



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

October 31, 2018

Re: Animal Welfare Assurance  
#A3518-01 [OLAW Case 1S]

Randolph W. Hall, Ph.D.  
Vice Provost of Research  
University of Southern California  
3720 South Flower St., Room [REDACTED]  
Los Angeles, CA 90089-0706

Dear Dr. Hall,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 26, 2018 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Southern California. Your letter supplements the information provided in the initial telephone report from Dr. Casebolt on July 31, 2018. According to the information provided it is understood that on July 25, 2018 the IACUC suspended two protocols belonging to one PI. This action was prompted by April 17 and June 14, 2018 reports of rats exhibiting signs of pain, swelling and lameness of the hind feet. The laboratory staff had performed foot pad injections of Complete Freund's Adjuvant (CFA) that were not protocol-approved. The animals were euthanized. The related protocols were not supported by PHS funds.

The PI was required to submit a plan to prevent future noncompliance in the laboratory. All individuals in the laboratory, including the PI, were required to undergo re-training and were not allowed to perform animal work until completion of training and lifting of the protocol suspensions. The suspensions were lifted on October 17, 2018. The PI was also required to refrain from use of any language stating or implying IACUC approval in any possible publications of data from these animals.

OLAW appreciates the consideration of these matters by the University of Southern California, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate these incidents, correct the non-compliances, and prevent recurrence. OLAW concurs that the incidents warranted reporting. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



October 26, 2018

Brent Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Dear Dr. Morse:

This is to report suspensions of animal use activities by the IACUC at the University of Southern California (animal welfare assurance number D16-00320/A3518-01). Dr. Donald Casebolt provided a preliminary report to you on July 31, 2018. The IACUC protocols for this work were not associated with Public Health Service nor Department of Defense funding at the time of suspension.

The suspensions occurred because laboratory staff members performed unapproved foot pad injections that contained Complete Freund's Adjuvant (CFA) in rats and failed to provide adequate analgesia for the animals. On April 17, 2018 and June 14, 2018, animals were reported to Department of Animal Resources veterinarians because the animals exhibited signs of pain, swelling, and lameness of the hind feet. The animals were euthanized. Upon investigation, it was determined that foot pad injections with CFA were not approved on either of the two IACUC protocols.

A review of billing records showed that all direct costs associated with the procurement, care, and use of these rats were paid with nonfederal funding sources.

The following corrective actions were taken by the IACUC with respect to these incidents:

The IACUC reviewed the incidents at its July 25, 2018 meeting of a full committee with a quorum in attendance. The committee voted to suspend the two rat protocols and required a written response from the Principal Investigator with a plan to prevent future noncompliance in the laboratory. The IACUC also required that the PI refrain from use of any language stating or implying IACUC approval in any possible publications of data from these animals.

All members of the laboratory, including the Principal Investigator, were required to undergo re-training. All members of the laboratory were suspended from conducting any animal research on these two protocols until the successful completion of this training and lifting of the suspensions from the IACUC.

The Principal Investigator provided a complete response to all of the required items on August 28, 2018. The written response from the Principal Investigator and training documentation for the staff members were reviewed at the full IACUC meeting on October 17, 2018. The response was complete and deemed acceptable by the committee and the suspensions were lifted. To date there have been no other instances of noncompliance in this Principal Investigator's laboratory.

Should you have any questions about these incidents or the corrective actions outlined above, please contact Dr. Donald Casebolt at (b) (6)

Sincerely,

(b) (6)

Randolph W. Hall, Ph.D.  
Vice President of Research

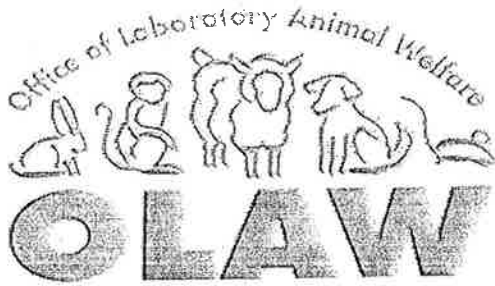
CC: Dr. Brett Lund  
Dr. Donald Casebolt

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## Initial Report of Noncompliance

By: [Signature]Date: 7/31/18Time: 2:20Name of Person reporting: Don Cascholt, AVTelephone #: [Redacted] (b) (6)Fax #: [Redacted]Email: [Redacted]Name of Institution: Univ. of So. Calif. (use)Assurance number: A3518Did incident involve PHS funded activity? NoFunding component: [Redacted]Was funding component contacted (if necessary): [Redacted]

What happened? 20 rats had Freund's CA injected into footpads. No analgesics given. Severe inflammation. Not allowed in protocol.

Species involved: RatPersonnel involved: InvestigatorDates and times: Reported to IACUC.Animal deaths: [Redacted]Projected plan and schedule for correction/prevention (if known): [Redacted]

2 protocols suspended by IACUC on 7/25/18

Projected submission to OLAW of final report from Institutional Official: [Redacted]

OFFICE USE ONLY

Case # [Redacted]