**VA IACUC Training Exercise #2 – 2018 (Part 2 – Final Report)**



The following exercise may be useful in stimulating discussion regarding compliance with PHS Policy and VA Handbook 1200.07. To facilitate discussion, pages 1 and 2 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.

After Dr. Rossi emailed the preliminary report to OLAW [See IACUC Training Exercise #1-2018 (Part 1 – Preliminary Report) for details], he appointed a subcommittee consisting of two IACUC members and himself to investigate the matter further. The subcommittee reviewed Sylvia’s written account in which she described her observation of 20 rats assigned to Dr. McCormack’s approved protocol 1016; all the rats had healed skin incisions. Her report noted that protocol 1016 authorized Dr. McCormack to perform drug administration followed by a terminal procedure under anesthesia; survival surgery was not an approved procedure. The subcommittee verified Sylvia’s observations by visiting the VMU room where the rats with the healed skin incisions were housed; the Attending Veterinarian confirmed that all 20 rats were healthy. The subcommittee then decided to meet with Dr. McCormack as soon as he returned from his vacation.

Both Dr. McCormack and Sally were back at work on Monday morning, 2/12/18. As soon as Dr. McCormack greeted his secretary, she told him Dr. Rossi had scheduled a meeting to see him at 9:00 am and asked that Sally also be in attendance. Dr. McCormack was a bit surprised but assumed it was nothing serious. He began to feel uneasy when Dr. Rossi and two IACUC members entered his office at 9:00 am. Not one to beat around the bush, Dr. Rossi got right to the point of the meeting. He said the IACUC had received a report that 20 rats assigned to protocol 1016 had been found with healed skin incisions; survival surgery was not an approved procedure on protocol 1016. When Dr. Rossi said a preliminary report had already been sent to OLAW regarding this observation, Dr. McCormack was slack-jawed and Sally gasped. Dr. McCormack said it was a huge misunderstanding and that he and Sally had not done anything wrong. He showed the subcommittee his previous animal order for 20 rats on protocol 1036, his protocol approved for survival surgery. Sally said she hadn’t noticed until 2/5/18 that the printed cage cards listed “protocol 1016” instead of “protocol 1036”, but had immediately informed the VMU supervisor of the error. The VMU Supervisor had said that he would print new cards as soon as he returned to his office. Sally showed the subcommittee the email she had sent to the VMU supervisor reminding him to print new cage cards with the correct protocol number (i.e. 1036). Sally said she didn’t go back to the VMU to check and see whether the new cage cards had been placed on the rats’ cages later in the day because she had been feeling flu-ish and left work early.

The subcommittee then interviewed the VMU supervisor and asked what he knew about Dr. McCormack’s 20 rats assigned to protocol 1016. The VMU supervisor confirmed that Dr. McCormack had ordered 20 rats on protocol 1036 in January. He also acknowledged that Sally had told him that the cage cards were printed with the wrong protocol number and had followed up with an email. Somehow, protocol 1016 had been entered instead of 1036 when the cage cards were originally printed; the error went unnoticed until Sally discovered it last week. He had intended to print the new cage cards shortly after Sally reported the problem but he had forgotten because half the animal care staff was out with the flu, and he had gotten overwhelmed with husbandry duties. He had placed the new cage cards with the correct protocol number on the rat cages on 2/8/18 and made a notation to this effect on the room log sheet.

Do you think a reportable incident has occurred?

**Discussion:**

At the 2/28/28 IACUC meeting, the subcommittee informed the other members of their findings. They reported that Dr. McCormack had ordered 20 rats on protocol 1036, which was approved for survival surgery. Sally, Dr. McCormack’s technician, performed the surgical procedure as described in protocol 1036. She discovered the cage cards were printed with protocol 1016, not protocol 1036, several days later and reported the problem to the VMU Supervisor. Unfortunately, the VMU Supervisor had been unable to reprint the cage cards immediately because of extreme short staffing related to the flu epidemic. Based on this information, the IACUC concluded that protocol noncompliance had not occurred. Shortly after the IACUC meeting, Dr. Rossi sent the final report via email to OLAW (see below).

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From: Rossi, Carmine <Carmine.Rossi@va.gov> Sent: Wednesday 2/28/18 4:30 PM

To: olawdco@mail.nih.gov

Bcc: Segal, Ann Marie <AnnMarie.Segal@va.gov>

Subject: Final Report from Hometown VAMC-IACUC

The attached PDF file contains the final report of potential protocol noncompliance brought to your attention on 2/6/18.

Thank you for your consideration of this matter,

Carmine Rossi, MD

Chair, Hometown VAMC-IACUC

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February 28, 2018

Director, Division of Compliance Oversight

Office of Laboratory Animal Welfare

National Institutes of Health

Rockledge 1, Suite 360

6705 Rockledge Drive

Bethesda, MD 20892

In accordance with our PHS Assurance #AXXX-01 and consistent with VA agency policies, we are following up on the preliminary report provided on 2/6/18 by the IACUC Chair regarding an incident of potential protocol noncompliance. This research was funded by the National of Heart, Lung, and Blood Institute, which is copied on this report.

On 2/5/18, the Research Compliance Officer (RCO) discovered, and reported to the IACUC Chair, a group of rats with healed skin incisions that were assigned to a protocol that did not include survival surgery as an approved procedure. The IACUC members and the Institutional Official were promptly notified of this concern. Neither the principal investigator (PI) nor his research technician were available for questioning by the RCO immediately after this discovery. The rats with healed skin incisions were examined by the Attending Veterinarian and found to be in good health. An IACUC subcommittee was appointed to investigate the matter and met with the PI and his technician, once they returned to work on 2/12/18 and subsequently, interviewed the VMU Supervisor. The subcommittee determined through interviews and documentation provided that a data entry error had resulted in cage cards being printed with the incorrect IACUC approval number. The rat surgeries were in fact conducted appropriately according to an approved protocol, but not the protocol listed on the card. The research technician had notified the VMU Supervisor of the incorrect protocol number on the cards, but influenza had reduced staffing and delayed re-printing of the cage cards. A new SOP has now been approved that allows manual corrections on cage cards immediately upon discovery of any incorrect information and subsequent notification of the VMU Supervisor. After reviewing the subcommittee’s report, the IACUC voted that this incident was not reportable.

Should you have further questions regarding this matter, please contact the IACUC Chair at 555-121-0123 ext. 4567.Sincerely,

Agnes Devonshire

Agnes Devonshire, FACHE

Medical Center Director

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 As of 12/31/13, OLAW will only accept an institution’s final report electronically by email in PDF format to olawdco@mail.nih.gov or by fax to 301-480-33871. OLAW requires the final report to be signed by the Institutional Official and include the following (as stated by OLAW) 1.

* Name of institution
* Assurance number (see list of [domestic](https://grants.nih.gov/grants/olaw/assurance/300index.htm) and [foreign](https://grants.nih.gov/grants/olaw/assurance/500index.htm) Assured institutions)
* Reporting requirement: Identify the reporting requirement of the PHS Policy IV.F.3. under which the incident qualifies (i.e., serious or continuing noncompliance with the PHS Policy, serious deviation from the provisions of the *Guide*, or suspension of an activity by the IACUC).
* Preliminary report: Note when, by whom, and to whom a preliminary report was made, if applicable.
* Explanation of incident: Explain in detail what happened, when and where, the species of animals(s) involved, and the category (but not the names) of the individuals involved.
* Corrective actions: Describe the corrective and preventative actions taken to address the situation. Include all the short or long-term corrective plans along with the implementation schedule. Indicate whether the IACUC reviewed and accepted the corrective actions submitted by the responsible party and any ongoing actions taken by the IACUC (e.g., enhanced oversight).
* Grant/contract number: Include the relevant grant or contract number (for situations related to PHS-supported activities).
* Impact on PHS-supported activities: Describe any potential or actual effect on PHS-supported activities. This also applies to incidents that have occurred in a functional, programmatic, or physical area not supported by the PHS that could affect PHS-supported activities (see also [NOT-OD-05-034](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html)).
* Compliance with terms and conditions: If the incident involved PHS-supported activities and was not compliant with the terms and conditions of grant award, confirm that the situation was reported to the funding component and that all unauthorized costs initially paid from the grant have been removed and covered by other sources (see also [NOT-OD-10-081](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html)). Or, certify that no unallowable costs were charged during the noncompliant period.

In this case, the Hometown VAMC-IACUC determined noncompliance had not occurred. The IACUC could contact OLAW’s Division of Compliance Oversight for guidance or the institution may elect to submit a final report that provides the information requested by OLAW, factually accurate and devoid of extraneous details, and is FIOA ready.2 Note: OLAW guidance indicates that documents related to compliance oversight evaluations are usually exempt from the disclosure provisions of FOIA while the evaluation is in in progress and are treated with confidentiality by OLAW. However, once OLAW issues its finding, these documents become publicly available under FOIA.

Key points to remember:

* A preliminary report is followed up with a final report after the IACUC conducts an investigation.
* The preliminary report notifies OLAW that a potential problem has occurred.
* The final report provides a factual account of the incident, what the IACUC determined and what corrective actions were taken (if applicable).

**References:**

1<https://grants.nih.gov/grants/olaw/reporting_noncompliance.htm>

2<https://grants.nih.gov/grants/olaw/ComplianceOversightProc.pdf>