**IACUC Training Exercise #1 2014**

 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 remaining pages of the exercise may be distributed to provide ideas for the committee’s consideration.

Ann Marie, the IACUC Coordinator at the Hometown VAMC, was scheduled to take the Certified Professional IACUC Administrator (CPIA) exam in April. She had been studying for the last several weeks and was feeling pretty confident. Last week, the Hometown VA- IACUC conducted its semiannual program review and facilities inspection. Although the entire IACUC was invited to participate, Dr. Rossi (the IACUC Chair), Dr. Diaz (the Attending Veterinarian), and Dr. Sharp (another IACUC member) were the only IACUC members who actually performed the semiannual self-assessment review. At the request of the IACUC, the Chief of Engineering joined the team when they inspected the animal facility. Ann Marie accompanied the team as the official recorder of the team’s findings. She had downloaded the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities from <http://www.research.va.gov/programs/animal_research> to make sure the IACUC inspection team had the most current form and conducted a thorough and proper review.

At today’s meeting of the Hometown VA-IACUC, Dr. Rossi promptly called the meeting to order at 1:00 pm. Ann Marie noted that five of the seven IACUC members were present, only Drs. Patel and Wu, VA scientists were absent. The first item on the agenda was the semiannual evaluation report. Ann Marie passed out copies of the draft semiannual evaluation report, Dr. Rossi summarized the findings, reviewed the recommendations of the IACUC team, and asked if anyone had concerns or wanted to express a minority view. Hearing no objections, he asked for a motion to approve the report as written. Ms. Cox replied “I move that the semiannual evaluation report be approved as written.” Dr. Diaz seconded the motion. Dr. Rossi called for a vote; the report was approved unanimously and Dr. Rossi asked the members who conducted the semiannual self-assessment to sign the report. He also asked Ann Marie to make sure that the Chief of Engineering signed, as he was a participant. Dr. Rossi noticed Ann Marie had a pained expression, which worsened when one of the committee members present suggested not bothering with the Chief of Engineering’s signature, as the three members who conducted the assessment would constitute a majority of the quorum present at the meeting. Ann Marie abruptly stopped taking notes and asked if she could speak with Dr. Rossi in private.

What do you think Ann Marie was concerned about?

In this exercise, the committee has reviewed, approved, and is about to sign the semiannual evaluation report. Ann Marie seems to be concerned about Dr. Rossi’s and another IACUC member’s statements about who should sign the report and what constitutes a majority in regard to signing the report. She is right to be concerned, as both OLAW Guidance and VHA Handbook 1200.07 require the report be approved by the IACUC and signed by a majority of (all voting) IACUC members, to indicate their approval of the findings and conclusions of the evaluation, regardless of whether they participated personally in the review of the program or the inspection of the facilities. Likewise, it is also important to remember that the signatures of consultants, alternate members (unless taking the place of their assigned regular voting member), and other institutional (non-voting) participants are not relevant and should not be included. After Ann Marie’s counsel, Dr. Rossi requested that all voting members present sign the report.

Section D (shown below) from Part 3 (Post-Review Documentation) makes the point clear that a majority of all voting members must sign the report and then directs the IACUC to meet with and review the report with the Medical Center Director. The Medical Center Director is required to personally sign the report to confirm it has been reviewed. Only the Medical Center Director may sign the semiannual report; the Associate Chief of Staff or other VA officials may not sign in place of the Medical Center Director. Once the Medical Center Director has signed the report, it must be sent to the CVMO through the Medical Center Director within 60 days of the self-review date. A signed copy of the report should also be provided to the R&D Committee for review; it is not necessary to obtain R&D approval prior to forwarding the report to the CVMO.

**D. DOCUMENTATION of REVIEW and APPROVAL by IACUC MEMBERS.**  *A majority of all voting members (not merely a majority of a quorum) must approve and sign the report [1200.07 (8.f(1)(e)); 9 CFR (2.31(c)(3))]. The report must be completed within one month of the date of the semiannual evaluation to facilitate timely progress on any corrective actions required.*

**The undersigned verify that we**

**1) have reviewed and approved Forms 1 (Checklist, Parts A and B) and 2 (Table of Deficiencies and Departures),**

**2) have read any minority opinions appearing in item E of this report, and**

**3) hereby authorize IACUC representatives to review this report with the Medical Center Director:**

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| TYPED NAME | ROLE ON IACUC | SIGNATURE | DATE |
| ►[Alt: ] | Chairperson |  |  |
| ►[Alt: ] | Attending Veterinarian |  |  |
| ►[Alt: ] | Scientist with Animal Research Experience |  |  |
| ►[Alt: ] | Non-affiliated (Community) Member |  |  |
| ►[Alt: ] | Non-scientific (Lay) Member |  |  |

**Sources:**

<http://www.research.va.gov/programs/animal_research>

<http://grants.nih.gov/grants/olaw/sampledoc/ioreport.htm>)