



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 26, 2017

Re: Animal Welfare Assurance
#A3288-01 (OLAW Case V)

Michaele Schuler, DVM, Ph.D.
Attending Veterinarian
University of South Alabama
oom Central Services/Administration Building
307 University Blvd., N
Mobile, Alabama 36688

Dear Dr. Schuler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 24, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of South Alabama. According to the information provided, OLAW understands that one mouse was re-inoculated with tumor cells prior to approval of the protocol amendment covering this activity by the Institutional Animal Care and Use Committee (IACUC). The investigator mistakenly thought that two submitted amendments had been approved whereas only one had.

The corrective actions consisted of stopping any additional inoculations. The mouse was examined by the veterinarian and judged to be in good condition. The investigator was counseled on carefully reading approval letters.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. In future, please submit all final noncompliance reports through the Institutional Official. Thank you for informing OLAW about this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair
Dr. Lynne Chronister, Institutional Official



UNIVERSITY OF
SOUTH ALABAMA

TELEPHONE (251) 460-6239
MSB 992 • MOBILE, ALABAMA, 36688-0002
FAX: (251) 460-7783

A3288 ✓
Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 10/17/2020

April 24, 2017

Axel Wolff, DVM, MS
Director, Division of Compliance Oversight
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Wolff:

The purpose of this letter is to provide a written report of a noncompliance that occurred at the University of South Alabama (Assurance A3288-01) on April 7, 2017. The species is *mouse*.

An investigator has an IACUC-approved protocol studying a tumor model in nude mice. She injected a cohort of mice and the tumors did not grow. She submitted an amendment on March 21, 2017 to re-inject the animals after evaluating the cells in culture. Her intent was to evaluate the tumor cell line viability in a small number of animals (the animals to be re-injected) before repeating the experiment in a cohort of new animals. This amendment was referred for full committee review since the change was considered significant. The investigator had another pending amendment which was considered minor and was approved. Unfortunately, when the investigator received the approval letter for the minor amendment, she told her laboratory staff that both amendments were approved and they could reinject.

On April 17, 2017, the investigator realized her mistake and self-reported to the Research Compliance Coordinator. The Coordinator notified the Attending Veterinarian, the IACUC Chair, and the IACUC Vice-Chair. There was a single animal that had been re-injected and the Attending Veterinarian verified that the animal was healthy and in good condition. The investigator immediately told her staff not to re-inject any animals.

On April 20, 2017, the IACUC met and voted to report the incident to OLAW since this noncompliance represented a deviation from IACUC-approved procedures. However, the IACUC voted to *not* suspend the protocol since this was an honest mistake and the investigator self-reported. In addition, no animals died as a result of this noncompliance. The Institutional Official was notified of the incident and IACUC actions on April 20, 2017. To ensure that such an incident will not be repeated, the investigator was counseled on the importance of reading approval letters carefully.

Because no active IACUC protocols were suspended and no grant funds were affected, no funding agency was notified. The University of South Alabama is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please feel free to contact me.

Sincerely,

Michele Schuler, DVM, PhD, Attending Veterinarian

CC: Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
Lynne Chronister, Vice President for Research and Economic Development, Institutional Official
Research Compliance Coordinator
University of South Alabama IACUC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 24, 2017 11:47 AM
To: 'Michele Schuler'
Subject: RE: noncompliance report (Assurance A3288-01)

Thank you for this report, Dr. Schuler. We will respond soon.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: Michele Schuler [mailto:mschuler@southalabama.edu]
Sent: Monday, April 24, 2017 10:37 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Lynne Chronister <lchronister@southalabama.edu>; Secondary Individual @southalabama.edu
Subject: noncompliance report (Assurance A3288-01)

Dr. Wolff,

Please find the attached letter which describes a recent noncompliance. This noncompliance was an isolated incident and there are no continued animal welfare concerns regarding this noncompliance. The attached letter is the final report unless OLAW would like further action by our IACUC.

I look forward to hearing from you.

thank you,
Michele

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Michele Schuler, DVM, PhD
Director, University Biologic Resources
Associate Professor
Departments of Comparative Medicine and Microbiology
University of South Alabama
TEL Phone Number
FAX Phone Number
mschuler@southalabama.edu