review of future protocols. When an investigator submits a revised ACORP that does not adequately address all of the Level 2 concerns, the IACUC is expected to recognize this and bring it to the attention of the investigator. Allowing incomplete responses to be submitted in JIT only delays the processing and may result in another Level 2 score.
3. The revised protocol was not accompanied by the required memorandum, signed and dated by the investigator, IACUC Chair, and Attending Veterinarian, summarizing the responses to each of the concerns noted in the secondary review. Although revision of the ACORP is only required for L2 concerns before the Animal Research JIT area can be approved, the IACUC is expected to review all L1 concerns and decide what response is needed. The IACUC may require the investigator to address some or all of the L1 concerns in the revised protocol; this approach is preferred because all corrections will then have been made in the final approved version of the protocol. Alternatively, the IACUC may decide to address some or all of the L1 concerns in future protocols, which is acceptable but increases the likelihood that the L1 concerns be forgotten before the next opportunity to address them comes up. The memorandum should indicate, either way, what the IACUC decided should be done.
4. The changes to the revised ACORP are not identified (i.e. *italics, bold font, underlined text, etc.)* as specified in the instructions, which substantially slows the review process and increases the risk that changes may be missed, by the IACUC and by the ORD reviewer.

Should an investigator at your VA station receive a Level 2 score on a protocol submitted for JIT processing, the IACUC can most effectively assist the investigator in resolving the concerns by:

* adhering to the instructions shown in the table on the preceding page.
* ensuring the secondary veterinary review as written by the reviewer is provided to the investigator.
* ensuring the memorandum is formatted to present each concern, provide the response/explanation immediately following the concern, and specify the location (item number in the ACORP) where the text of the protocol has been revised – investigators may find it useful to think of this as analogous to the approach that they take routinely as authors when responding to reviewer comments about a manuscript that has been submitted for publication.
* ensuring all changes to the revised protocol are clearly indicated.

If either the investigator or the IACUC has questions about how to address specific concerns raised in the secondary veterinary review, they are encouraged to directly contact the ORD reviewer; the reviewer’s email and phone number are provided on every secondary veterinary review immediately before the itemized list of concerns identified. The collective goal of the station’s IACUC and the Office of the CVMO is to assist the investigator in satisfactorily addressing the concerns raised in the review so the ACORP can be cleared in JIT, funding can be released, and research can move forward.