



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
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

May 11, 2018

Re: Animal Welfare Assurance
A3046-01 [OLAW Case 1C]

Mr. Gregory Furrow
Vice President of Quality and Compliance
Southern Research
2000 9th Avenue South
Birmingham, AL 35205

Dear Mr. Furrow,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 10, 2018 letter provided in response to our March 30, 2018 letter that requested additional information regarding Southern Research's plans and schedule for correction to improve communication across matrix lines and how documentation/recordkeeping, either through use of data recording software or other methods, and/or changes in processes will be utilized to enable proper accounting for every animal in the future.

Your response indicated that the in vivo and post-life personnel now report to the same supervisor, a group meeting with all Operations personnel and Management occurred, all Operations personnel received mandatory training on effective team communication, and SOPs are under review/revision to include additional procedures to confirm the scheduled number of carcasses transferred or disposed of and confirmation that all cages are empty prior to leaving the room or area. Revised SOPs are scheduled to be effective and rolled out no later than May 31, 2018.

We appreciate the submission of the additional information in order to facilitate a complete assessment of the incident. OLAW assumes that revisions to the SOPs and subsequent implementation will ensure that processes include or will include mechanisms for any necessary documentation or recordkeeping which may be especially useful in the event of multiple personnel working together or transfer of duties such as that described in the original reported incident. Please contact our office if this is not the case or if the corrective actions are not carried out as described. Apart from this, OLAW is satisfied that the described additional actions are appropriate for the reported noncompliance. Additionally, we encourage application of similar measures to improve communication with any necessary documentation to ensure appropriate animal welfare for other procedures such as animal room transfers or animal import/export, if applicable. OLAW appreciates your organization's commitment to the humane care and use of animals and finds no cause for further action by this Office at this time.

Sincerely,

(b) (6)

Jane Na, DVM
Veterinary Medical Officer, OLAW
Office of Laboratory Animal Welfare

cc: IACUC Chair



Solving the world's hardest problems.

May 10, 2018

Dr. Jane Na, DVM
Veterinary Medical Officer, OLAW
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MCS 7982
Bethesda, MD 20892-7982

Dear Dr. Na,

In response to your letter dated March 30, 2018, referencing Animal Welfare Assurance A3046-01 OLAW Case 1 C.

As stated in our preliminary response to OLAW's letter dated 30 MAR 2018, Southern Research takes responsibility for the humane care and use of animals very seriously. As such, the following plan has been implemented to increase communication among team members and to ensure proper accounting of animals following euthanasia procedures.

1. Re-organization of the In Vivo and Post-life personnel occurred on Tuesday, 10 APR 2018, so that all personnel working with live animals are now one team reporting to one Operations Supervisor.
2. Group meeting with all Operations personnel and Management occurred on 10 APR 2018.
3. Mandatory training on effective team communication (AALAS Learning library module) was completed as a group for all Operations personnel on 19 APR 2018.
4. The following SOPs are currently under review/revision to include additional procedures regarding confirming the scheduled number of carcasses has been transferred to necropsy or otherwise disposed of and confirmation that all cages are empty prior to leaving the room/area: GSOP-IL569, "Euthanasia of Laboratory Animals" and GSOP-IL935, "Handling and Disposition of Dead and Euthanized Animals". These revised SOPs will be effective and rolled out to the staff no later than 31 MAY 2018.

Please let me know if you have any further questions or concerns.

Regards,

(b) (6)

Gregory Furrow
Vice President Quality and Compliance – Institutional Official

cc: The Office of Laboratory Animal Welfare (OLAW); olawdco@mail.nih.gov
Joan Ward, Program Specialist; wardjoa@od.nih.gov



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March 30, 2018

Re: Animal Welfare Assurance
A3046-01 [OLAW Case 1C]

Mr. Gregory Furrow
Vice President of Quality and Compliance
Southern Research
2000 9th Avenue South
Birmingham, AL 35205

Dear Mr. Furrow,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter on March 26, 2018 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) at Southern Research. This report was preceded by a preliminary report on March 8, 2018 to OLAW via email. According to the information supplied, OLAW understands that on the morning and afternoon of March 5, 2018, mice were euthanized for pathology technicians to conduct necropsies. That evening, it was discovered that necropsy data for one animal was absent and the animal could not be located. The following morning, it was discovered that the mouse had been missed on the euthanasia/necropsy day and was still located in its cage on the rack in a hallway with access to food and water. Plans for euthanasia were carried out later that day. Upon investigation, it was determined that there was a miscommunication between technicians performing the euthanasia procedures and a failure to confirm that all animal cages were empty at the end of the work day. The letter indicated that the associated animal activity was supported by NIH funding.

Corrective actions included disciplinary action for the technician who failed to ensure that all animal cages were empty at the end of the work day and discussion and training on communication for involved technical staff. Planned corrective actions include a meeting for management to discuss measures for improvements in communication; revising the SOP on euthanasia and/or handling of animals scheduled for euthanasia to include an additional empty cage check; and potential for generation of a list of animals scheduled for euthanasia and necropsy by the data recording software to permit tracking. It was noted that most, but not all, situations already include a list of this type.

OLAW commends your institution on the timeliness of the prompt and final reporting and believes that the completed corrective actions are appropriate but requests an implementation schedule and further detail regarding the planned corrective actions. Adequate communication, documentation/recordkeeping, and processes are necessary to ensure accurate tracking and accounting of animals in cases like that described in this incident as well as in other situations such as room transfers. Please describe how Southern Research plans to improve communication across matrix lines and how documentation/recordkeeping, either through use of data recording software or other methods, and/or changes in processes will be utilized to enable proper accounting for every animal in the future. Please provide this additional information with a schedule for correction of all planned actions or an update of progress to OLAW **no later than May 15, 2018** by emailing olawdco@mail.nih.gov and carbon copying jane.na@nih.gov. We appreciate being informed of these matters and look forward to your response.

Page 2 – Mr. Furrow
March 30, 2018
OLAW Case A3046-1C

Sincerely,

(b) (6)

Jane Na, DVM
Veterinary Medical Officer, OLAW
Office of Laboratory Animal Welfare

cc: IACUC Chair



Dr. Brent Morse, DVM Acting Director
Division of Compliance Oversight
Office of Laboratory Welfare, NIH
Rockledge 1, Suite 360 MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse,

In accordance with Assurance #D16-00025 (A3046-01) and PHS Policy IV.F.3, Southern Research (SR) provides this final report of noncompliance regarding ACUP 15-12-029B. Southern Research study (b) (4)

(b) (4) that was initially reported to you on 08 MAR, 2018. This non-compliance was reported to the Study Director and the IACUC Chair on 06 MAR and an investigation was initiated. Presumed non-pregnant mice were scheduled to be euthanized followed by macroscopic examination on the morning and afternoon of 05 MAR, 2018. On the evening of 05 MAR 2018 it was noted there was no necropsy data for one of the mice (animal 86) and the animal could not be located. The animal was found alive the morning of 06 MAR 2018 in her cage on a rack in the limited access animal facility hallway. There was food in the cage and the manifold on the rack still contained water. Upon further investigation, this incident was found to be the result of a miscommunication between the technician who was initially performing the euthanasia on 5 MAR 2018 and a second technician who relieved this individual in the afternoon, as well as a failure of the second technician to adequately confirm all animal cages were empty at the end of the work day.

Disciplinary action has been conducted for the technician who failed to ensure all of the cages were empty at the end of the day. Discussion and general training on communication has been conducted among the involved technical groups. The management of those groups will be meeting to discuss measures to improve communication across matrix lines. The SOP on laboratory animal euthanasia and/or handling of scheduled euthanasia animals will be revised to include an additional empty cage check to confirm that all animals have been euthanized and none are remaining. We are also exploring the potential in our data recording software to allow the necropsy technicians to have a list of animals scheduled to be euthanized and necropsied. This type of list is already available in most, but not all, situations. Such a list would allow the necropsy technicians to note if any animals were missing from their schedule, which would alert the technician performing the euthanasia that an animal may have been missed.

Southern Research 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 Dr. Jill Mann, IACUC Chairperson @ jmann@southernresearch.org.

Regards,

(b) (6)

Gregory Furrow
Vice President Quality and Compliance-Institutional Official

(b) (6)

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Na, Jane (NIH/OD) [E]

A3046-16
Preliminary

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 09, 2018 7:35 AM
To: Mann, Jill
Cc: IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report of noncompliance regarding the ACUP 15-12-029B, Southern Research study 14140.14.04

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

Jane

Jane Na, DVM
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
(301) 402-1922

From: Mann, Jill <jmann@southernresearch.org>
Sent: Thursday, March 08, 2018 4:11 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: IACUC <IACUC-BIRMINGHAM@sriemail.sri.org>
Subject: preliminary report of noncompliance regarding the ACUP 15-12-029B, Southern Research study (b) (4)

Dear Dr. Morse,

In accordance with Assurance #D16-00025 (A3046-01) and PHS Policy IV.F.3, Southern Research (SR) provides this preliminary report of noncompliance regarding the ACUP 15-12-029B, Southern Research study (b) (4)

This non-compliance was reported to the Study Director and the IACUC Chair on 06 MAR and an investigation was initiated.

Presumed non-pregnant mice were scheduled to be euthanized followed by macroscopic examination on the morning and afternoon of March 5, 2018. On the evening of March 5, 2018 it was noted there was no necropsy data for one of the mice (animal 86) and the animal could not be located. The animal was found alive the morning of March 6, 2018 in her cage on a rack in the limited access animal facility hallway.

The process of euthanasia of animals by a technician followed by macroscopic examination involves loading the non-pregnant animals in their cages onto a rack and transporting the rack to the limited access hallway adjacent to the necropsy area. During this process, the rack was placed with one side flush against the wall in the hallway.

The animal technician performing the euthanasia had a scheduling conflict and was not going to be available for the entire time that euthanasia would be required. It was arranged that a separate technician would take over the euthanasia duties partway through the process. This technician arrived and the task was handed off between technicians. The remaining visible mice on the outside of the rack were euthanized and examined. Animal 86 was unnoticed on the other side of the rack (the side flush against the wall). That evening, it was noted that animal 86 was removed in the Provantis system, but was missing from the data tables from post-mortem examination. Pathology technicians confirmed that the carcass for this animal was not with the other animals examined that day. A technician searched the animal room that evening and it was confirmed that the animal was not in the animal room. The next morning, a separate technician was able to locate the animal (still on the rack). Arrangements were made for euthanasia (performed a short time later on March 6, 2018).

The investigation into this matter is still on going and steps will be taken to make sure that this does not happen again. We will send the final report when this investigation is concluded.

Thank you,

Jill F. Mann, D.V.M., DACVP
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