

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
<u>Telephone</u>: (301) 496-7163
Facsimile: (301) 402-7065

November 27, 2017

Re: Animal Welfare Assurance #A4148-01 (OLAW Case J)

Dr. David Strauss
Deputy Director for Research
New York State Psychiatric Institute
Research Foundation for Mental Hygiene, Inc.
1051 Riverside Drive — Room #
New York, New York 10032

Dear Dr. Strauss,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 20, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the New York State Psychiatric Institute, following up on an initial report on October 11, 2017. According to the information provided, OLAW understands that a nonhuman primate was left unattended overnight in a restraint chair in a testing room not approved by the Institutional Animal Care and Use Committee (IACUC) for animal use. No adverse effects on the monkey were reported.

The corrective actions consisted of terminating the individual responsible from employment at the institution. The protocol was amended to include new staff, all investigators were reminded to use only IACUC approved areas for animal activities, investigators were informed to submit time-sensitive amendments separately, the IACUC will continue to inspect all animal care and use areas during the semiannual review, primate investigators must inform other personnel about after hours testing and when primates are returned to their cages, and the IACUC will develop procedures to ensure that approval is in place before spaces are assigned for animal testing or housing.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

Signature

Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair



ANDREW M. CUOMO
Governor

ANN MARIE T. SULLIVAN, M.D.

Commissioner

JEFFREY A. LIEBERMAN, M.D.

Director

November 20, 2017

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892-7982
E-mail: olawdco@mail.nih.gov

Re: Nonhuman Primate Left Unattended Overnight

New York State Psychiatric Institute

NIH Animal Welfare Assurance A4148-0

Dear Sir or Madam:

On 10/11/17, we reported an incident involving a nonhuman primate (NHP) left unattended overnight in a testing space as follows:

- 1. At 8 AM on Wednesday, 09/27/17, our animal care staff discovered that a NHP was left unattended overnight in a chair in a testing laboratory. There was no evidence that the monkey was harmed.
- 2. On the following day, 09/28/17, the full IACUC reviewed this incident and appointed a 4-member subcommittee to investigate it.
- 3. Later on 9/28, the principal investigator terminated the individual who was responsible for leaving the monkey unattended.
- 4. The IACUC is investigating whether the use of the testing space was approved as required.

Below are our IACUC's findings, and measures intended to prevent the occurrence of similar incidents in the future.

Findings of the IACUC:

- 1) The was no evidence of harm to the NHP.
- 2) The individual directly responsible for this lapse had worked reliably for several months before this incident. He was unable to explain why he left the NHP in the testing laboratory overnight. He was formally removed from the study, from the animal use protocol, and he was terminated from his position at NYSPI.
- 3) The testing room where the NHP was left unattended was not approved by the IACUC for animal studies. The IACUC found the following information relating to the unapproved use of this space.
 - a) On 05/09/17, the Principal Investigator submitted to the IACUC a modification of his animal use protocol with a request to use the new testing room, and to add new personnel (not involved in this incident). However, the IACUC did not approve the modification, pending completion of the training of the new personnel.
 - b) On 05/26/17, with approval of the protocol modification pending, a representative of Institute administration provided access to the testing room to the Principal Investigator.
 - c) With the mistaken belief that the IACUC had approved the modification to include the testing room, the Principal Investigator began testing animals in the room.
 - d) On 08/31/17, the Principal Investigator submitted a Year 03 continuation of the protocol, but did not include the testing room, as it was to be closed pending planned renovations of the area, which are now commencing. The new personnel (not involved in the incident) were included and approved.
 - e) The grant associated with the protocol is R01 MH081153.

Preventive measures taken by the IACUC:

The IACUC will:

- 1) Remind all investigators that experiments involving live animals must be conducted in IACUC-approved locations.
- 2) Encourage NYSPI investigators to submit separate modifications for time-sensitive changes in order to avoid delays in approval.
- 3) Continue to inspect all area of animal care and use during its semi-annual inspections, including newly added ones.

- 4) Require investigators performing research on NHPs after regular working hours to inform one or more colleagues about the planned testing, before and again once they have finished testing and returned NHPs to their home cages.
- 5) Develop procedures to ensure that administration allocates space for animal testing rooms and facilities only after confirming that IACUC approval is in place.

Sincerely,

Signature

David H. Strauss, M.D.
Director, Research Operations and Compliance
New York State Psychiatric Institute
1051 Riverside Drive, Room #

New York, NY 10032
Tel. Phone Number

david.strauss@nyspi.columbia.edu

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)

Sent: Tuesday, November 21, 2017 1:57 PM

To: andary Indiv(NYSPI); OLAW Division of Compliance Oversight (NIH/OD)

Cc: Strauss, David (NYSPI); Secondary Individual (NYSPI); nyspi.dl.IACUC; Shalev, Moshe (NYSPI);

Rayport, Stephen (NYSPI)

Subject: RE: Incident Report re NIH Animal Welfare Assurance A4148-0

Thank you for this final report dary Indi We will send an official response soon.

Regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: pndary Indiv (NYSPI) [mailto ndary Indiv@nyspi.columbia.edu]

Sent: Tuesday, November 21, 2017 10:28 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Strauss, David (NYSPI) < David.Strauss@nyspi.columbia.edu >; Secondary Individual (NYSPI)

Secondary Individual @nyspi.columbia.edu>; nyspi.dl.IACUC <IACUC@nyspi.columbia.edu>; Shalev, Moshe (NYSPI)

<Moshe.Shalev@nyspi.columbia.edu>; Rayport, Stephen (NYSPI) <Stephen.Rayport@nyspi.columbia.edu>

Subject: Incident Report re NIH Animal Welfare Assurance A4148-0

Dear Sir or Madam:

On behalf of the New York State Psychiatric Institute, please find attached report from Dr. David Strauss, Director of Research Operations and Compliance.

Thank you,

dary Ind

ANDREW M. CUOMO

ANN MARIE T. SULLIVAN, M.D.

Commissioner

JEFFREY A. LIEBERMAN, M.D.

Director

Governor

October 11, 2017

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892-7982
E-mail: olawdco@mail.nih.gov

Unattended Nonhuman Primate Left Overnight

New York State Psychiatric Institute NIH Animal Welfare Assurance A4148-0

Dear Sir or Madam:

We are writing to report an incident involving a non-human primate (NHP) at the New York State Psychiatric Institute.

1. At 8 AM on Wednesday, 09/27/17, our animal care staff discovered that a NHP was left unattended overnight in a chair in a testing laboratory. There was no evidence that the monkey was harmed.

2. On the following day, 09/28/17, the full IACUC reviewed this incident and appointed a 4-

member subcommittee to investigate it.

measures to prevent the occurrence of similar incidents in the future.

Re:

3. Later on 9/28, the principal investigator terminated the individual who was responsible for leaving the monkey unattended.

4. The IACUC is investigating whether the use of the testing space was approved as required.

I will provide a follow-up report once our IACUC completes its investigations and we develop

Sincerely

Signature

David H. Strauss, MD
Director for Research Operations and Compliance
New York State Psychiatric Institute
1051 Riverside Drive, Room #
New York, New York 10032

Phone: Phone Number

E-mail: David Strauss@nyspi.columbia.edu

cc: Secondary Individual MD, IACUC Vice Chair Dr. Stephen Rayport, IACUC Chair Moshe Shalev, VMD, Attending Veterinarian Secondary Individual IACUC Coordinator

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Friday, October 13, 2017 8:17 AM

To:

Strauss, David (NYSPI); OLAW Division of Compliance Oversight (NIH/OD)

Cc: Shalev, Moshe (NYSPI); Rayport, Stephen (NYSPI); Secondary Individual (NYSPI); Indary Individual (NYSPI)

Subject:

RE: Incident Report re NIH Animal Welfare Assurance A4148-0

Thank you for this preliminary report. We will open a case file and await your final report. At that time, please note if the incident involved PHS funding and if so, include the grant number. Thank you again.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM Acting Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Strauss, David (NYSPI) [mailto:David.Strauss@nyspi.columbia.edu]

Sent: Wednesday, October 11, 2017 5:40 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Shalev, Moshe (NYSPI) < Moshe. Shalev@nyspi.columbia.edu>; Rayport, Stephen (NYSPI)

<Stephen.Rayport@nyspi.columbia.edu>; Secondary Individual (NYSPI) Secondary Individual @nyspi.columbia.edu>; Indary Individual

dary Ind NYSPI) econdary Individua@nyspi.columbia.edu>

Subject: Incident Report re NIH Animal Welfare Assurance A4148-0

Please find attached an incident report for your review and consideration. Thank you.

David H. Strauss, M.D.
Director, Research Operations and Compliance
New York State Psychiatric Institute
1051 Riverside Drive, Room #
New York, NY 10032
Tel. Phone Number

david.strauss@nyspi.columbia.edu