



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) 402-7065

August 12, 2019

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

Dr. Moshe Shalev
Attending Veterinarian
Director of Comparative Medicine
New York State Psychiatric Institute
Research Foundation for Mental Hygiene, Inc.
1051 Riverside Drive – Unit #10
New York, New York 10032

Dear Dr. Shalev,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 6, 2019 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. According to the information provided, OLAW understands that seven mice were used for a pilot study that had not been approved by the Institutional Animal Care and Use Committee (IACUC). Also, a head bar had been attached which was an unapproved procedure.

The corrective actions consisted of the IACUC chair directing the Principal Investigator (PI) to stop the unauthorized activities. The PI was counseled and agreed to perform only IACUC approved activities. The IACUC retrained the PI and staff.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Jeffrey Lieberman, M.D., Institutional Official

August 6, 2019

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
301-496-7163
olaw@od.nih.gov

To OLAW:

On behalf of Institutional Official Dr. Jeffrey Lieberman, Director of the New York State Psychiatric Institute (NYSPI), I am reporting to you a non-compliance incident of animal care that our IACUC discovered recently at NYSPI.

During its July 12, 2019 semiannual inspections, the New York State Psychiatric Institute (NYSPI) IACUC discovered 7 mice on which a pilot experiment was conducted without IACUC approval. The mice underwent surgery, as approved on the investigator's IACUC protocol. In addition, a head bar was attached to enable a head-fixed behavioral assay, which was then conducted on a subsequent day. This was not described in the investigator's protocol.

On July 15, 2019, the IACUC Chair requested that the investigator *"cease immediately performing these studies and provide an explanation for this non-compliance"*, and *"within 1 week of this notice, the IACUC requests that a corrective plan of action and/or a modification be submitted to address the issue of the virtual burrow experiment."*

On July 24, 2019, the IACUC Chair reviewed the details of this incident with the investigator. The investigator confirmed in writing that on April 4, 2019 he performed the above one-day experiment on 7 mice to test the recently published "Virtual burrow assay for head-fixed mice measures habituation, discrimination, exploration and avoidance without training", BA Fink et al., eLife 2019. He did not perform the procedure again. Admitting the reason for that non-compliance was oversight/negligence, the investigator recognized the IACUC notification, and confirmed that he will refrain from conducting future animal experiments without IACUC approval.

At its July 25, 2019, Full Committee meeting, the IACUC determined this was a significant deviation from its policies, PHS Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals 8th ed. 2011. The IACUC will provide refresher training to the investigator and his staff about animal welfare regulations and NYSPI IACUC policies.

On July 30, 2019, The Attending Veterinarian visited the investigator's laboratory and discussed this incident, its significance to animal welfare, and the requirement for IACUC-approval of all animal experimentation.

Moshe.

(b) (6)

Moshe Shalev, MSc, VMD, DACLAM
Attending Veterinarian
Professor of Comparative Medicine in Psychiatry at CUMC
Director of Comparative Medicine
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cc:

Jeffrey A. Lieberman, MD, Institutional Official, Director of the New York State Psychiatric Institute.
Stephen Rayport, MD, IACUC Chair.

Ward, Joan (NIH/OD) [E]

From: Ward, Joan (NIH/OD) [E] on behalf of Laboratory Animal Welfare, Office of (NIH/OD)
Sent: Wednesday, August 7, 2019 10:32 AM
To: 'Shalev, Moshe (NYSPI)'
Subject: RE: A pilot experiment conducted at the New York State Psychiatric Institute without IACUC approval

Thank you for this report Dr. Shalev. Dr Wolff will respond soon.

Regards,
Joan

From: Shalev, Moshe (NYSPI) <Moshe.Shalev@nyspi.columbia.edu>
Sent: Tuesday, August 6, 2019 5:20 PM
To: Laboratory Animal Welfare, Office of (NIH/OD) <OLAW@OD.NIH.GOV>
Cc: Lieberman, Jeffrey (NYSPI) <Jeffrey.Lieberman@nyspi.columbia.edu>; Rayport, Stephen (NYSPI) <Stephen.Rayport@nyspi.columbia.edu>
Subject: A pilot experiment conducted at the New York State Psychiatric Institute without IACUC approval
Importance: High

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National Institutes of Health
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To OLAW:

On behalf of Institutional Official Dr. Jeffrey Lieberman, Director of the New York State Psychiatric Institute (NYSPI), I am reporting to you a non-compliance incident of animal care that our IACUC discovered at NYSPI recently (Attached).

During its July 12, 2019 semiannual inspections, the New York State Psychiatric Institute (NYSPI) IACUC discovered 7 mice on which a pilot experiment was conducted without IACUC approval. The mice underwent surgery, as approved on the investigator's IACUC protocol. In addition, a head bar was attached to enable a head-fixed behavioral assay, which was then conducted on a subsequent day. This was not described in the investigator's protocol.

At its July 25, 2019, Full Committee meeting, the IACUC determined that this incident was a significant deviation from its policies, PHS Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals 8th ed. 2011, the reason for this report.

Moshe.

Moshe Shalev, MSc, VMD, DACLAM
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