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

October 1, 2019

Re: Animal Welfare Assurance
A3099-01 [OLAW Case 1F]

Dr. Paul Fuestel
Director of Research Administration,
Basic Science
Albany Medical College
47 New Scotland Avenue, MC #1
Albany, NY 12208-3479

Dear Dr. Feustel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 20, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Albany Medical College, which had been preceded by a preliminary report to OLAW on September 6, 2019. According to the information provided, our office understands that on August 28, 2019 one mouse was found dead and another mouse was moribund as a result of improper surgical closures. Upon investigation, it was found that the surgeon, though experienced in surgery, had little experience performing surgeries in mice. The surgeon closed the incision without wound clips, as is routine in human patients. Failure to use wound clips constituted a protocol deviation.

Immediate corrective actions included termination of the surgeon's facility access and requiring the surgeon and Principal Investigator (PI) to attend the September 19, 2019 Institutional Animal Care and Use Committee (IACUC) meeting. The PI sent all the laboratory staff involved with the surgical procedure to receive additional training at the institution where it was developed in early September. Documentation of this training was provided to the IACUC at this meeting. As a result of the training, the procedure required modification and the PI submitted an amendment to the IACUC, which was approved. The IACUC also directed that an experienced veterinarian and an IACUC member monitor the initial surgery.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. Although this activity was not PHS funded, the establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals are commendable and avoid the perception of a double standard. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Contact

3099-1F
final

Research Office • Mail Code #1 • 47 New Scotland Avenue, Albany, NY 12208
Phone: (518) 262-5182 • Fax: (518) 262-5890

Albany Medical College

20 Sept 2019

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

As Institutional Official of Albany Medical College (AMC), I am submitting this final report regarding an incident that occurred on August 28th which I previously reported in an initial communication on Sept. 6, 2019.

Name of Institution: Albany Medical College, Albany, NY 12208
Animal Welfare Assurance Number: D16-00062 (A3099-01)
ACUP # and Title: 19-04004 Aortocaval fistula remodeling
Grant Number: none, institutional support for preliminary work

Impact on PHS-Supported Activities: none.

Explanation of Incident (previously reported): On August 28th it was discovered that one mouse had died, and another mouse was moribund because of improperly done surgical closures. The moribund mouse was immediately euthanized. Upon investigation it was discovered that the abdominal closure was performed by a surgeon with little experience with this new procedure. The surgeon had closed with sutures without adding wound clips using techniques she used in humans. However, according to the protocol wound clips were to be used; both the surgeon and PI admitted that wound clips had not been added and the protocol was not followed. The ARF director immediately removed the surgeon's facility access. Both the surgeon and the PI were asked to attend the IACUC meeting on September 19th.

Corrective Actions: Facility access removed pending IACUC action on September 19th.

At the Sept 19th meeting: Due to the difficulties involved in performing these new procedures, the PI sent the individuals who were and will be responsible for this surgery to another institution where the procedure was developed and routinely used. There they received instruction in how the surgery should be performed for optimal results. This occurred early in September and documentation (dated 6 Sept.) of the training was provided to the IACUC chair by the other institution. The IACUC decided that this action was appropriate and acceptable. As the procedures were slightly different from those described in the existing protocol, the PI was

directed to submit a protocol amendment describing the updated procedures to be performed. Following approval of that amendment, the IACUC further directed that an experienced veterinarian and committee member monitor the initial surgery and, if deemed acceptable, to restore access to the facility.

The Albany Medical College remains committed to assuring the welfare of all animals used in research. This final report describes the circumstances and actions taken in this incident. If you have any questions, please do not hesitate to contact me.

Sincerely,

(b) (6)

Paul J. Feustel, Ph.D.
Institutional Official
Director, Office of Research Affairs
Phone: (b) (6)
e-mail: feustep@amc.edu

Na, Jane (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 20, 2019 9:25 AM
To: Feustel, Paul
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report Albany Medical College D16-00062 (A3099-01)

Dear Dr. Feustel,

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

Jane

Jane Na, DVM, CPIA
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Phone (301) 402-1922
E-fax (301) 451-5609

From: Feustel, Paul <FeusteP@amc.edu>
Sent: Friday, September 20, 2019 9:19 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: RE: preliminary report Albany Medical College D16-00062 (A3099-01)

Dear Dr. Na,
Please see below for a final report on the outcome of this case. Attached is a PDF of the final report duplicating what is below.
Thanks,
Paul

20 Sept 2019

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

As Institutional Official of Albany Medical College (AMC), I am submitting this final report regarding an incident that occurred on August 28th which I previously reported in an initial communication on Sept. 6, 2019.

Name of Institution: Albany Medical College, Albany, NY 12208
Animal Welfare Assurance Number: D16-00062 (A3099-01)

ACUP # and Title: 19-04004 Aortocaval fistula remodeling
Grant Number: none, institutional support for preliminary work

Impact on PHS-Supported Activities: none.

Explanation of Incident (previously reported): On August 28th it was discovered that one mouse had died, and another mouse was moribund because of improperly done surgical closures. The moribund mouse was immediately euthanized. Upon investigation it was discovered that the abdominal closure was performed by a surgeon with little experience with this new procedure. The surgeon had closed with sutures without adding wound clips using techniques she used in humans. However, according to the protocol wound clips were to be used; both the surgeon and PI admitted that wound clips had not been added and the protocol was not followed. The ARF director immediately removed the surgeon's facility access. Both the surgeon and the PI were asked to attend the IACUC meeting on September 19th.

Corrective Actions: Facility access removed pending IACUC action on September 19th.

> At the Sept 19th meeting: Due to the difficulties involved in performing these new procedures, the PI sent the individuals who were and will be responsible for this surgery to another institution where the procedure was developed and routinely used. There they received instruction in how the surgery should be performed for optimal results. This occurred early in September and documentation (dated 6 Sept.) of the training was provided to the IACUC chair by the other institution. The IACUC decided that this action was appropriate and acceptable. As the procedures were slightly different from those described in the existing protocol, the PI was directed to submit a protocol amendment describing the updated procedures to be performed. Following approval of that amendment, the IACUC further directed that an experienced veterinarian and committee member monitor the initial surgery and, if deemed acceptable, to restore access to the facility.

The Albany Medical College remains committed to assuring the welfare of all animals used in research. This final report describes the circumstances and actions taken in this incident. If you have any questions, please do not hesitate to contact me.

Sincerely,

(b) (6)

Paul J. Feustel, Ph.D.
Institutional Official
Director, Office of Research Affairs
Phone: (b) (6)
e-mail: feustep@amc.edu

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Friday, September 06, 2019 2:55 PM
To: Feustel, Paul <FeusteP@amc.edu>
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: preliminary report Albany Medical College D16-00062 (A3099-01)

STOP! THINK! External Email!
Dear Dr. Feustel,

Thank you for this preliminary report. We will open a case file and await further information.

Jane

Jane Na, DVM, CPIA

3099-1F

Na, Jane (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 6, 2019 2:55 PM
To: Feustel, Paul
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report Albany Medical College D16-00062 (A3099-01)

Dear Dr. Feustel,

Thank you for this preliminary report. We will open a case file and await further information.

Jane

Jane Na, DVM, CPIA
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
Phone (301) 402-1922
E-fax (301) 451-5609

From: Feustel, Paul <FeusteP@amc.edu>
Sent: Friday, September 6, 2019 2:27 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: preliminary report

6 Sept 2019

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

As Institutional Official of Albany Medical College (AMC), I am submitting this preliminary report regarding an incident that occurred on August 28th.

Name of Institution: Albany Medical College, Albany, NY 12208
Animal Welfare Assurance Number: D16-00062 (A3099-01)
ACUP # and Title ACUP # 19-04004 Aortocaval fistula remodeling
Impact on PHS-Supported Activities: Uncertain at this time.

Explanation for Incident (as currently understood): On August 28th it was discovered that one mouse had died and another mouse was moribund because of improper abdominal surgical closures. The moribund mouse was

immediately euthanized. Upon investigation it was discovered that wound closure was performed by a surgeon having little experience with a new disease model procedure. The surgeon had closed with sutures without adding wound clips. According to the protocol wound clips were to be used; both the surgeon and PI admitted that wound clips had not been added and the protocol was not followed. The ARF director immediately removed facility access. Both the surgeon and the PI were asked to attend the next IACUC meeting on September 19th.

Corrective Actions: Facility access removed until IACUC action on September 19th.

A fuller report of this incident will be prepared after the IACUC has reviewed the situation on 19 September. If you have any questions, please do not hesitate to contact me.

Sincerely,

(b) (6)

Paul J. Feustel, Ph.D.
Institutional Official

Director, Office of Research Affairs
Office of Research Affairs, (b) (4), Mail Code 1
Albany Medical College
47 New Scotland Avenue
Albany NY 12208
phone: (b) (6)
feustep@amc.edu