

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

July 8, 2022

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 480-3387

Re: Animal Welfare Assurance A3922-01 [OLAW Case 2X]

Mr. Michael B. Henderson Vice President, Office of Research Rhode Island Hospital 167 Point Street, (b) (4) Providence, RI 02903

Dear Mr. Henderson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 27, 2022 letter reporting an adverse event at the Lifespan (Rhode Island Hospital). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Lifespan Animal Care and Use Committee (ACUC) determined that an adverse event occurred with respect to unexpected mortality in mice. The final report states on May 9, 2022, five mice received IP injections of pristane as part of an IACUC-approved protocol. The same day, the animals were found dead by CRF staff. It is stated the lab has been using this drug and antibody production protocol for over 40yrs without incident.

An investigation was performed but the root cause for the mortality could not be determined. It is understood that two separate vials of pristane were combined for the experiment. The lab and veterinary services presume that one of the vials was contaminated. In response, the IACUC required all pristane be discarded and new pristane be obtained for future experiments. The committee voted to accept the corrective action plan.

It is noted that this research is not supported by PHS funding. Based on its assessment of this explanation, OLAW understands that Lifespan (Rhode Island Hospital) has implemented appropriate measures to correct and prevent recurrences of these problems.

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

Sincerely, Jacquelyn T. Tubbs -S Jacquelyn Tubbs, DVM, DACLAM Senior Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From:	McCoy, Devora (NIH/OD) [E]	
Sent:	Friday, July 8, 2022 8:33 AM	
To:	MHenderson1@lifespan.org	
Cc:	OLAW Division of Compliance Oversight (NIH/OD);	(b) (6)
Subject:	OLAW Case A3922-2X	
Attachments:	SIGNED Compliance Case Lifespan (Rhode Island Hospital) 2X.pdf	

Good morning Mr. Henderson,

Attached please find Dr. Tubbs' final response to OLAW Case A3922-2X. If you have any questions, feel free to contact us by phone or by e-mail.

1

Best, Devora

Devora McCoy, BS, MBA Program Analyst Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health 301-435-2390

Lifespan

A3922-27

Office of Research Administration Administrative Office for the Animal Welfare Committee 167 Point St, Suite 1A Providence, RI 02903 Phone: 401-444-2093 Fax: 401-444-7960

Rhode Island Hospital The Miriam Hospital

June 27, 2022

Brent Morse, DVM, DACLAM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare (OLAW) Rockledge 1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982

RE: Animal Welfare Incident at Rhode Island Hospital (Institutional Assurance No: A3922-01)

Dear Dr. Morse,

I am writing to report an unanticipated problem that resulted in harm to animals at our institution. The work supported internally, and not with federal funds.

In brief, on 5/9/22, pristane was injected intraperitoneally into 5 mice as part of an IACUCapproved antibody production protocol. The mice were found dead later in the day by the CRF staff. The lab has been using this drug and antibody production protocol without incident for over 40 years.

In accordance with institutional policy, a sub-committee was formed to investigate the matter. The sub-committee found no clear explanation for the fatalities, though two separate vials of pristane had been combined for this experiment. The presumption by the lab and veterinary services is that one of the vials had become contaminated.

As corrective action, the IACUC required that all pristane be discarded and new pristane obtained for future experiments.

The incident was reviewed at the regularly scheduled meeting of the full IACUC on June 22, 2022, at which time the IACUC voted to accept the corrective action plan.

Sincerely,

(b) (6)

Michael BI Henderson, JD, LLM, MS Vice President, Office of Research Lifespan Institutional IO

cc:

(b) (6)

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)	
Sent:	Wednesday, July 6, 2022 8:33 AM	
То:	(b) (6)	
Cc:	OLAW Division of Compliance Oversight (NIH/OD)	
Subject:	RE: Animal welfare incident A3922-01	
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)	
Sent: Tuesday, July 5, 2022 8:5	4 AM	
To: OLAW Division of Complian	ce Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>	
Subject: [EXTERNAL] Animal we	elfare incident A3922-01	
Good morning,		

Enclosed please find a letter from our IO reporting an unfortunate incident involving animals at our institution. Please reach out to me if you have any questions about this matter.

(b) (6)