



Stop Animal Exploitation NOW!

Dr. Elizabeth Goldentyer
USDA/APHIS/AC
920 Main Campus Drive, Suite 2000
Raleigh, NC 27606

5/22/19

Dr. Goldentyer,

I am writing to you today to file an Official Complaint against the Nationwide Children's Hospital (31-R-0116), for clear violations of the Animal Welfare Act which occurred recently.

Nationwide Children's Hospital correspondence provides details relevant to the unnecessary death of an animal.

This correspondence states:

"Surgery was carried out on five pigs following the procedure approved in the IACUC protocol. Surgery on the sixth pig carried out on February 28, 2019 deviated from the approved protocol. Briefly, cells recovered from resected gut were placed on the scaffolds and one was placed within the gut rather than the abdominal wall. To prevent stricture of the gut, a bypass loop was created in the intestine. This is a significant deviation from the approved protocol. The animal was euthanized on March 3, 2019 . . . as it met humane endpoints defined in the IACUC protocol. Necropsy revealed leakage from the gut surgical site.

At the request of the IACUC, the PI barred the researcher from further work with animals . . . "

This botched surgical procedure clearly took the life of this animal. As referenced in the document from the initial phone report in the incident, there was a "leak in intestine" causing the animal to develop "sepsis." This incident may violate multiple sections of the Animal Welfare Act including, but not limited to: Sec. 2.38(f)(1) MISC. Animal Handling; Sec. 2.32 Personnel Qualifications; Sec. 2.33 Attending veterinarian and adequate veterinary care; and Sec. 2.31 Institutional Animal Care and Use Committee (IACUC).

The death of this pig was entirely unnecessary and the leakage of the surgical site clearly demonstrates the truly flawed nature of the botched procedure. It is also clear that the leakage from the surgical site led to the decision to euthanize.

I hereby file an Official Complaint against the Nationwide Children's Hospital (31-R-0116) for multiple serious violations of the Animal Welfare Act. I must insist that your office institute an immediate investigation, and at the conclusion of that investigation this facility must receive a maximum penalty -- \$10,000 per infraction/per animal.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

Michael A. Budkie, A.H.T.

Michael A. Budkie, A.H.T.,
Executive Director, SAEN

Attachments: OLAW Report



NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.™

April 1, 2019

Axel Wolff, 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. Wolff:

The Research Institute at Nationwide Children's Hospital, in accordance with Assurance A3544-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding one of our researchers performing a surgical procedure not approved on the IACUC protocol. I first reported this incident to you on March 21, 2019 via a telephone call.

One Animal Resource Core veterinary technician who was monitoring the pig during surgery noticed that the procedure varied from the previous 5 surgeries. The veterinary technicians reported the variation immediately to the Lead Veterinary Technician who reported it to Dr. Goodchild, the attending veterinarian. By the time Dr. Goodchild was apprised of the deviation, the surgery was completed.

The research is funded by NIH Grant: NIH STTR R42 DK107168 entitled "Production of Tissue Engineered Intestine". No charges from this incident have been applied to the NIH fund.

The purpose of the protocol is to develop engineered gut tissue for recovery from necrotizing enterocolitis, a devastating condition in preterm human infants. In brief, the procedure approved by the IACUC involved 2 surgeries. In the first surgery, a small section of gut is resected for isolation of cells as a source of engineered gut tissue. Cells are implanted on graft scaffolds. Scaffolds are implanted in the abdominal wall or wrapped in mesentery to generate engineered tissue. A second surgery performed one month later involves recovery of engineered gut cell scaffolds from the abdominal wall and implantation in line at a second site in the gut.

Surgery was carried out on five pigs following the procedure approved in the IACUC protocol. Surgery on the sixth pig carried out on February 28, 2019 deviated from the approved protocol. Briefly, cells recovered from resected gut were placed on the scaffolds and one was placed within the gut rather than the abdominal wall. To prevent stricture of the gut, a bypass loop was created in the intestine. This is a significant deviation from the approved protocol. The animal was euthanized on March 3, 2019 as it met humane endpoints defined in the IACUC protocol. Necropsy revealed leakage from the gut surgical site.

At the request of the IACUC, the PI barred the researcher from further work with animals pending resolution of the IACUC investigation and development of a remedial plan for the researcher. The researcher's card key access to the vivarium was suspended. It will be restored when a plan for remedial training and monitoring of future work with animals is instituted.

The following corrective action plan was implemented after the incident:

1. Completion of online AALAS training courses identified by the IACUC under supervision by the Director of Research Integrity.

Alex Wolff, DVM
April 1, 2019
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2. Upon successful completion of AALAS courses, the researcher's work with animals will be supervised for three months under conditions defined by the IACUC.
3. Any serious violation of IACUC protocols or policies by the researcher in the next 12 months will be referred directly to Dr. Durbin, the Institutional Official, for action.

The protocol is not suspended as the non-compliant activity was carried out by the researcher who acted without informing the PI or other study staff. The PI voluntarily halted activity on the protocol until progress towards study goals is evaluated based on data from 5 pigs that were treated according to the approved protocol.

The PI lab has always been very conscientious with regards to protocols and activities. We believe our remediation steps will adequately address this issue.

At the IACUC meeting on April 1, 2019, the IACUC reviewed and accepted the corrective action plan. The IACUC determined that this was an isolated incident and not a programmatic failure.

Please do not hesitate to contact me if you require further information.

With regards,

 (b) (6)

Dennis Durbin, MD
Institutional Official
Chief Scientific Officer



Initial Report of Noncompliance

By: *aw*

Date: *3/21/79*

Time: *8:00*

Name of Person reporting: *Dennis Durbin, I.O.*

Telephone #: *(b) (6)*

Fax #:

Email:

Name of Institution: *Newcastle Institute National Children's Hospital*

Assurance number: *A3544*

Did incident involve PHS funded activity? *Yes*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*2 surgical procedures, intestine of stem cells
Didn't do as per protocol & lead in intestine, septic.*

Species involved: *Fig*

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

*Voluntary hold, euthanize, remove animal and privileges
Training, enhanced oversight, take pictures*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____