



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

August 13, 2021

Re: Animal Welfare Assurance
#A3284-01 (OLAW Case 20)

Dr. Jill C. Pipher
Vice President for Research
Brown University
47 George St. - Box 1937
Providence, Rhode Island 02912

Dear Dr. Pipher,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 2, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Brown University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Brown University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol and institutional policies. The final report states on June 5, 2021, twenty-one mice were gavaged with a substance in a new solvent and four mice died. It is also stated the new solvent was IACUC-approved and confirmed by the manufacturer as acceptable for use. Following consultation with the veterinarian, the lab discontinued use of the new solvent and returned to the previous formulation. It is stated no further incidents have been reported. The IACUC discussed the matter on July 9th and acknowledged the following corrective actions took place:

- The lab discontinued use of the new formulation and returned to the previously approved formulation as intended. In the future, a pilot study will be conducted whenever a new formulation is to be tested.

The final report also states on June 14, 2021, lab members were discovered handling mice and chemotherapeutic agents outside the biosafety cabinet in a location not approved for use on the protocol. The lab was corrected by the Center for Animal Resources and Education (CARE) staff at the time of discovery. However, two days later the lab members were discovered conducting the procedure the exact same way. Also, cages with hazardous agents were not labeled per institutional policy and were not being transferred per institutional policy. No animal concerns were observed in this incident.

The IACUC discussed the matter at the meeting on July 9th and understood that the following corrective actions have occurred or would take place:

- Retraining of all lab members in animal handling and safety equipment by the CARE staff and Environmental Health and Safety (EHS).
- All lab members must read the animal use protocol.
- The principal investigator must submit a plan to the IACUC detailing the lab's cage labeling process and team organization and individual training plan as it relates to each protocol.
- Future incidents may result in suspension of individuals and/or animal work.

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In the future, please include the source of funding and provide grant numbers for all PHS, NSF or NASA supported work. Based on its assessment of this explanation, OLAW understands that the Brown University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.08.13 08:00:26 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



BROWN

August 2, 2021

Brent Morse, DVM
 Director, Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360
 6705 Rockledge Drive
 Bethesda, MD 20892

RE: Report of noncompliance, Assurance #A3284-01
 GR5270858

Dear Dr. Morse:

The Brown University Institutional Animal Care and Use Committee (IACUC), through the Institutional Official (Jill C. Pipher, Ph.D.), is writing to provide OLAW with a final report of the following noncompliance with the *PHS Policy on Humane Care and Use of Laboratory Animals* ("PHS Policy"):

- On June 5, 2021, 21 mice were gavaged with a substance in a new solvent and four mice died. The new solvent was approved on the IACUC animal use protocol and was chosen as an alternative to the prior formulation and confirmed by the manufacturer as acceptable for use. In consultation with the veterinarian, the lab discontinued use of the new solvent and returned to the previous formulation. No further incidents were reported.

The IACUC discussed the incident of animal welfare concern at its July 9, 2021 convened meeting and understands that the following corrective actions have taken place:

The lab discontinued use of the new formulation and returned to the previously approved formulation as intended. In the future, a pilot study will be conducted whenever a new formulation is to be tested.

- On June 14, 2021, lab members were observed violating their IACUC-approved animal use protocol by handling mice and chemotherapeutic agents outside the biosafety cabinet in a location not approved for use on the protocol. The Center for Animal Resources and Education (CARE) staff corrected the lab at the time, however, lab members were observed two days later conducting the procedure the same exact way. Additionally, cages with hazardous agents were not labeled in accordance with institutional policy and cages were not being transported according to institutional policy. No concerns pertaining to animals were identified for this particular situation.

The IACUC discussed this incident at its July 9, 2021 convened meeting and understands that the following corrective actions have taken, or will take, place:

- Retraining of all lab members in animal handling and safety equipment by the CARE staff and Environmental Health and Safety (EHS)
- All lab members must read the animal use protocol
- The PI must submit a plan to the IACUC detailing the lab's cage labeling process and team organization and individual training plan as it relates to each protocol.
- Future incidents may result in suspension of individuals and/or animal work.

Brown University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. If you have any questions or concerns regarding this report, please contact (b) (6)

Thank you for your consideration of this matter.
Sincerely,

Jill C. Pipher, Ph.D.
Vice President for Research, Institutional Official
Brown University

cc: Diane Hoffman-Kim, PhD, IACUC Chair (b) (6)
Keri Godin, Senior Director, Office of Research Integrity
Lara Helwig, DVM, Director of CARE, Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 6, 2021 7:37 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance, Assurance #A3284-01 GR5270858

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6) On Behalf Of IACUC
Sent: Wednesday, August 4, 2021 3:49 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Jill Pipher <jill_pipher@brown.edu>; Diane Hoffman-Kim <Diane_Hoffman-Kim@brown.edu>; Keri Godin <keri_godin@brown.edu>; Lara Helwig <lara_helwig@brown.edu>; (b) (6)
Subject: Report of noncompliance, Assurance #A3284-01 GR5270858

Good afternoon,

Please find attached a recent incident of noncompliance discussed by the Brown University IACUC during its July 9, 2021 convened meeting.

Please let us know if you have any questions.

Thanks,

(b) (6)

