



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 12, 2021

Re: Animal Welfare Assurance
A3362-01 [OLAW Case A]

Dr. Salomon Amar
Vice President of Research,
Provost for Biomedical Research and
Chief Biomedical Research Officer
New York Medical College
Sunshine Cottage Road - Administration Building (b) (4)
Valhalla, NY 10595

Dear Dr. Amar,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 25, 2021 letter responding to our request for additional information related to an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the New York Medical College. According to the additional information provided, OLAW understands that the NYMC Biosafety Office was notified of the associated matter and that the animal activity was funded by HHS.

OLAW thanks you for providing this additional information. We appreciate your program's transparency and of being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse - Digitally signed by Brent C. Morse
-S
Date: 2021.07.12 15:53:03 -04'00'

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

cc: IACUC contact



**TOURO COLLEGE &
UNIVERSITY SYSTEM**
NEW YORK MEDICAL COLLEGE



A3362-A

Salomon Amar, DDS, PhD

Senior Vice President for Research Affairs

Touro College and University System

Vice President for Research

Professor of Pharmacology, Microbiology and Immunology

New York Medical College

Professor of Dental Medicine

Touro College of Dental Medicine at New York Medical College

June 25, 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

Dear Dr. Morse:

Further to my letter dated June 7, 2021 and in response to your letter dated June 16, 2021, please allow me to confirm that the activity subject to the noncompliance report was funded by HHS. Also, the NYMC BioSafety Office was notified of this matter.

New York Medical College is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard.

Sincerely,

(b) (6)

Salomon Amar, DDS, PhD
Vice President for Research
Institutional Official
New York Medical College

Wolff, Axel (NIH/OD) [E]

From: [REDACTED] (b) (6)
Sent: Friday, June 25, 2021 11:01 AM
To: Walker, Keri (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Amar, Salomon; Patric K Stanton; [REDACTED] (b) (6)
Subject: Re: OLAW Case A3362-A
Attachments: NYMC OLAX.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Sent on behalf of Salomon Amar, DDS PhD
Institutional Official New York Medical College

Dear Keri,

You will find attached a reply to Dr. Morse's interim response.

Please confirm receipt,

(b) (6)

From: Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Sent: Wednesday, June 16, 2021 10:48 AM
To: Amar, Salomon <Salomon_Amar@nymc.edu>
Cc: Patric K Stanton <PATRIC_STANTON@NYMC.EDU>; [REDACTED] (b) (6)
Subject: OLAW Case A3362-A

External Email

Dear Dr. Amar,

Attached please find Dr. Morse's *interim* response to OLAW Case A3362-A.

If you have any questions, feel free to contact us by phone or by e-mail.

Regards,
Keri

Keri Walker
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-435-2390



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June 16, 2021

Re: Animal Welfare Assurance
#A3362-01 (OLAW Case A)

Dr. Salomon Amar
Vice President of Research,
Provost for Biomedical Research and Chief Biomedical Research Officer
New York Medical College
Sunshine Cottage Road
Administration Building (b) (3) (B)
Valhalla, NY 10595

Dear Dr. Amar,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 7, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the New York Medical College. According to the information provided, OLAW understands that lentiviral vector constructs were used in rats by a PI despite not being approved in a NYMC IACUC protocol. It was not stated if the associated activity was PHS funded.

Corrective and preventive actions: The IACUC will release a statement to the entire NYMC academic community stressing that all co-authors on publications are responsible for proper care and use of the laboratory animals which includes proper coverage of all procedures in the publication in their own and their co-authors' animal protocols. Also, investigators personally performing experiments must be listed as part of the protocol personnel prior to performing the studies. Although OLAW understands and supports your institution's process to allow investigators to correct their processes, in future reports, please describe the specific actions taken to correct the described noncompliance.

The consideration of this matter by the New York Medical College was consistent with the philosophy of institutional self-regulation, as far as described. OLAW advises that the associated journal be notified that the activity was not IACUC-approved. Please note, all future reports should state whether the associated activity was funded by the PHS, HHS, BARDA, or NASA. Please notify our office if the associated activity was funded by one of these entities and if your institution's Biosafety Officer and/or Committee was notified of this matter. **Please provide this information to OLAW by July 12, 2021.** Thank you.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse
-S
Date: 2021.06.16 08:44:47 -04'00'

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

cc: IACUC contact



**TOURO COLLEGE &
UNIVERSITY SYSTEM**
NEW YORK MEDICAL COLLEGE



Salomon Amar, DDS, PhD

Senior Vice President for Research Affairs

Touro College and University System

Vice President for Research

Professor of Pharmacology, Microbiology and Immunology

New York Medical College

Professor of Dental Medicine

Touro College of Dental Medicine at New York Medical College

June 7, 2021

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

To whom it may concern:

New York Medical College (NYMC), in accordance with Assurance D16-00235 (A3362-01) and PHS Policy IV.F.3., provides this final report of noncompliance regarding an incident related to usage of certain viral vectors at NYMC.

1. The PI published that lentiviral vector constructs were used at NYMC despite not having approved NYMC IACUC protocols.
2. The PI's work using GPR75-shRNA-Lnv was not approved by IACUC. The PI's IACUC protocol was approved for the use of a lentiviral vector *but not the GRP-75 insert* (GPR75-shRNA-Lnv) indicating lentiviral delivery of the GPR75. Another investigator's protocol contains approval for a lentiviral vector to deliver GPR-75. This mode of delivery and the drug were approved for mice, but not for rats, the species used in the above-mentioned publication. The PI was added to the other investigator's protocol as personnel on 5/30/2019. However, the PI's publication appeared in April 2018. Therefore, if the PI performed experiments with GPR75-shRNA-Lnv, this inclusion did not cover her use of this specific lentivirus vector in animals prior to 5/30/2019. Further, the procedure, vector and drug were approved by the NYMC IACUC for use in mice, not rats. These constitute deviations from the approved protocols. If the PI personally conducted experiments using GPR75-shRNA-Lnv, she was not part of approved personnel.
3. Since the PI did not inform the Department of Comparative Medicine staff about the implementation of the viral vector experiments; this constitutes endangerment

of people. Endangerment of animal welfare was applicable in the case of rats injected with GPR75-shRNA-Lnv, as this vector was only approved for use in mice.

The NYMC IACUC has taken the following corrective actions:

- (a) *For current protocols:* The IACUC has a post-approval monitoring system and the IACUC policy is to allow the investigator and named individuals on the IACUC protocol to correct their processes if they are not consistent with the approved animal protocols. This post-approval monitoring has been very effective as an additional validation that investigators have not inadvertently deviated from their approved protocol.
- (b) *For the entire body of the academic community at NYMC:* The NYMC IACUC Committee will release a statement to the entire NYMC academic community stressing that:
 - a. ALL co-authors on publications are responsible for proper care and use of the laboratory animals which includes proper coverage of all procedures in the publication in their own and their co-authors' animal protocols.
 - b. Investigators personally performing experiments must be listed as part of the protocol personnel prior to performing the studies.
- (c) *For the NYMC community at large:* IACUC has sent a memo to the entire administration and NYMC community at large indicating that ANY concerns regarding laboratory animal care and use should be IMMEDIATELY brought to the attention of the NYMC IACUC Committee via either Dr. Stanton, Chair of IACUC, or Dr. Popilskis, Attending Veterinarian and Director, DCM. The focus is on "ANY concern" and "IMMEDIATE report" to ensure a timely response consistent with NYMC IACUC Committee policies.

New York Medical College 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 contact Patric Stanton, PhD, IACUC Chair.

Sincerely,

(b) (6)

Salomon Amar, DDS, PhD
Vice President for Research
Institutional Official
New York Medical College

cc: Patric Stanton, PhD, IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 9, 2021 7:20 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Noncompliance Report

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: Monday, June 7, 2021 12:21 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Amar, Salomon <Salomon_Amar@nymc.edu>; Patric K Stanton <PATRIC_STANTON@NYMC.EDU>
Subject: Noncompliance Report

Sent on behalf of Salomon Amar, DDS PhD
Institutional Official New York Medical College

To whom it may concern:

Please find attached a final noncompliance report with a full explanation of the circumstance and actions taken.

Thank you for your consideration,

(b) (6)