



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) 480-3387

July 19, 2023

Re: Animal Welfare Assurance
A3217-01 [OLAW Case 10]

Matthew Hulver, Ph.D.
Vice President of Research
Arizona State University
300 East University Drive, (b) (4)
PO Box 877205
Tempe, AZ 85287

Dear Dr. Hulver,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 3, 2023, update to the series of noncompliance reported previously to this Office at Arizona State University (ASU). According to the information provided, OLAW understands that the IACUC suspended the entire protocol at a June 22, 2023, convened meeting, based on the Principal Investigator's (PI's) failure to fulfill the IACUC requirements to submit a revised protocol with IACUC-imposed restricted animal activities. During a subsequent convened meeting on June 29, 2023, the PI appealed the IACUC's decision to suspend the protocol. However, the IACUC approved a motion to deny the appeal and the Institutional Official was informed of the IACUC's decision to suspend on June 30, 2023. Relevant funding agencies will be notified of the suspension. All animals were transferred to an IACUC-approved protocol pending identification of alternate PIs and/or institutions by the current responsible PI no later than July 29, 2023. Those animals identified for transport to alternate institutions will be held for an additional three months, as needed, in the event planned transfers are delayed. Please be advised that prior approval from the NIH awarding Institute or Center will be required for a change in PI or performance site where PHS-supported animal activities will be performed.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of this matter and find no cause for further action by this Office.

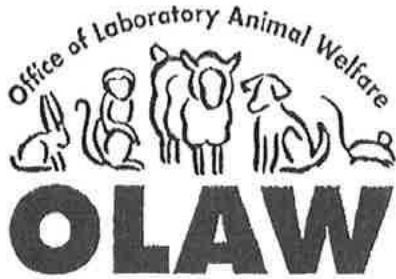
Sincerely,

Neera V. Gopee -S

Digitally signed by Neera V.
Gopee -S
Date: 2023.07.19 16:36:32 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair



Division of Compliance Oversight

Record of Call for Case # A3217-1Q/1O

Date & Time	Message	Initials
7/18/23 3:58 pm	(b) (6) confirmed that the July 3, 2023 memo submitted to OLAW and assigned as compliance case A3217-1Q is an update to the compliance case A3217-1O	NVG

July 3, 2023

Brent Morse, DVM
Division of Compliance Oversight
Office of Laboratory Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-7892

Re: Case number: A3217-1Q; Report of IACUC suspension or other institutional interventions that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

NIH Funding: K22 CA241803; "Metabolic and epigenetic drivers of stem cells in obesity and cancer"

The committee previously reported that the PI would be required to submit a revised protocol to be reviewed at the convened June IACUC meeting. On June 22nd, at a convened meeting of the IACUC, the committee was informed that the PI had not fulfilled the requirements conveyed following the May 25th convened meeting. A revised protocol was submitted but it included many restricted activities.

The committee determined at the June 22nd convened meeting that since the May 25th convened meeting, the PI has not demonstrated overall improvement in responding to animal welfare notifications, IACUC guidance, or to program compliance.

The committee voted to suspend the protocol in its entirety. The PI was formally notified following the meeting. The IACUC Institutional Official and PI's academic unit Director were notified of the committee's decision.

ASU's Policies and Procedures Manual (PPM) provides the PI the right to request a hearing for an appeal of the committee's decision. The PI was given until 5:00pm on June 27th to request a hearing, and that request was conveyed to the Chair by the deadline.

A preliminary report was sent to OLAW by email on June 23rd.

An emergency convened meeting of the IACUC was held on June 29th. The committee was provided a copy of the PI's appeal and attendees at the meeting were invited to ask questions. The PI, academic unit Director, and PI's mentoring team representative were present. The committee then approved a motion to deny the appeal. The ASU IACUC IO was informed of the decision on June 30th.

Funding sources will be notified of the actions taken by the committee.

The animals under the protocol were transferred to an approved holding protocol where basic husbandry and maintenance of the strains will be performed while alternate PIs and/or institutions are identified that can use the animals. The PI will have until July 29th to identify alternate PIs and/or institutions. Animals identified for transport to other institutions will be held for an additional three months as needed, should planned transfers be delayed (e.g., heat embargo on shipping, awaiting approval from the recipient institution's veterinarian).

Please let us know if you have any questions.

(b) (6)

Karen Kibler, PhD
Chair, IACUC
Assistant Research Professor
Karen.Kibler@asu.edu

(b) (6)

Matthew Hulver, PhD
Institutional Official, IACUC
Vice President
Matthew.Hulver@asu.edu

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 6, 2023 6:52 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report under Assurance D16-00136 (Arizona State University)

Good morning (b) (6)

Thank you for sending us this final report for case A3217-1Q and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Wednesday, July 5, 2023 4:09 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Matthew Hulver <Matthew.Hulver@asu.edu>; (b) (6) Karen Kibler <Karen.Kibler@asu.edu>; IACUC@asu.edu
Subject: [EXTERNAL] Final Report under Assurance D16-00136 (Arizona State University)

Good afternoon,

On behalf of the ASU IACUC, attached is the final report for case A3217-1Q.

Confirmation of receipt is requested.

Please let me know if you have any questions.

Thanks!

(b) (6)

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Friday, June 23, 2023 10:34 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Preliminary Report under Assurance D16-00136 (Arizona State University)

Good afternoon (b) (6)

Thank you for sending us this preliminary report, assigned OLAW case number **A3217-1Q**. Please reference this case number when sending the final report.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Friday, June 23, 2023 10:52 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Karen Kibler <Karen.Kibler@asu.edu>; (b) (6)
(b) (6) Matthew Hulver <Matthew.Hulver@asu.edu>; (b) (6)
(b) (6) IACUC@asu.edu
Subject: [EXTERNAL] Preliminary Report under Assurance D16-00136 (Arizona State University)

Good morning,

On behalf of ASU IACUC, I am submitting a preliminary report regarding the IACUC suspension or other institutional interventions that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

Confirmation of receipt is requested.

Please let me know if you have any questions.

Thank you,

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 23, 2023 1:34 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report under Assurance D16-00136 (Arizona State University)

Good afternoon (b) (6)

Thank you for sending us this preliminary report, assigned OLAW case number **A3217-1Q**. Please reference this case number when sending the final report.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Friday, June 23, 2023 10:52 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Karen Kibler <Karen.Kibler@asu.edu>; (b) (6)
(b) (6) Matthew Hulver <Matthew.Hulver@asu.edu>; (b) (6)
(b) (6) IACUC@asu.edu
Subject: [EXTERNAL] Preliminary Report under Assurance D16-00136 (Arizona State University)

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Thank you,

(b) (6)