Administrative Closure
Research Follow-Up and BSL-3 Issues
Office of Research Oversight
Washington, DC
MCI # 2012-03247-HI-0411

The VA Office of Inspector General Office of Healthcare Inspections received allegations from an anonymous complainant regarding concerns related to research oversight and Biosafety Level 3 (BSL-3) safety issues. The complainant alleged that the Research Safety and Animal Welfare Group has been delinquent in issuing its Site Visit Reports; of concern was a "For Cause" Animal Site Visit that was conducted to investigate the death of large primates at the Michael E. DeBakey VA Medical Center, (MEDVAMC) Houston, TX. Secondly, a Routine Review Site Visit was conducted in June of 2011 at the VA Syracuse Medical Center, Syracuse, NY, and the report was issued on April 30, 2012. The site visit focused on the review of the BSL-3 Research program and the report contained numerous regulatory and safety concerns.

The Office of Research Oversight (ORO) serves as the primary Veterans Health Administration (VHA) office for advising the Under Secretary for Health (USH), and conducting compliance oversight relative to the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and Government wide debarment for research impropriety.

On May 18, 2012, an anonymous complainant wrote a letter to the OIG Hotline Division and alleged that the following issues exist in the Office of Research Oversight.

1. Operational Mismanagement
2. Financial Mismanagement
3. Possible Conflict of Interest
4. History of Targeting Employees for Removal from the Organization
5. Hostile Work Environment

The complainant further alleged that no action was taken by the ORO Chief Officer to address these concerns.

Case 1. We contacted [b)(6)] the Associate Director of the Research Safety and Animal Welfare Program, and requested a copy of the *On-Site For-Cause Post Incident Review: Animal Care and Use Program* Michael E. DeBakey VA Medical Center, Houston, Texas, October 31, 2012. The review was initiated following the unexpected deaths of five animals that were used in research activities by a MEDVAMC investigator. The deaths occurred over a 20-month interval between April 2009 and

December 2010 and were associated with surgeries and/or other manipulations, which required prolonged periods of anesthesia.

ORO's objective in conducting this review was to perform a retrospective analysis of the specific events associated with these incidents and to assess the overall effectiveness of local oversight mechanisms related to the MEDVAMC Animal Care and Use Program (ACUP). ORO also provided technical assistance to the investigator and veterinary staff following the on-site review, which was intended to facilitate and support continued refinements in the complex animal procedures associated with these research activities.

The conclusion reached after a comprehensive evaluation was that overall the MEDVAMC ACUP has implemented a number of commendable practices and was found to be a high quality and compliant program. The relationship that MEDVAMC had established with its affiliate institution was cooperative and beneficial. Both parties worked as a team to investigate mutual concerns involving animal care and to implement appropriate actions as necessary. As a result, ORO did not identify any additional regulatory concerns.

Case 2. We reviewed the ORO report *Routine Review Biosafety Level 3 Research Program,* Syracuse VA Medical Center (SVAMC), Syracuse, New York, April 3, 2012. ORO evaluated the facility's BSL-3 Research Safety and Security Program (RSSP) ACUP. The following regulatory and policy concerns were identified:

- Some BSL-3 laboratory procedures and design features were not consistent with minimum requirements in *Biosafety in Microbiological and Biomedical Laboratories (BMBL),* 5th edition and VHA policies were observed during inspections at the BSL-3 research laboratories.
- Access and egress records of BSL-3 laboratories were not consistently generated and reviewed.
- The BSL-3 facility design and operational parameters must be re-verified and documented at least annually. This has not been consistently done.
- The process for exiting a BSL-3 laboratory that involved the use of Personal Protective Equipment and hand washing needed to be evaluated to determine if it met regulatory standards.
- The SVAMC administration was encouraged to continue its support of training opportunities and professional conferences for local oversight personnel and research staff.

The SVAMC submitted a Remedial Action Plan that addressed the findings and recommendations. [redacted] wrote that the SVAMC research program was conducted by a cadre of well-trained individuals and overseen by a highly knowledgeable Subcommittee on Research Safety that was dedicated to ensuring that research was conducted in a safe and secure manner. The ORO will monitor implementation of the action plan.

We conducted a telephone interview with [b:6:] D.V.M., PhD, Chief Veterinary Medical Officer on October 9, 2012. He stated that [b:6:] was very competent and well respected. He said she went out of her way to work collegially with ACUP staff in VA facilities to address concerns identified on ORO inspections. He explained that resolving the identified issues took precedence over timely publication of reports.

The complainant included allegations that fell out of the scope of this review. We therefore focused on the allegation of Operational Mismanagement.

The ORO conducted extensive and comprehensive reviews of both MEDVAMC and SVAMC facilities. The SVAMC submitted a Remedial Action Plan that ORO will monitor for implementation and the other regulatory issues were resolved. No other regulatory concerns were identified.

Our review did not support the allegation of Organizational Mismanagement.

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