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) 480-3387

November 4, 2020

Re: Animal Welfare Assurance
A3230-01 [OLAW Case 5F)

Ms. Pamela S. Caudill
Senior Associate Provost
for Research Administration
Yale University – New Haven
25 Science Park, (b) (4)
New Haven, CT 06520

Dear Ms. Caudill,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 30, 2020 letter responding to my September 30, 2020 request for an investigation into allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Yale University made by an individual requesting anonymity. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) conducted an extensive review of records, interviewed numerous staff members, and determined the following:

1) It was confirmed that rodents were routinely kept in the laboratory over a 24-hour time period although the area had not been approved as a satellite facility. See corrective action A.

2) Food and/or fluid regulation was approved along with a maximum weight loss of 15%. However, two rodents exceeded the weight loss limit, were kept on study, were subsequently given water and regained their acceptable body weight. See corrective action B.
No evidence was found that a rat had died of dehydration, but four healthy animals were found without food/water. See corrective action C.

3) Two instances were confirmed of rodents moving during procedures due to inadequate anesthesia. Staff was retrained and no further incidents occurred.
One instance was confirmed of the use of one anesthetic agent rather than the two approved in the protocol. See corrective action A.

4) It was confirmed that institutional controlled drug procedures were not being followed and that the safe had often been left open all day. See corrective action D.

5) It was confirmed that post-operative analgesia was not always given according to the schedule approved in the protocol. See corrective actions A and D.

6) The allegation of improper sterile technique and inadequate use of personal protective equipment during surgery was not confirmed. The matter is addressed in corrective action A.

7) The allegation of feeding contaminated sucrose solution to rats was not confirmed.

8) It is permissible to weigh rats and mice in the same box if cleaned in between. No problems were identified with this practice.

9) No problems were identified regarding cleanliness of laboratory floors.

10) Twelve additional rats were bred than approved in the protocol. See corrective action E.

11) The number of rodents used was not in excess of the number approved by the IACUC.

12) Keeping animals in the animal facility for future experimental activities or approved disposition is an acceptable institutional practice.

Corrective action plans:

A) The Principle Investigator (PI) reviewed animal housing, surgical procedures, post-operative care, and expiration of laboratory made solutions with all animal users.

B) The laboratory staff has re-reviewed the institutional policy on regulating food and/or fluids in rodents.

C) The laboratory staff was retrained on relevant policies and procedures to ensure that all animals have adequate food/water.

D) The Office of Animal Research Support (OARS) will monitor surgery and controlled substance records. The IACUC will monitor breeding and usage data.

E) The protocol was amended to include additional bred rat offspring and to expand the rat breeding program. OARS will monitor the number of animals produced and euthanized but not used on the protocol.

Additional actions:

1) The noncompliant incidents confirmed had not been reported to OLAW because they were still under IACUC investigation. A report was going to be submitted upon completion of the investigation.

2) Animal concerns may be reported to the Attending Veterinarian, IACUC chair, OARS director, Institutional Official, University Research Compliance Officer, or anonymously through the University Hotline. No individual will be discriminated against or subject to any reprisal for raising a concern or reporting a violation.

3) The PI and laboratory staff were informed about the protection against reprisal.

4) The Environmental Health and Safety division conducted its own investigation and addressed safety concerns raised by the complainant.

Based on its assessment of these explanations, OLAW understands that some allegations could not be sustained while others were confirmed with reasonable and specific corrective/preventive measures implemented accordingly. OLAW concurs with the actions taken by the institution to comply with the PHS Policy and commends Yale University for its prompt and thorough response to this matter. As the informant has shared their identity with OLAW, a synopsis of these findings will be shared with the individual. OLAW hereby closes this case and finds 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
Director, OARS

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) 480-3387

November 4, 2020

Re: Animal Welfare Assurance
A3230-01 [OLAW Case 5F)

Dear Dr. Williams,

The Office of Laboratory Animal Welfare (OLAW) has completed its investigation into your September 25, 2020 allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Yale University. Following an extensive review of records and interviews with numerous staff members, it was determined that some allegations could not be confirmed while others were confirmed, and reasonable and specific corrective/preventive measures were provided. The findings are as follows:

1) It was confirmed that rodents were routinely kept in the laboratory over a 24-hour time period although the area had not been approved as a satellite facility. See corrective action A.

2) Food and/or fluid regulation was approved along with a maximum weight loss of 15%. However, two rodents exceeded the weight loss limit, were kept on study, were subsequently given water and regained their acceptable body weight. See corrective action B.
No evidence was found that a rat had died of dehydration, but four healthy animals were found without food/water. See corrective action C.

3) Two instances were confirmed of rodents moving during procedures due to inadequate anesthesia. Staff was retrained and no further incidents occurred.
One instance was confirmed of the use of one anesthetic agent rather than the two approved in the protocol. See corrective action A.

4) It was confirmed that institutional controlled drug procedures were not being followed and that the safe had often been left open all day. See corrective action D.

5) It was confirmed that post-operative analgesia was not always given according to the schedule approved in the protocol. See corrective actions A and D.

6) The allegation of improper sterile technique and inadequate use of personal protective equipment during surgery was not confirmed. The matter is addressed in corrective action A.

7) The allegation of feeding contaminated sucrose solution to rats was not confirmed.

8) It is permissible to weigh rats and mice in the same box if cleaned in between. No problems were identified with this practice.

9) No problems were identified regarding cleanliness of laboratory floors.

10) Twelve additional rats were bred than approved in the protocol. See corrective action E.

11) The number of rodents used was not in excess of the number approved by the IACUC.

12) Keeping animals in the animal facility for future experimental activities or approved disposition is an acceptable institutional practice.

Corrective action plans:

A) The Principle Investigator (PI) reviewed animal housing, surgical procedures, post-operative care, and expiration of laboratory made solutions with all animal users.

B) The laboratory staff has re-reviewed the institutional policy on regulating food and/or fluids in rodents.

C) The laboratory staff was retrained on relevant policies and procedures to ensure that all animals have adequate food/water.

D) The Office of Animal Research Support (OARS) will monitor surgery and controlled substance records. The IACUC will monitor breeding and usage data.

E) The protocol was amended to include additional bred rat offspring and to expand the rat breeding program. OARS will monitor the number of animals produced and euthanized but not used on the protocol.

Additional actions:

1) The noncompliant incidents confirmed had not been reported to OLAW because they were still under IACUC investigation. A report was going to be submitted upon completion of the investigation.

2) Animal concerns may be reported to the Attending Veterinarian, IACUC chair, OARS director, Institutional Official, University Research Compliance Officer, or anonymously through the University Hotline. No individual will be discriminated against or subject to any reprisal for raising a concern or reporting a violation.

3) The PI and laboratory staff were informed about the protection against reprisal.

4) The Environmental Health and Safety division conducted its own investigation and addressed safety concerns raised by the complainant.

Based on its assessment of these explanations, OLAW understands that some allegations could not be sustained while others were confirmed with reasonable and specific corrective/preventive measures implemented accordingly. OLAW concurs with the actions taken by the institution to comply with the PHS Policy and hereby closes this case. No further action will be taken by this Office regarding this matter. Thank you for your interest in animal welfare.

Sincerely,

(b) (6)

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

Yale *Office of Research Administration*

PAMELA S. CAUDILL
Senior Associate Provost
for Research Administration

PO Box 208327
New Haven CT 06520-8327
T 203 785-3012
F 203 785-3510
pamela.caudill@yale.edu

courier
25 Science Park, Suite 322
New Haven CT 06511

October 30, 2020

Axel Wolff, MS, DVM
Office of Laboratory Animal Welfare
National Institute of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: D16-00146 Case 5F

Dear Dr. Wolff:

In accordance with the Public Health Service Policy and Yale University's Animal Welfare Assurance (#D16-00146), I write to describe the results of a University investigation of activities following a report regarding animal care and use in a Yale School of Medicine laboratory.

On August 6th, 2020, the Office of Animal Research Support (OARS) received a report of animal welfare and safety concerns from a member of the lab. Later the same day, the member sent a follow-up email to principal investigator and copied Dr. Troy Hallman (Director of OARS) and a representative from Environmental Health and Safety (EHS). That same day, Dr. James Macy (Attending Veterinarian), Dr. Gary Cline (IACUC Chair), and I were all also notified of the report. Because of the potentially serious implications not related to animals, the University decided to keep the investigation confidential until completed. After hearing a summary of the investigation to date, at the September 9th, 2020 monthly meeting, the IACUC agreed to have the investigation remain confidential and that the case would be reported to OLAW promptly when the investigation was fully completed.

Both the internal report and the anonymous report to OLAW included the following allegations:

1. Rodents being kept outside of designated animal facilities for greater than 24 hours, without IACUC approval
2. A rat succumbing to dehydration
3. Inadequate anesthesia
4. Improper storage of controlled drugs
5. Inadequate post-operative care
6. Improper aseptic technique
7. Contaminated sucrose solution
8. Poor cleanliness of equipment and procedure spaces
9. Overbreeding of rodents
10. Rodents used in excess of the number approved

The following items were not included in the internal report, and thus were not part of the University investigation:

- ***Rats and mice anesthetized in the same box and weighed on the same scale.*** The use of the same box for anesthetizing both mice and rats is a common practice, provided the box is thoroughly cleaned between cohorts of rodents and between species. It is expected that following this sanitation practice is confirmed as part of Post-Approval Monitoring (PAM) activities. The lab has had no PAM findings associated with this allegation, nor were any concerns raised about this sanitation practice during the course of the investigation.

- ***Rats left in the animal facility without a disposition plan following completion of experiments.*** Keeping animals in the animal facility after the conclusion of an experiment is not uncommon, for reasons including, but not limited to: analyzing data to determine if a procedure would need to be repeated (if IACUC-approved); anticipating the reuse of the animal (if IACUC-approved); or awaiting potential adoption.

Over the course of several weeks that followed receipt of the internal report, Dr. Hallman and/or representatives from the Yale School of Medicine (YSM) Office of the Dean, and/or the Office of General Counsel (OGC) conducted several individual interviews and meetings with most animal users in the lab, including the user who made the internal report, as well as principal investigator and the Department Chair. Additionally, numerous documents were reviewed, including, but not limited to: the general compliance and PAM history (back to 2012); food and fluid regulation records; anesthesia and surgery records; controlled drug logs; post-operative care logs; breeding records; and animal census data. EHS conducted an individual investigation and addressed the safety concerns in the internal report.

Results of the extensive investigation are as follows, in the sequence of the allegations presented in your September 30th, 2020, letter.

1. Interviews with the animal users in the lab indicated that rodents were routinely kept in the lab for an extra day or two post-operatively (up to ~72 total hours). Satellite housing in the lab is not approved by the IACUC. This finding is addressed in A of the resolution plan, below.

2. The IACUC has approved food and/or fluid regulations for specific experiments, with a maximum of a 15% weight loss. Any rodent with a weight loss higher than 15% is to be removed from the study. After the review of weight and well-being logs, there were two instances when two rodents exceeded 15% (16% and 21%) but remained in the study. The rodent losing 21% of its weight was provided additional water. Both rodents remained in good health and body weight quickly stabilized at less than 15%. This finding is addressed in B of the resolution plan, below.

   Lab members who were interviewed, other than the member who made the report, had no recollection of a rat dying of dehydration, nor did the principal investigator. A review of eight years of facility incident reports and PAM activities did not corroborate this allegation. Although, in the past 22 months, there were 4 instances of healthy animals identified from facility incident reports without food and/or water, which is not permitted in the IACUC-approved protocol. This finding is addressed in C of the resolution plan, below.

3. Interviews with the animal users in the lab identified two findings regarding anesthesia during procedures. Two lab members recalled difficulties maintaining anesthesia in their first few recording sessions (in Fall 2019), when rodents exhibited movement when they were supposed to be under full anesthesia. Both individuals were retrained with no further evidence of inadequate anesthesia identified on any anesthesia records with these two lab members. Additionally, there was a third, relatively new, member of the lab who had been anesthetizing rodents for cranial implant surgeries with only ketamine, despite a combination of ketamine and xylazine being required by policy and approved in the protocol. This finding is addressed in A of the resolution plan, below.

4. Interviews with the animal users in the lab identified a finding related to managing controlled drugs. The general practice of the lab was to unlock the safe in the morning and leave it open throughout the day. When initially mentioned to the principal investigator, he promptly acknowledged that this practice was not appropriate and confirmed that it would stop immediately. While no additional allegations concerning the handling of controlled substances could be substantiated, including no evidence of unauthorized use of the controlled substances, this topic is addressed in D of the resolution plan, below.

5. Review of controlled drug and post-operative care logs revealed several inconsistencies. Post-operative logs were cross referenced with controlled drug logs (drugs are signed out to an "animal" and by an authorized user). There were instances when buprenorphine was not signed out of the safe when it should have been in order to be administered as part of the approved post-operative care plan. For example, buprenorphine was consistently signed out on the day of surgery and the 1st post-operative day, but not the 2nd post-operative day, while administering 2 post-operative days of BID buprenorphine is approved in the protocol. These findings are addressed in A and D of the resolution plan, below.

6. Interviews with the animal users in the lab required each to describe their individual practices concerning sterile technique and personal protective equipment use during surgeries, from bringing a rodent from the facility to the lab, to preparing for surgery (both the animal and the surgeon), and through recovery. All interviewees described appropriate aseptic technique, including but not limited to a 3-stage scrub, sterile surgical gloves, appropriate surgeon attire, and a conscientious recovery period. Additionally, a review of eight years of facility incident reports did not identify a rodent with a condition that was interpreted as a surgery-associated infection. While there were no findings to support this allegation, this topic is addressed in A of the resolution plan, below.

7. The approved protocol includes the voluntary oral intake of a 50% sucrose solution as positive reinforcement when training rodents for behavioral tests. Interviews with the animal users in the lab and the principal investigator did not pinpoint any such time when the sucrose appeared to be contaminated. IACUC policy limits the use of lab-made solutions to 30 days after making the solution. While there were no findings to support the allegation, this topic is addressed in A of the resolution plan, below.

8. When interviewed, animal users in the lab were aware of the requirements for cleaning equipment. The specific topic in the internal report was that the laboratory floors were not kept clean. There were no specific findings to support this allegation. Housekeeping has had more limited access to the laboratories throughout the SARS-CoV-2 pandemic, so laboratory floors may not have been as tidy as previously.

9. The internal investigation included the collection of animal census records from the Yale Animal Resources Center (YARC). The IACUC authorized 360 rats to be produced from breeding. Within the first 15 months of the protocol (during the internal inspection), the lab produced 372 rats from breeding. This finding is addressed in E of the resolution plan, below.

10. The census records from YARC, for the first 15 months of the protocol approval, the lab used 35% of the mice and 24% of the rats that the IACUC originally authorized when the protocol was approved in mid-2019. Thus, looking at the total animal numbers by species, the number of animals used was not in excess of the number the IACUC has approved.

The IACUC received a partial report of the University investigation at its regularly scheduled monthly meeting on September 9th, 2020 and concurred with the proposed resolution plan. The IACUC received the full report of the University investigation at its regularly scheduled monthly meeting on October 14th, 2020 and expanded the resolution plan to the five points below.

A. The principal investigator will review animal housing, all surgical procedures and post-operative care plans, and expiration of lab-made solutions with all animal users in the laboratory in order to ensure that everyone is aware of what is approved in the protocol and the animal care and use principles everyone is expected to follow. The principal investigator will confirm with OARS when everyone has read and has confirmed understanding of -these policies. This was completed during the week of October 12th and on October 20th, 2020.

B. All members of the laboratory using animals will re-review the Regulated Food and/or Fluids in Rodents policy by October 31st, 2020. This was completed on October 20, 2020.

C. In order to address the incidents where animals were in the facility without food or water, all members of the laboratory using animals will undergo "PI Direct Care" training with the OARS Training Manager. The training will include, but not be limited to: setting up new cages; how to obtain food for empty cages; and assuring water availability (automatic watering, water bottle or Hydropac®). Training was completed on October 22nd, 2020.

D. All surgery records and controlled substance logs will be sent to OARS each month, beginning on October 1st and continuing through at least December 31st, 2020. At the January 2021 IACUC meeting, the breeding and usage data will be presented, and the Committee will decide whether the evaluation of these data should continue into 2021.

E. The protocol will be modified to accommodate additional rats produced by breeding. Additionally, the number of animals produced by breeding and euthanized without ever being on study will be reported to OARS each month, beginning on October 1st and continuing through at least December 31st, 2020. At the January 2021 IACUC meeting, the breeding and usage data will be presented, and the Committee will decide whether the evaluation of these data should continue into 2021. On October 15, 2020, the protocol was modified to expand the rat breeding program because the number of animals previously expected to complete current experiments were underestimated.

Yale University's Reporting Animal Care and Use Concerns policy was last updated in 2019 and describes several ways to report observations that may potential impact animal welfare. Concerns may be reported to any member of Program Leadership or their designees (AV, IACUC Chair, OARS Director, IO, and the University Research Compliance Officer). Reports may also be made anonymously through the "University Hotline," which is managed by a third party and Yale only receives identifying information if the person reporting the concern authorizes sharing their identity. Yale University ensures that no individual will be discriminated against or be subject to any reprisal for raising a concern or reporting violations. The YSM Office of the Dean and OGC reinforced the protection against reprisal with all animal users in the lab, including especially detailed discussions with the reporter and the principal investigator.

This incident will be reported to the appropriate NIH Institutes/Centers in accordance with University procedure. Please contact Dr. Troy Hallman (troy.hallman@yale.edu) directly if you require additional information.

Sincerely,

(b) (6)

Pamela S. Caudill
Institutional Official
Senior Associate Provost for Research Administration

Cc: Kathryn Bayne, Chief Executive Officer, AAALAC International
Gary Cline, IACUC Chair, Yale University
James Macy, Attending Veterinarian, Yale University
Troy Hallman, Director, Office of Animal Research Support, Yale University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 2, 2020 7:19 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A Final Report from Pamela Caudill of Yale University dated October 30, 2020 (Case 5F)

Thank you for this report, (b) (6) I will reply soon.
Axel Wolff

From: (b) (6)
Sent: Friday, October 30, 2020 10:36 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Macy, James <james.macy@yale.edu>; Hallman, Troy <troy.hallman@yale.edu>; Caudill, Pamela <pamela.caudill@yale.edu>; accredit@AAALAC.org; Cline, Gary <gary.cline@yale.edu>
Subject: A Final Report from Pamela Caudill of Yale University dated October 30, 2020 (Case 5F)

Dear Dr. Wolff:

I've attached a final report from Pamela Caudill of Yale dated October 30, 2020 (Case 5F).

Regards,

(b) (6)

(b) (6)

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

September 30, 2020

Re: Animal Welfare Assurance
A3230-01 [OLAW Case 5F)

Ms. Pamela S. Caudill
Senior Associate Provost
for Research Administration
Yale University – New Haven
25 Science Park, (b) (4)
New Haven, CT 06520

Dear Ms. Caudill,

The Office of Laboratory Animal Welfare (OLAW) has received several allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Yale University from an individual requesting anonymity. Numerous documents such as emails, laboratory meeting notes, and records were submitted to support the claims made. In reviewing prior noncompliance reports, we could not definitively confirm that any of the alleged incidents had been reported to OLAW. Please direct the Institutional Animal Care and Use Committee (IACUC), avoiding any conflicts of interest, to review the allegations, investigate the charges, and if noncompliance is confirmed provide a reasonable and specific plan and schedule for correction.

Background:

1) The species involved are rats and mice.

2) Grants supporting the project:
   - 2R01NS066974-05 Remote Effects of Focal Hippocampal Seizures on Neocortical Function
   - 1R01NS096088-01A1 Network Mechanisms of Seizure-induced Cardiorespiratory Impairment
   - 1R37NS100901-01A1 Neuroimaging, neuronal firing and behavior in spike-wave seizures

3) Location: (b) (4) (b) (6) 11/2/20

4) Timeframe: from October 2019 until present

Allegations:

1) Rats and mice were kept in the laboratory over a 24 hour period although the area had not been approved as a satellite facility by the IACUC.

2) A rat died of dehydration due to lack of access to water.

3) Inadequate anesthesia provided during surgical procedures.

4) Improper handling of controlled drugs.

5) Inadequate post-operative care, including lack of analgesia.

6) Inadequate use of sterile technique and personal protective equipment (PPE) during surgery.

7) Contaminated sucrose solution fed to rats.

8) Rats and mice anesthetized in the same box and weighed on the same scale.

9) Inadequate sanitation of procedure spaces and equipment.

10) Inadequate oversight of the rodent breeding colonies, resulting in euthanasia of hundreds of rats.

11) Rodent populations exceeding the number approved on the protocol.

12) Rats left in the animal facility without a disposition plan following completion of experiments.

OLAW questions/comments:

1) Have any of these incidents been reported to OLAW? If not, why?

2) Provide information regarding the policies in place for reporting animal concerns.

3) Explain the protections against reprisal afforded to whistleblowers. The complainant feared reprisal and was not comfortable with the practices in place to allow addressing of concerns without fear of repercussions.

4) Based on review of the supporting evidence, it is clear that some of the items (improper use of PPE) had been reported to appropriate oversight bodies such as the Environmental Health and Safety division and that action was taken.

5) There were references to mishandling of data and possible harassment of laboratory staff. If this is substantiated, reports will need to be submitted to other federal oversight offices.

Please provide a final or interim report by **October 30, 2020**. Feel free to contact me should you have any questions.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director, OARS

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

Dear lab members,
I have been notified by EHS that they received a complaint that staff from our laboratory are wearing personal protective equipment (namely gloves) outside of both the laboratory and the animal rooms.

I need to remind you that it is a Yale University biosafety requirement to remove gloves and other personal protective equipment and to wash hands prior to exiting both the laboratory and animal care and use areas.

I understand that some may be concerned about touching elevator buttons or other surfaces outside the lab due to COVID-19. However if others see you wearing gloves outside the lab they cannot know if you are wearing clean gloves or gloves that have been used in the laboratory. Therefore it is essential that you continue to comply with the policy of no gloves outside the lab and outside animal use areas. If you are concerned about touching elevator buttons or other surfaces outside the lab please wash your hands frequently and of course wear a mask.

I will discuss this with you verbally as well at our upcoming meetings. Please let me know if you have any questions.

Please be advised that to address this complaint two Safety Advisors will visit our laboratory to conduct a lab inspection this week and will return again for a subsequent visit. Yale EHS will also schedule a ZOOM biosafety refresher training for our laboratory in the near future to review personal protective equipment use and rules, and other basic laboratory biosafety measures (this will be educated by the inspection by the two Safety Advisors this week).

I have not been informed when these inspections will take place, so please be prepared to greet Yale EHS personnel if they arrive at our laboratory and let me know when they are there so we can best cooperate with their inspection and guidance.

As always I hope that by working together we can maintain a safe as well as a pleasant and conducive environment in our laboratory. If anyone has questions or concerns please let me know so we can discuss further.

Thanks very much and all the best,
Hal

(b) (6)

Yale EHS has received a concerning complaint that staff from your laboratory are wearing personal protective equipment (namely gloves) outside of both the laboratory and the animal rooms. Each infraction is a violation of CDC, NIH and Yale University biosafety requirements, even at the lowest Biocontainment level (BSL1).

I've cc'd our two EHS Safety Advisors for your lab past and present and our EHS Deputy Director. The two Safety Advisors will visit your laboratory to conduct a lab inspection this week and will return again for a subsequent visit.

I do need you to review basic laboratory safety elements with your staff, particularly the requirement to remove gloves and other personal protective equipment and wash hands prior to exiting both your laboratory and animal care and use areas. After you have discussed this particular issue with your staff:

- Please send us your plan on how you will prevent recurrence of this issue, and what you will do if future non-conformity is observed.
- Please review the EHS non-compliance pathway so that you understand where continued non-conformity could lead to if not corrected.

Yale EHS will also schedule a ZOOM biosafety refresher training for your laboratory in the near future to review personal protective equipment use and rules, and other basic laboratory biosafety measures (hopefully this will be educated by the inspection by the two Safety Advisors this week).

Please let me know if you have any questions regarding this issue and if you need any further information.
I will follow up with you after receiving your review and report back to us along with the Safety Advisor inspection report. We'll then schedule the biosafety refresher training for your lab.

Best and safe wishes,
(b) (6)

(b) (6)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

Framework for Addressing Non-Compliance
EHS Safety Advisor Program

Last Revision – 6/5/2005 (Kevin Charbonneau)

Standard/Routine Findings:

- Reviewed with group with verbal communication
- Documented on periodic (quarterly – annually) inspection report to PI

Follow-up:

- Correction required within x days (i.e. 30 days)
  i. Revisit to confirm
  ii. Document failure or success
- Check on next scheduled inspection or visit

Repeat offense or finding repeated multiple times:

- Require written correction plan from PI to address issues
- Offer or require safety intervention
  i. Repeat verbal/written safety information to correct issue
  ii. Retrain (classroom and hands-on in lab) and document for file
  iii. Unannounced periodic walk through to verify corrections (document success or failure). Periodicity determined by finding (weekly, monthly, quarterly, etc.)
- Finding tied to financial issue (i.e. – Insufficient funds to purchase safety equipment)
  i. Inform and meet with Department Business Office, Chair, and if necessary Dean's Office for School.
  ii. Set correction plan and remediation dates
  iii. Follow-up to ensure correction
- PI/Lab Manager meeting with senior OEHS program manager
  i. Outline issues
  ii. Reinforce severity of non-compliance
  iii. Set time-line for corrections
  iv. CC: Dept. Chair to raise awareness of issue
  v. CC: applicable campus safety committee
- Findings Corrected
  i. Continue to watch periodically

Subsequent Repeat of Finding(s):

- Meeting with PI, Safety Advisor, OEHS Senior Program Manager(s), Department Chair, representatives of relevant campus safety committee.
- Notify Provost's Office
- Meeting of relevant campus safety committee for review
- Identify why behavior hasn't changed
- Case by case assessment of further actions

i. Suspension of research privileges for worker
ii. Shut down of specific project, lab (duration determined by campus safety committee in consultation with Dean, Provost's Office).

- Identify other ramifications of non-compliance

Significant Finding (Regulatory or Safety):

- Immediate verbal report to PI, Committee Chair, OEHS Director, Provost's Office, and if applicable Department Chair, Dean of School and Office of Public Affairs.
    1. Mandatory verbal and/or written report to a Regulatory Agency
        - State of Connecticut Department of Public Health
        - NIH Office of Biotechnology Activities
        - OSHA
            - $\geq$ 3 injured w/ loss of work time or fatality
        - City of New Haven Department of Public Health (public health threat)
        - Nuclear Regulatory Commission
        - U.S. Environmental Protection Agency
        - State Department of Environmental Protection
        - U.S. DHHS CDC (Select Agent issue, import issue)
        - U.S. DOT (transport issue)
        - USDA, APHIS (Select Agent, animal or plant import or transfer issue)

- Meeting with PI, OEHS, and relevant representatives from above mentioned groups to identify root cause of incident, review the regulatory section, outline recommendations and issue requirements to prevent recurrence of incident.
- Case by case assessment by OEHS, relevant campus safety committee chair, Department Chair, and Provost's Office to outline range of possible options.
    i. Immediate cessation of lab procedure until review by peer committee
    ii. Immediate cessation of individual research work privileges until further review by peer committee
    iii. Cessation of procedure/work until:
        - Retraining (class and field)
        - Documentation that group/individual is aware of appropriate practices and proficiency observed
    iv. Periodic unscheduled visit of lab to verify that safe practices are being followed (periodicity determined on case by case basis).
    v. Document correction of practices to confirm adequate safety measures are in place to prevent recurrence.

Repeat of Regulatory or Safety Issue:

- Immediate notification to OEHS Director, Dean of School, Department Chair, PI, Provost's Office, Office of Public Affairs, OEHS Senior Managers

- Report to Regulatory Agencies if needed (with Yale specific corrections identified)
- Emergency meeting of relevant campus safety committee, sub committee, or other group as needed
    - Identify corrective measures
    - Consider campus sanctions
- Suspension w/ additional retraining
- Obtain assistance from other OEHS, campus or outside groups (consultants) as needed to outline plan to prevent recurrence.
- Implement and document corrective measures

Subsequent Repeat of Regulatory or Safety Issue:

- Stop procedure and notify all relevant groups mentioned above
- Immediate meetings to review notifications, facts of the incident
- Determine sanctions on a case by case basis.

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)

(b) (3) (A)