	Meeting Minutes Animal Care and Use Committee	a paragraph
	October 24, 2019	(b)(6) (b)(6)
	L-4A @ 9:00 a.m.	95
	Members present:	(b)(6)
0)(6)		
	Absent: S	(b)(6)
	Guest:	
	The meeting was called to order by Vice Chair at 9:00 a.m. and was adjourne at 11:55 a.m.	<u>d</u>
	Old Business:	
	Meeting Minutes	
0)(6)	Minutes of September 19 Meeting- Approved as written	
0)(6)	Previous Protocol Reviews	
	Topaz Ref# 100210 — Full Committee Review 08/16/2018; Comments sent to P 08/17/2018; PI response 11/27/2018; Under DMR; Returned to PI 04/04/2019  Topaz Ref# 100227 — Full Committee Review 11/15/2018; Comments sent to PI 11/20/2018  Topaz Ref# 100264 (b)(6) — Full Committee Review 09/19/2019; Comments sent to PI 09/20/2019; PI response 10/08/2019; Under DMR; Approved 10/15/2019	
	New Business:  (Adverse Events, Compliance Issues, Post Approval Monitoring, Animal SOPs, Committee Membership, etc. addressed in the following reports)	
	Chair Report	(b)(6)
	Conflict of Interest and Confidentiality Reminder  Adverse Event Follow up – 19-001  Adverse Event Follow up – 18-010  PAM performed, 10/22/19  IO sent report to OLAW, 10/02/19  Semi-annual Inspection of Labs/ Animal Facility- sending the inspection forms out ahea of time to the PIs to fill out before the inspection reduced the time of the inspection process; the Spring Semi-annual Inspection will be scheduled for 2 days (1 day for all labs and 1 day for the animal facility) instead of the current 4 days; noted that there still seems to be confusion about what are 'child bottles' for controlled substances.	

IACUC Administrator Report

(b)(6)

Fall Semiannual Inspection- 10/3, 10/7-10/9; revised inspection forms for AF and laboratories will be further revised as a result of the inspection to improve/clarify questions and information gathered; inspection findings- mostly minor findings: labs-ACUC notebook recordkeeping; key to controlled substance locked drawer not stored in a concealed location in 1 lab; animal facility - 2 bottles of expired antibiotic in 2 locations (immediately removed); expired disinfectant (removed/ replaced) in several locations

FY2019 Annual Review of Animal Use- due back to IA, 10/31/19; IA provided animal numbers to PIs due to Topaz software issue (PIs couldn't access the information for their specific protocols); to date- 37/63 reports reviewed & approved; 4/63 reports need revised; 22/63 reports outstanding.

IACUC Inter-Institutional/ Collaborative Agreement – no update CDC-Morgantown IACUC Charter- submitted to CDC/OLSS/OD for re-formatting, 05/09/19; IACUC Chair, Administrator, and Attending Veterinarian had two conference call with OLSS IACUC Liaison 9/30 & 10/18; Charter will be edited to reflect our suggestions, forwarded to IO

## Attending Veterinarian/ Facility Director Report

AALAS Meeting (Denver, CO), 10/13- 10/17/ 2019 Summary- Protocol Annual Reviews may not be required next year; USDA & OLAW annual report dues will soon coincide; EPA director initiative to reduce animal research 30% by 2025 and completely eliminate it (with loophole for exceptions) by 2035; 2 new (rare) viruses discovered; another mouse adenovirus and rat polyoma virus 2- IDEXX is developing tests for these.

Animal census numbers- steady but low, and am not seeing a new FY surge yet.

AF Working Standards — working with AF Manager & AV in updating & reformatting working standards

Façade renovation (Oct- Dec 2019)- may have effect on IF exposure studies and breeding colony production. This remains a concern, but lately has made much less noise than expected. Vibration recording conducted two weeks ago, but two of the data loggers are missing.

#### Program

Semi-annual Program Review: FCR of CDC-IACUC Policies P-0001(Social Housing); P-0003 (Euthanasia); P-0004 (Conflict of Interest); P-0005 (Satellite Animal Facility) – IACUC approved revisions suggested by AV to P-0003 on Euthanasia regarding cervical dislocation; also look into training and proficiency assessment for cervical dislocation. After discussion of P-0005 on Satellite Animal Facility- the AV will further review, discuss with Chair and IA, and bring suggested revisions, or recommendation to not revise at this time, to the November IACUC Meeting. Need to determine if (b)(6) should be considered a Satellite room, consider relaxing some room (macroenvironment) standards and whether and with what conditions to reopen the with IVC housing for short period use.

Adverse Events-

Follow-up: 19-001 (b)(6) – Post-Approval Monitoring performed, 10/22/2019
Post Approval Monitoring (PAM)
19-001
IACUC discussion- The committee concluded that the investigation into the adverse event cannot be closed until the PI is observed performing the restraint procedure that initiated the Adverse Event Report and the subsequent IACUC investigation & PAM.
NIOSH Breeding Program
Discussion of 55% relative humidity improving breeding, as reported in seminars at the National AALAS meeting. Assessing levels of vibrations caused by the building façade renovation and being vigilant for possible effects on the breeding colonies; plan to move one breeding colony from an outer room to a inner room in the animal quarters. Looking for short term money (10K or so) for installing light timer alarms in the AF rooms. May consider installation of blue LED lights for the major HVAC controls renovation, which we hope will begin in about 1 year.
Upcoming IACUC 101/201/301 meetings
November 6, 7, 8, 2019: IACUC 101, 201 and 301 in Houston, TX - Hosted by Rice University
Reports:
Investigators trained or re-trained:
NONE

ACUC SOPs reviewed:	
NONE	
SOPs nearing expiration (120 days):	
SOP-OD-00314 (exp. 01/26/2020)- Mouse oropharyn	geal aspiration
Amendments: Records of reviews by e-mail are kept with pro	stocol files.
<b>Topaz Ref# 100156</b> to 17-005 (b)(6) Rec've Comments sent to PI 04/09/19	d 04/04/19; Under DMR;
	d 04/09/19; Under DMR;
Comments sent to PI 04/15/19; PI response 04/22/19;	
05/01/19 Tanag Pof# 100215 to 10 001 (b)(6) Pag'yd 10	MANAGEMAN MANAGEMAN (MINES ONLY EXCENSIVE AND EXCENSIVE AN
<b>Topaz Ref# 100215</b> to 19-001 Rec'vd 10.	/08/19; Under DMR; Approved
(1-1/0)	5/19; Under DMR; Comments sent
to PI 10/22/19; PI response 10/22/19	5/15, Older Divik, Comments sent
(b)/G)	0/16/19; Under DMR; Comments (b)(6)
sent to PI 10/23/19; PI response 10/24/19	
[시간 1746년 - 12일 전입하는 - 제 20 전에 대한지를 모르아 보이고 있다고 되었습니다	0/18/19; Under DMR
<b>Topaz Ref# 100158</b> to 17-014 - Rec'vo	d 10/21/19; request for FCR
10/24/19	
Protocols that have expired: (3 Legacy protocols remaining for	or CY2019 expiration)
17 001 (10/20/2010)	
17-001 (10/20/2019)	
Protocols nearing expiration (120 days): (Investigators have l	been notified.)
17-002 (10/28/2019) 17-004 (11/21/20	019)
17-005 (11/21/2019) 17-006 (11/16/20	
17-007 (12/23/2019)	
Protocols closed at request of PI:	
2	

17-015 (7/11/2020)

17-001 (10/20/2019) 18-007 (12/21/2020)

19 November 2019
Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 03/22/2021

Ref# 100261

1. Committee discussed at length the roles and responsibilities of the protocol associates pertaining to euthanasia methods, particularly by focused-beam microwave irradiation. Only two associates are well trained in this procedure. Committee suggested removing this task from associates not trained in this procedure. Alternatively, PI needs to provide adequate training to all associates, after which a PAM is to be done to ensure the procedure is conducted properly by the newly trained associates. 2. Suggested expansion of the duplication search strategy to include AChE inhibitors & the treatments (drugs) proposed in the protocol. 3. Suggested providing drug dose ranges and routes of exposures. 4. The anticipated 50% mortality rate was discussed and a decision was made to have subcommittee (consisting of the Chair, Administrator, primary reviewer, secondary reviewer) to meet with PI and/or lab members to discuss the mortality issues. 4. Suggested providing a list of anticipated adverse effects & a plan for detection/mitigation. IACUC unanimously agreed the re-submitted revised protocol be reviewed by DMR.

Follow-up meeting by sub-committee: On 10/31/2019 (9.30 – 10.30 am) the sub-committee met with the research associates from the PI was not present. The associates presented historical data on the mortality rate and it was determined that the mortality followed a specific pattern based on whether it was an acute exposure study or a long-term study. In general, there was a lower incidence of mortality in acute studies (~15-20%) and a higher incidence of mortality (~40-70%) in the long-term recovery studies. The sub-committee suggested reporting these separately and reassessing animal requirement based on the type of study (short vs long) in an effort to reduce animal numbers.

CDC-Morgantown IACUC Policy P-009 USDA Pain Categories- discussed the examples of USDA Pain Category E- kept the antibody production- *in vivo* ascites methods in mice example and decided to omit language regarding food and water restrictions as this does not apply to research currently performed at NIOSH and if this type of research were performed it would be scrutinized during the protocol review process. The policy was unanimously approved with the recommended revision.

## **Topics for Discussion**

Upcoming reviews for November meeting- amendment called for FCR during 48-hour amendment review; FCR of 3 new protocols

#### Next Meeting:

Next Meeting - Thursday, November 21, 2019 at 9:00 a.m. in L-4A.

(b)(6)

## Meeting Minutes Animal Care and Use Committee November 21, 2019 L-4A @ 9:00 a.m.

Members present: (b)(6)
Absent: (b)(6)
Guest: [10](0)  The meeting was called to order at 9:00 a.m. and was adjourned at 10:30 a.m.
Old Business:
Meeting Minutes
Minutes of October 21 Meeting- Approved as written
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# 100227   Full Committee Review 11/15/2018; Comments sent to PI 11/20/2018; Withdrawn 10/25/19  Topaz Ref# 100261   Full Committee Review 10/24/2019; Comments sent to PI 10/31/19; PI response 11/1/2019; Under DMR; Approved 11/13/2019
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 Follow up $-19-001$ (b)(6) PAM performed on 11/18/19 to confirm PI's skill in performing animal restraint and tail nick procedures; IACUC unanimously agreed that no additional action needed regarding this adverse event; Chair will draft a memo to PI summarizing the IACUC's final opinion.

IACUC Administrator Report

Fall Semiannual Inspection & Program Review- report sent to IO, 11/07/2019

FY2019 Annual Review of Animal Use- completed 11/13/2019; report sent to ACUPO, 11/13/2019

IACUC Inter-Institutional/ Collaborative Agreement – no update CDC-Morgantown IACUC Charter- OLSS IACUC Liaison will edit our Charter to reflect our suggestions (10/18/19 conference call) and then forward Charter to IO Semi-Annual Inspections- new proposed Spring schedule for Labs- Wednesday, 4/1/20, & Animal Facility- Thursday, 4/2/20; new proposed Fall schedule for Labs- Wednesday, 10/7/20, & Animal Facility- Thursday, 10/8/20

## Attending Veterinarian/ Facility Director Report

Animal census numbers—numbers are slightly lower than from this time last year AF Working Standards—steadily updating & reformatting working standards Facade renovation update—work appears to be taking longer due to weather conditions

## Program

PHS Assurance for Domestic Institutions- in the process of making final revisions to address comments from OLAW

Reviewed revised CDC-Morgantown IACUC Policy P-0003 on Euthanasia- revision unanimously approved

Reviewed new CDC-Morgantown IACUC Policy P-0010 on Prolonged Restraint-discussed the definition of prolonged restraint; IACUC approved change in time of prolonged restraint from 5 minutes to 30 minutes (provided that the animals are not observed to be in distress); policy was unanimously approved with the recommended revision.

CDC-Morgantown IACUC Policy P-0005 on Satellite Animal Facility- discussed the definition of the satellite facility and the definitions of holding vs housing of animals outside of the animal facility. The policy will be revised and reviewed by the IACUC at the December Meeting

Post Approval Monitoring (PAM)

19-001 (b)(6) performed 11/18/19 (Adverse event follow-up)

PAM summary- Post-approval monitoring (PAM) was conducted on November 18, 2019 for the purposes of executing the IACUC request for PAM to observe the PI performing the restraint of mice in Broome restrainers and nail nick procedure.

Observation: The PI was observed to be proficient in performing the restraint and tail-nick procedures.

IACUC discussion- The IACUC unanimously agreed that this is not a reportable event to OLAW and the investigation into the adverse event is closed

#### **NIOSH Breeding Program**

	Upco	ming	IACUC	101/20	1/301	meetings
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2020 course dates and locations not finalized

Re	ports

Report of non-compliance- 18-015 (b)(6) A report of protocol noncompliance was reported to the IACUC on 11/5/2019. One set of animals were exposed to 3D printer fumes for 8 days of total exposure, 5 days the first week and 3 days the second week. However, the approved protocol states that animals will be exposed for 4 days/ week for a period of 8 days. This change in exposure regimen was not approved in the protocol. (The animals were not adversely affected by the change). The IACUC Chair discussed the non-compliance with the PI and encouraged the PI to amend the protocol to include ranges of exposure to avoid additional incidents on protocol non-compliance. The PI submitted an amendment to the protocol as recommended.

Investigators trained or re-trained:

NONE

ACUC SOPs reviewed:

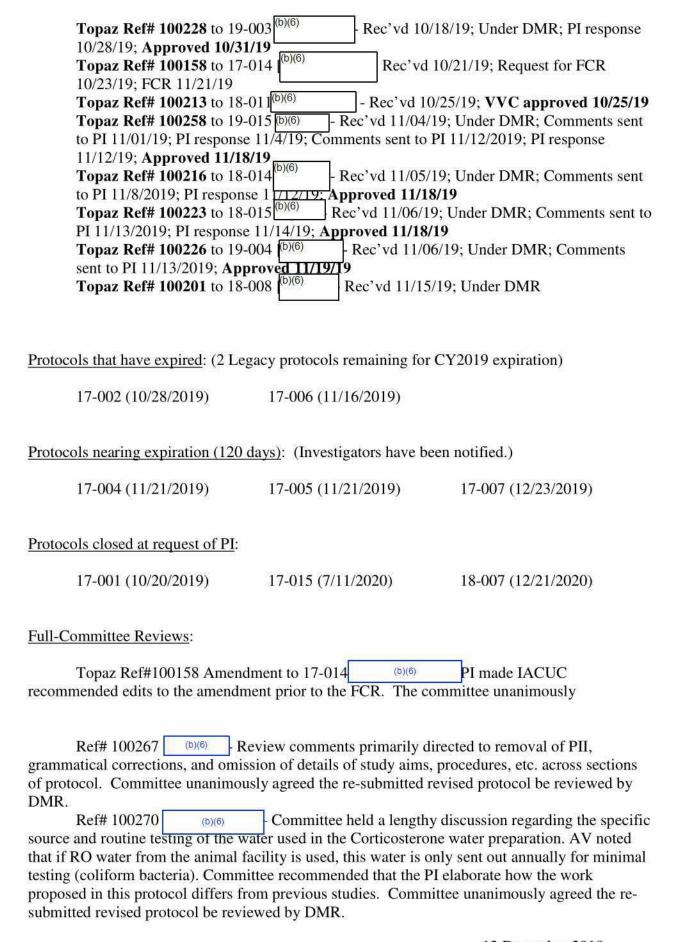
NONE

SOPs nearing expiration (120 days):

SOP-OD-00314 (exp. 01/26/2020)- Mouse oropharyngeal aspiration

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

<b>Topaz Ref# 100156</b> to 17-005 (b)(6)	Rec'vd 04/04/19; Under DMR;
Comments sent to PI 04/09/19; Withdray	wn 10/25/19
<b>Topaz Ref# 100174</b> to 17-016 (b)(6)	- Rec'vd 04/09/19; Under DMR;
Comments sent to PI 04/15/19; PI respons	se 04/22/19; Under DMR; Comments sent to PI
05/01/19; Withdrawn 10/24/19	
<b>Topaz Ref# 100215</b> to 19-001 (b)(6)	- Rec'vd 10/08/19; Under DMR; Approved
10/18/19	<u> </u>
<b>Topaz Ref# 100231</b> to 19-007 (b)(6)	Rec'vd 10/15/19; Under DMR; Comments sent
to PI 10/22/19; PI response 10/22/19; Ap	proved 10/28/19
Topaz Ref# 100238 to 19-011 (b)(6)	- Rec'vd 10/16/19; Under DMR; Comments
cent to PI 10/23/10: PI recourse 10/24/10	Annroyed 10/31/10



Ref# 100273 — Committee held a lengthy discussion covering the same topics discussed in Ref# 100270. Committee also recommended that the PI add data from previous experiments using this animal model and to add information regarding the mouse strains used in this protocol, including if a difference in mortality rates is expected after dosing with DFP. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

## **Topics for Discussion**

Discussed a protocol that has been lingering in the review process for over a year; committee recommended that the Chair contact the PI and ask when the protocol will be re-submitted. The Chair will also inform the PI that all literature searches will have to be repeated and the protocol updated.

Upcoming reviews for December meeting- FCR of 2 new protocols and one new CDC-Morgantown IACUC policy on justification of animal numbers IACUC Training- scheduled for December meeting

## Next Meeting:

Next Meeting – Thursday, December 12, 2019 at 9:00 a.m. in L-4A.

# **Meeting Minutes Animal Care and Use Committee** December 12, 2019 L-4A @ 9:00 a.m.

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	L-4A @ 9:00 a.m.
	Members present:
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(b)(6)	
100/100 300/35333	Absent: F
	Guest
	The meeting was called to order at 9:00 a.m. and was adjourned at 10:55 a.m.
	Old Business:
	Meeting Minutes
(b)(6)	Minutes of November 19 Meeting- Approved as written
(b)(6)	Previous Protocol Reviews
(b)(6)	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
(b)(6)	Topaz Ref# 100267 — Full Committee Review 11/21/2019; Comments sent to PI 11/21/2019; PI response 12/09/2019; Under DMR; Approved 12/12/2019 Topaz Ref# 100270  — Full Committee Review 11/21/2019; Comments
	sent to PI-11/21/2019; PI response 11/22/2019; Under DMR; <b>Approved 11/27/2019 Topaz Ref# 100273</b> — Full Committee Review 11/21/2019; Comments
	sent to PI 11/21/2019; PI response 11/22/2019; Under DMR; Approved 12/02/2019
	New Business: (Adverse Events, Compliance Issues, Post Approval Monitoring, Animal SOPs, Committee Membership, etc. addressed in the following reports)
	Chair Report (b)(6)
	Conflict of Interest and Confidentiality Reminder  Adverse Event Follow up – 19-001 PAM performed on 1/18/19 to confirm  PI's skill in performing animal restraint and tail nick procedures; IACUC unanimously agreed that no additional action needed regarding this adverse event; Chair will draft a memo to PI summarizing the IACUC's final opinion.

## IACUC Administrator Report

IACUC Inter-Institutional/ Collaborative Agreement – no update

CDC-Morgantown IACUC Charter- edits completed 12/02/19 by OLSS IACUC Liaison and forwarded to IO

Annual Report to OLAW sent to ACUPO on 12/10/19 to review then forward to IO who will sign and send to OLAW

Ref 100210 ([b)(6) protocol proposal lingering in review process for over a year has been contacted by the IACUC Chair; PI understands that a new literature search will need to be performed and other sections of the protocol may have to be updated when PI resubmits the protocol for review

## Attending Veterinarian/ Facility Director Report

AF Working Standards—dermatitis working standard will be the next to be drafted Facade renovation update—work has stopped for the season

AAALAC Program Description submitted to AAALAC on 7 December 2019 Current animal census – 1700

App strain Mouse found dead in mummified condition in AF; concern about pox virus infection in the mouse colony; PCR/ virology tests were sent to IDEXX for testing; all results came back negative; colony is clean; conclusion mouse death could have been the result of a lethal buildup of amyloid protein- a condition associated with the App phenotype mouse

## Program

PHS Assurance for Domestic Institutions- revised to address comments from OLAW; revised document sent to ACUPO/ IO for review & IO re-submits document to OLAW

Reviewed new CDC-Morgantown IACUC Policy P-0011 on Justification of Animal Numbers- policy was discussed at great length; draft will be revised per committee members' comments and reviewed again by the full committee at the 16 January 2020 IACUC Meeting.

Reviewed revised CDC-Morgantown IACUC Policy P-0005 on Satellite Animal Facilitydiscussed the definition of the satellite facility and the definitions of holding vs housing of animals outside of the animal facility. Revision unanimously approved with minor edits to references.

Post Approval Monitoring (PAM)

19-001 ((b)(6) — Memo re. adverse event & PAM findings sent to PI by IACUC Chair, 12/05/19; investigation of adverse event is closed.

**NIOSH Breeding Program** 

Upcoming IACUC 101/201/301 meetings
2020 course dates and locations not finalized PRIM&R Meeting, Orlando, FL, April 5-7, 2020 (pre-conference sessions, 4/4)
Reports:
NONE
<u>Investigators trained or re-trained</u> :
NONE
ACUC SOPs reviewed:  NONE
SOPs nearing expiration (120 days):
SOP-OD-00314 (exp. 01/26/2020)- Mouse oropharyngeal aspiration revised; in HELD SOP approval process
Amendments: Records of reviews by e-mail are kept with protocol files.
Topaz Ref# 100158 to 17-014 - Rec'vd 10/21/19; Request for FCR 10/23/19; FCR 11/21/19; Approved 11/21/19  Topaz Ref# 100201 to 18-008 - Rec'vd 11/15/19; Under DMR; Comments sent to PI 11/21/19; PI response 11/21/19; Under DMR; Comments sent to PI 12/03/19; Approved 12/04/19  Topaz Ref# 100215 to 19-001 - Rec'vd 11/22/19; VVC approved 12/02/19
Protocols that have expired: (0 Legacy protocols remaining for CY2019 expiration)
17-004 (11/21/2019) 17-005 (11/21/2019)
Protocols nearing expiration (120 days): (Investigators have been notified.)
17-007 (12/23/2019)
Protocols closed at request of PI:  NONE

#### Full-Committee Reviews:

Ref# 100269 (b)(6) - Review comments primarily directed to clarification of number of animals in study cohort/grouping of animals in the study design. Committee unanimously agreed the re-submitted revised protocol be reviewed by DMR.

Ref# 100277 (b)(6) - Committee held a lengthy discussion regarding the study design, exposures and animal cohorts. Significant number of questions and review comments from committee members. Committee unanimously agreed to have a subcommittee from the IACUC meet with the PI to discuss the protocol review comments before the protocol is revised and resubmitted for review. The subcommittee met on December 18th, 2019 and concerns of the IACUC were communicated to the investigators. Specifically, the IACUC members emphasized the importance of animal number justification with respect to proposed experimental exposure incidence and burden and the correction of the term "mixed exposures". 2nd FCR for the protocol scheduled for the 16 January 2020 IACUC Meeting.

## Topics for Discussion

IACUC Training- IACUC Scenario reviewed and discussed Reviewed journal article regarding the effect of animal microbiome on study results and consideration during study design

## Next Meeting:

Next Meeting – Thursday, December 12, 2019 at 9:00 a.m. in L-4A.