

**Meeting Minutes
Animal Care and Use Committee
January 16, 2020
L-4A @ 9:00 a.m.**

(b)(6)

(b)(6)

Members present:

Absent

Guest:

The meeting was called to order at 9:00 a.m. and was adjourned at 11:25 a.m.

Old Business:

Meeting Minutes

Minutes of December 12 Meeting– Approved with edits

Previous Protocol Reviews

Topaz Ref# 100210 – Full Committee Review 08/16/2018; Comments sent to PI 08/17/2018; PI response 11/27/2018; Under DMR; Returned to PI 04/04/2019
Topaz Ref# 100269 – Full Committee Review 12/12/2019; Comments sent to PI 12/13/2019; PI response 12/16/2019; Under DMR; **Approved 01/08/2020**
Topaz Ref# 100277 – Full Committee Review 12/12/2019; Comments sent to PI 12/13/2019; meeting w/ PI 12/18/2019;

New Business:

(Adverse Events, Compliance Issues, Post Approval Monitoring, Animal SOPs, Committee Membership, etc. addressed in the following reports)

Chair Report

Conflict of Interest and Confidentiality Reminder

Adverse Event – 17-010 v1 (b)(6) reported an incident on 12/18/2019 regarding potential adverse effects in animals that were inadvertently exposed to excessive noise and vibration due to construction in the laboratory corridor (the animals could not be used for the intended studies); the Chair will contact the NIOSH facilities engineer and maintenance supervisor and discuss how future construction-related adverse events can be avoided

IACUC Administrator Report

17 February 2020

IACUC Inter-Institutional/ Collaborative Agreement – IA will follow-up on status
CDC-Morgantown IACUC Charter- edits completed 12/02/19 by OLSS IACUC Liaison
and forwarded to IO- IA will follow-up on status
Change in IACUC March Meeting date to Wednesday, 3/25/2020 due to AAALAC site
visit (3/26/2020)
AALAS Webinar- Barbering & Ulcerative Dermatitis in Mice- 01/14/2020
20-00331 FOIA Update- Memo & redacted documents sent to FOIA requestor from
CDC/ASTDR FOIA Officer, 01/13/2020

Attending Veterinarian/ Facility Director Report

AF Working Standards– currently have a list of 21 AFWs; 10 AFWs approved; several
under revision and/or in draft; AV may request IACUC members to review pertinent
AFWs.
Moving some animals to different rooms in AF (rooms with increased relative humidity)
AAALAC Site Visit- 26 March 2020

Program

PHS Assurance for Domestic Institutions Update- IO sent to OLAW, 12/20/2019

Reviewed revised draft of new CDC-Morgantown IACUC Policy P-0011 on Justification
of Animal Numbers. (Original draft reviewed during 12 December 2019 IACUC
Meeting). Revision unanimously approved.

Post Approval Monitoring (PAM)

NONE

NIOSH Breeding Program

Current animal census at approx. 2000 animals (mainly in the breeding program)

Upcoming IACUC 101/201/301 meetings

2020 course dates and locations not finalized (as of 01/13/20)
PRIM&R Meeting, Orlando, FL, April 5-7, 2020 (pre-conference sessions, 4/4)

Reports:

NONE

Investigators trained or re-trained:

NONE

17 February 2020

ACUC SOPs reviewed:

SOP-OD-00314 Rev 3.0 (exp. 12/09/2021)- Mouse oropharyngeal aspiration, Approved

SOPs nearing expiration (120 days):

SOP-ACI-00042 (exp. 03/29/2020)- Sheep Red Blood Cell Preparation for Immunizing Mice or Rats

SOP-OD-00309 (exp. 04/26/2020)- Euthanasia of Rodents by Carbon Dioxide Gas Using AIMS™ Flowmeter

Amendments: Records of reviews by e-mail are kept with protocol files.

Topaz Ref# 100217 to 18-013 (b)(6) - Rec'd 12/19/19; Under DMR; Comments sent to PI 12/24/19; PI response 01/08/20; **Approved 01/09/20**

Topaz Ref# 100269 to 20-006 (b)(6) - Rec'd 01/10/20; **Approved via VVC, 01/10/20**

Topaz Ref# 100203 to 18-009 (b)(6) Rec'd 01/10/20; in 48-hr amendment review

Protocols that have expired: (0 Legacy protocols remaining for CY2019 expiration)

17-007 (12/23/2019)

Protocols nearing expiration (120 days): (Investigators have been notified.)

17-008 (04/21/2020)

17-009 (04/27/2020)

Protocols closed at request of PI:

NONE

Full-Committee Reviews:

(b)(6) Ref# 100277 (b)(6) - 2ND FCR Committee agreed that most of the questions/ concerns raised by the committee were addressed by the PI and only some minor modifications were remaining. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

(b)(6) Ref# 100274 (b)(6) - Review comments primarily directed to clarification of the use of endotoxin-free agents; age of animals when delivered to the AF; group housing of animal cohort. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

(b)(6) Ref# 100278 (b)(6) - Review comments primarily directed to clarification & justification of the welding fume metals selected for the study. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

17 February 2020

Ref# 100276 (b)(6) - Extensive revisions required to protocol to address review comments. An IACUC subcommittee met with the PI on 01/21/20 to discuss the FCR comments. Primary concerns were the large number of animals requested; requested scientific justification for performing this third/ final phase of this ongoing study; requested data from the previous phases to support the request for animals at multiple study endpoints. Committee unanimously agreed the re-submitted revised protocol be reviewed by 2nd FCR.

Topics for Discussion

Spring Semiannual Inspection for Labs (04/01) & Animal Facility (04/02)- draft inspection schedule discussed; will need most of the IACUC Members participation to have 3 inspection teams on 04/01/20

AAALAC Site Visit- IA will draft tentative site visit agenda; committee voted unanimously to order a box lunch from Panera's for the IACUC lunch meeting with the AAALAC site visitors

Topaz Software Update- IA and AV are working with Attain contractor responsible for IT support for Topaz software to determine specifics of Topaz-provided training for upgraded software we will receive when the Topaz contract is renewed on 1 February 2020.

Next Meeting:

Next Meeting – Thursday, February 20, 2020 at 9:00 a.m. in L-4A.

**Meeting Minutes
Animal Care and Use Committee
February 20, 2020
L-4A @ 9:00 a.m.**

Members present:

(b)(6)

(b)(6)

Absent:

(b)(6)

Guest:

(b)(6)

The meeting was called to order at 9:00 a.m. and was adjourned at 10:40 a.m.

Old Business:

Meeting Minutes

Minutes of January 16 Meeting– Approved

Previous Protocol Reviews

Topaz Ref# 100210 (b)(6) – Full Committee Review 08/16/2018; Comments sent to PI 08/17/2018; PI response 11/27/2018; Under DMR; Returned to PI 04/04/2019

Topaz Ref# 100277 (b)(6) – Full Committee Review 12/12/2019; Comments sent to PI 12/13/2019; IACUC subcommittee meeting w/ PI 12/18/2019; 2nd FCR 01/16/2020; Comments sent to PI 01/17/2020; PI response 01/30/2020; Under DMR; **Approved 02/06/2020**

Topaz Ref# 100274 (b)(6) – Full Committee Review 01/16/2020; Comments sent to PI 01/16/2020; PI response 01/27/2020; Under DMR; **Approved 01/28/2020**

Topaz Ref# 100276 (b)(6) – Full Committee Review 01/16/2020; IACUC subcommittee meeting w/ PI 01/21/2020; Comments sent to PI 01/22/2020; PI response 02/11/2020; 2nd FCR 02/20/2020;

Topaz Ref# 100278 (b)(6) – Full Committee Review 01/16/2020; Comments sent to PI 01/17/2020; PI response 01/28/2020; Under DMR; **Approved 01/31/2020**

New Business:

(Adverse Events, Compliance Issues, Animal SOPs, Committee Membership, etc. addressed in the following reports)

Chair Report

Conflict of Interest and Confidentiality Reminder

Adverse Event – 19-012 v1 (b)(6) reported an incident on 1/29/2020 regarding adverse effects in mice that received intraperitoneal injections of naphthalene on 1/29/2020 as

20 February 2020

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 03/22/2021

described in the protocol. Fourteen mice were exposed to naphthalene (200 or 300 mg/kg in sterile corn oil) by intraperitoneal injections of naphthalene on 1/29/2020 as described in the protocol. Ten mice received 200 mg/kg and 4 received 300 mg/kg. One 300 mg/kg mouse immediately died, was necropsied, the cause of death identified as hemorrhage due to inadvertent laceration of a large vessel, and the AV was notified. All other mice displayed normal behavior after being returned to their cages. The following morning (1/30/2020), one of the mice in the 300 mg/kg group was found dead, and 5 additional mice displayed unanticipated clinical signs indicative of distress/ pain, including both remaining mice in the 300 mg/kg group and three 200 mg/kg-exposed mice. The deceased mouse was necropsied and the cause of death was preliminarily identified as bronchopneumonia and necropsy reports were sent by the PI to the AV. The AV treated symptomatic mice with buprenorphine. The most affected mouse continued to display clinical signs and was euthanized by the PI on 02/02/2020. A necropsy was performed and the preliminary cause of death identified as peritonitis, but morphologic alterations were also noted in the liver and lung. Histopathology is pending on the euthanized mice and the PI plans to euthanize and necropsy the remaining 300 mg/kg mouse on 02/04 and submitted a protocol amendment on 02/03/ 2020 to respond to the events.

IACUC Administrator Report

OLAW 2019 Annual Report – OLAW Div. of Assurances acknowledge receipt, 1/27/20
IACUC Inter-Institutional/ Collaborative Agreement – informed by ACUPO Chief on 1/27/20 that this document will be an OLSS document

CDC-Morgantown IACUC Charter- Received official Charter from OLSS 02/07/20, (Charter signed by IO, 02/03/20)

Reminder- IACUC March Meeting is Wednesday, 3/25/2020

Approved minutes from Oct., Nov. & Dec. IACUC Meetings have been sent to the IO (& copied to ACUPO) as described in our 2019 PHS Assurance Renewal; moving forward will send on a monthly basis once approved by IACUC

Attending Veterinarian/ Facility Director Report

AF Working Standards– AV draft of AFWS V-03, Mouse Ulcerative Dermatitis Treatment and Humane Endpoints reviewed and request IACUC members to review and report edits to the AV.

Interviews for animal husbandry technician position are ongoing

AAALAC Site Visit- 26 March 2020

Program

Review draft of new CDC-Morgantown IACUC Policy P-0012 on Anesthesia and Analgesia Guidelines. Addition of compounds potentially used were requested. Approved with modifications.

Annual approval of FCR – DMR Process unanimously approved.

20 February 2020

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Reviewed Animal Emergency Response Plan (AERP) appendices, request IACUC members to send comments and revisions to IA to be discussed at the March IACUC meeting.

Post Approval Monitoring (PAM)

NONE

NIOSH Breeding Program

Current animal census at approx. 2000 animals (mainly in the breeding program).
(b)(6) AFS, will take over the role of lead breeding technician due to resigning.
(b)(6)

Upcoming IACUC 101/201/301 meetings

2020 course dates and locations not finalized (as of 01/13/20)

PRIM&R Meeting, Orlando, FL, April 5-7, 2020 (pre-conference sessions, 4/4)

Reports:

NONE

Investigators trained or re-trained:

NONE

ACUC SOPs reviewed:

NONE

SOPs nearing expiration (120 days):

SOP-ACI-00042 (exp. 03/29/2020)- Sheep Red Blood Cell Preparation for Immunizing Mice or Rats

SOP-OD-00309 (exp. 04/26/2020)- Euthanasia of Rodents by Carbon Dioxide Gas Using AIMS™ Flowmeter

Amendments: Records of reviews by e-mail are kept with protocol files.

Topaz Ref# 100203 to 18-009 (b)(6) - Rec'd 01/14/20; Under DMR;
Comments sent to PI 01/17/20; PI response 01/17/20; **Approved 01/22/20**
Topaz Ref# 100267 to 20-005 (b)(6) Rec'd 01/22/20; Under DMR; **Approved 01/24/20**
Topaz Ref# 100239 to 19-012 (b)(6) - Rec'd 01/23/20; **Approved via VVC, 01/24/20**
Topaz Ref# 100239 to 19-012 (b)(6) Rec'd 02/03/20; FCR requested; FCR 02/20/20
Topaz Ref# 100228 to 19-003 (b)(6) Rec'd 02/33/20; in VVC

Protocols that have expired: (0 Legacy protocols remaining for CY2019 expiration)

NONE

Protocols nearing expiration (120 days): (Investigators have been notified.)

17-008 (04/21/2020)	17-009 (04/27/2020)	17-010 (05/01/2020)
17-011 (05/04/2020)	17-012 (05/05/2020)	17-013 (05/11/2020)
17-014 (05/24/2020)		

Protocols closed at request of PI:

NONE

Full-Committee Reviews:

Ref# 100239 to 19-012 (b)(6) - review comments and discussion primarily directed to animal classification with pain relief given and humane endpoints and requiring PAM. PI then invited to discuss amendment and answer questions. Requests for adding signs of pain and distress to administer pain relief and an endpoint not to exceed 3 days of pain relief before requiring euthanasia. Also, request an early endpoint for weight loss of 25%. Requests for a definition of the increased N to maintain the study. Add PAM to amendment. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

Ref# 100276 (b)(6) - 2nd FCR Committee agreed that most of the questions/ concerns raised by the committee were addressed by the PI and only come minor modifications were remaining primarily the need of a summary of a ninety days timepoint in the table to justify the findings. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

Topics for Discussion

Spring Semiannual Inspection for Labs (04/01) & Animal Facility (04/02)- schedule reviewed by all members with the Chair to make edits for final review.

Animal Welfare Poster with edits reviewed by all members with no comments.

20 February 2020

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Next Meeting:

Next Meeting – Wednesday, March 25, 2020 at 9:00 a.m. in L-4A.

20 February 2020

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 03/22/2021

Meeting Minutes
Animal Care and Use Committee
Skype Meeting
March 23, 2020
@ 9:00 a.m.

(b)(6)

(b)(6)

Roll Call of Members present:

(b)(6)

(b)(6)

Absent:

Guest:

The Skype meeting was called to order at 9:00 a.m. and was adjourned at 10:25 a.m.

Old Business:

Meeting Minutes

Minutes of February 20 Meeting– Approved with edits

Previous Protocol Reviews

Topaz Ref# 100210 (b)(6) – Full Committee Review 08/16/2018; Comments sent to PI 08/17/2018; PI response 11/27/2018; Under DMR; Returned to PI 04/04/2019: PI intends to withdraw this protocol proposal once a new protocol has been drafted/ submitted

Topaz Ref# 100276 (b)(6) – Full Committee Review 01/16/2020; IACUC subcommittee meeting w/ PI 01/21/2020; Comments sent to PI 01/22/2020; PI response 02/11/2020; 2nd FCR 02/20/2020; Comments sent to PI 02/24/2020; PI response 03/04/2020; Under DMR; **Approved 03/11/2020**

New Business:

(Adverse Events, Compliance Issues, Animal SOPs, Committee Membership, etc. addressed in the following reports)

Chair Report

(b)(6)

(b)(6)

Conflict of Interest and Confidentiality Reminder

Departure of IACUC Scientist Member (b)(6) - the IACUC Chair is working w/ HELD leadership to identify a Scientist Member to replace (b)(6) & identify a new alternate scientist member for appointment to the IACUC

19-013 (b)(6) Post-PAM follow-up/ discussed pilot study results at a meeting w/ an IACUC subcommittee.

Adverse Event – 20-007 (b)(6) Event was reported 03/12/20. Mice arrived at the facility on 03/11/2020 and at approx. 4:30 pm, the PI and a protocol associate finished weighing and randomizing the mice for an upcoming study and had placed them in cages for the first time since their arrival. Two cages of mice ((1) N=3, (2) N=4) went without

2 April 2020

Obtained by Rise for Animals.

Uploaded to Animal Research Laboratory Overview (ARLO) on 03/22/2021

water overnight. The two bottles were present but were turned upside down. The following morning the animal husbandry technician discovered that the water bottles were upside down and re-positioned them properly. Other than appearing thirsty, the mice seemed fine the next morning. The PI and protocol associates were reminded to carefully check that cage lids and water bottles are properly positioned before cages were returned to the cage rack. Animal welfare wasn't compromised. The IACUC considered the adverse event closed.

IACUC Administrator Report

OLAW released a notice (NOT-OD-20-088) regarding flexibilities for assured institutions for activities of IACUCs due to COVID-19

Approved minutes from January IACUC Meeting sent to the IO, ACUPO Chief, & ACUPO, 02/25/2020

All actions re. AAALAC site visit have been cancelled

Spring Semi-annual Labs & Animal Facility Inspections & Program review- postponed

April IACUC Meeting- currently have 3 protocols and 1 amendment submitted for FCR; expect 1 more protocol (rodent breeding program)

Attending Veterinarian/ Facility Director Report

AAALAC Annual Report submitted 02/26/2020

AAALAC Site Visit- 26 March 2020- postponed to May- July

AF/ IF is operating at full capacity; DERT engineers have been in the IF to support on-going exposure studies

AV has been participating in daily Tag-up meetings with HELD OD. There has been discussion regarding on-going animal studies and animal ordering; he is encouraging PIs to continue with their work and use the animals that they have on site. Animal orders can be submitted but are being carefully reviewed. Orders for new animal studies will not be placed. The IACUC expressed concerns regarding how this information is being sent to the PIs and recommended that the IC, AV and IA draft a list of concerns for the AV to present to the OD during the Tuesday Tag-up meeting.

Program

Review of revised draft of new CDC-Morgantown IACUC policy P-0012 on Anesthesia and Analgesia Guidelines- approval delayed until after spring semi-annual inspection of labs when IACUC inspection teams will check PIs' protocols to confirm that approved anesthetics and analgesics are within the described dose ranges in P-0012.

Addition of ulcerative dermatitis (CDC-Morgantown policy P-0011) question to Topaz new protocol form on the Topaz development site; will eventually be a part of the new protocol form on the Topaz production site.

Post Approval Monitoring (PAM)

NONE

2 April 2020

Obtained by Rise for Animals.

Uploaded to Animal Research Laboratory Overview (ARLO) on 03/22/2021

NIOSH Breeding Program

Genotyping of weaned mice has been affected as technical staff in charge of genotyping are teleworking; AV will suggest to PIs that their animal colonies be put on maintenance status if no study activity is being performed

Upcoming IACUC 101/201/301 meetings

2020 course dates and locations not finalized (as of 03/10/20)
PRIM&R Meeting, Orlando, FL, April 5-7, 2020 (pre-conference sessions, 4/4)
2020 ICARE (Interagency Collaborative Animal Research Education) workshops:
Introduction to IACUC Function: St. Louis, MO, September 15-16, 2020
Refining IACUC Function: Denver, CO, April 28-30, 2020

Reports:

NONE

Investigators trained or re-trained:

NONE

ACUC SOPs reviewed:

SOP-ACI-00042 v2.2 - Sheep Red Blood Cell Preparation for Immunizing Mice or Rats;
Approved, 03/13/2020

SOPs nearing expiration (120 days):

SOP-OD-00309 (exp. 04/26/2020)- Euthanasia of Rodents by Carbon Dioxide Gas Using
AIMS™ Flowmeter

Amendments: Records of reviews by e-mail are kept with protocol files.

Topaz Ref# 100239 to 19-012 (b)(6) - Rec'd 02/03/20; FCR requested; FCR
02/20/20; Comments sent to PI 02/24/20; PI response 02/27/20; Under DMR; **Approved**
03/05/20

Topaz Ref# 100228 to 19-003 (b)(6) - Rec'd 02/13/20; **Approved via VVC**
02/18/20

Topaz Ref# 100231 to 19-007 (b)(6) - Rec'd 03/05/20; Under DMR 03/10/20;
Comments sent to PI 03/11/20; PI response 03/12/20; **Approved 03/16/2020**

Topaz Ref# 100174 to 17-016 (b)(6) - Rec'd 03/05/20; Under DMR 03/10/20;
Comments sent to PI 03/16/20; PI response 03/18/20; 2nd DMR 03/18/20

Topaz Ref# 100201 to 18-008 (b)(6) - Rec'd 03/05/20; Under DMR; **Approved**
03/13/20

Topaz Ref# 100260 to 19-016 (b)(6) - Rec'd 03/05/20; Under DMR; **Approved**
03/13/20

2 April 2020

Topaz Ref# 100208 to 18-010 [(b)(6)] - Rec'd 03/10/20; **Approved as an Administrative Review/ Change 03/11/20**
Topaz Ref# 100217 to 18-013 [(b)(6)] - Rec'd 03/10/20; **Approved as an Administrative Review/ Change 03/11/20**
Topaz Ref# 100278 to 20-008 [(b)(6)] - Rec'd 03/10/20; **Approved as an Administrative Review/ Change 03/11/20**

Protocols that have expired:

NONE

Protocols nearing expiration (120 days): (Investigators have been notified.)

17-008 (04/21/2020)	17-009 (04/27/2020)	17-010 (05/01/2020)
17-011 (05/04/2020)	17-012 (05/05/2020)	17-013 (05/11/2020)
17-014 (05/24/2020)		

Protocols closed at request of PI:

NONE

Full-Committee Reviews:

Ref# 100229 [(b)(6)] - Review comments and discussion primarily directed to scientific justification for the single housing of animals. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

Ref# 100287 [(b)(6)] - Review comments and discussion primarily directed to definition of acronyms, extensive PII and need to describe work conducted here at NIOSH related to the proposed study design. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

Ref# 100288 [(b)(6)] - Review comments and discussion primarily directed to referral of previous data indicating that longer chain PFs are toxic at concentrations > 2%; add justification for starting these studies using a 10% concentration. Clarification of exposure durations; description of animal husbandry or experimental procedures modified to minimize pain and distress and add the abnormal behavior/ signs that will be monitored; updating additional precautions for animal care staff for Perfluoropentanoic acid (PFPeA). Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

Ref# 100289 [(b)(6)] - Review comments and discussion primarily directed to roles and description of duties of protocol associates; GM strains should be listed in the animal information section if they will be used for surveillance, and the number of GM animals needed must be added to the authorized amounts ; clarification of when experimental animals need to be held on this protocol; database searches and keywords need to be included where specified in section; description of clinical signs used to determine euthanasia. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

2 April 2020

Topics for Discussion

None

Next Meeting:

Next Meeting – Thursday, April 16, 2020 at 9:00 a.m. in via Skype

2 April 2020