

Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Animal Care and Use Committee
Wednesday March 18, 2019

In accordance with the NIH Notice# NOT-OD-20-088, the NICHD ACUC did not meet in person, but chose to use designated member review (DMR) in lieu of full committee review (FCR). All members were given advanced notice of this change and provided with the electronic files for review (ASP and Mods) including a detailed memo about each file from the Chair. The committee unanimously voted to use DMR and sent any notes they had to the Chair. The comments sent to the Principal Investigators are below.

Discussion of other items listed on the March agenda were postponed to the April meeting.

Animal Study Proposals – Renewals

(b) (5)

By unanimous consent of the full committee, the [Redacted by agreement] ASP was reviewed by designated review by Karl Pfeifer, Ruth Woodward, and [Redacted by agreement] after receiving comments from other committee members. The proposal is clearly written. Especially the significance, use of animals, and animal numbers were very clearly justified.

The ASP is **TABLED** so that Dr. [Redacted by agreement] can address the following concerns:

(b) (5)

Review of Proposed Modification to Animal Study Proposal

Epigenetic regulation of early mouse development

Redacted by agreement.

- Mod – requests to do mouse perfusion

By unanimous consent by the full committee, the [Redacted by agreement] Amendment was reviewed by designated review by Karl Pfeifer, Ruth Woodward, and [Redacted by agreement] after receiving comments from other committee members.

During pre-review, Dr. [Redacted by agreement] clarified that this amendment to permit cardiac perfusion for tissue fixation would be performed on about 20 animals. The amendment included a clear description of how lab members will be trained.

The amendment was **APPROVED**.

Molecular regulation of skeletal development

Redacted by agreement.

- Mod – requests to add new gene, Spin4, to create and study

By unanimous consent of the full committee, the [Redacted by agreement] Amendment was reviewed by designated review by Karl Pfeifer, Ruth Woodward, and [Redacted by agreement] after receiving comments from other committee members.

Ms. [Redacted by agreement] confirmed that the necessary RD registrations had been submitted describing these new animals.

This amendment was **APPROVED**.

By unanimous vote of the full committee, the [Redacted by agreement] Amendment was reviewed by

designated review by Karl Pfeifer, Ruth Woodward, and [Redacted by agreement] after receiving comments from other committee members.

Dr. [Redacted by agreement] provided a careful and thorough response to our questions from our October 2019 memo.

The amendment was again **TABLED** so that Dr. [Redacted by agreement] could address the following points:

[Redacted by agreement] (b) (5)

Analysis of developmental malformations in genetically altered mice

[Redacted by agreement]

[Redacted by agreement]

- Mod – 1 – [Redacted by agreement] (b) (5)
By unanimous vote of the full committee, the [Redacted by agreement] Amendment was reviewed by designated review by Karl Pfeifer, Ruth Woodward, and [Redacted by agreement] after receiving comments from other committee members.

The amendment was **TABLED** so that Dr. [Redacted by agreement] could address the following concerns:

[Redacted by agreement] (b) (5)

- Mod – 2 – requests to amend humane endpoints
By unanimous vote of the full committee, the [Redacted by agreement] Amendment was reviewed by designated review by Karl Pfeifer, Ruth Woodward, and [Redacted by agreement] after receiving comments from other committee members.

During prereview, Dr. [Redacted by agreement] clarified that these are “humane” endpoints and not “human endpoints”.

He also clarified that there is no change in the method of monitoring.

The amendment was **APPROVED**.

- Mod – 3 – [Redacted by agreement] (b) (5)
By unanimous vote of the full committee, the [Redacted by agreement] Amendment was reviewed by designated review by Karl Pfeifer, Ruth Woodward, and [Redacted by agreement] after receiving comments from other committee members.

The amendment was **TABLED** so that Dr. [Redacted by agreement] could address the following concerns:

[Redacted by agreement] (b) (5)

[Redacted by agreement] (b) (5)

- Mod – 1 – [Redacted by agreement] (b) (5)
By unanimous vote of the full committee, the [Redacted by agreement] Amendment was reviewed by designated review by Karl Pfeifer, Ruth Woodward, [Redacted by agreement], and [Redacted by agreement]. [Redacted by agreement]

The amendment was **TABLED** so that Dr. [Redacted by agreement] could address the following concerns:

[Redacted by agreement] (b) (5)

- Mod – 2 – [Redacted by agreement] (b) (5)
By unanimous vote of the full committee, the [Redacted by agreement] Amendment was reviewed by designated review by Karl Pfeifer, Ruth Woodward, [Redacted by agreement], and [Redacted by agreement]. [Redacted by agreement]

The amendment was **TABLED** so that Dr. [Redacted by agreement] could address the following concerns:

(b) (5)

7. Proposed modifications to the following ASPs were approved using a designated review process.

Neuronal circuits controlling behavior: genetic analysis in zebrafish

[Redacted by agreement]

[Redacted by agreement]

- Mod 1 – requests to take adult fish prior to euthanasia off of feed for 4 days

8. Proposed Personnel Modifications to the following ASPS were approved using a designated review process.

[Redacted by agreement]

removed 19 Mar 2020

[Redacted by agreement]

– added 19 Mar 2020
– added 19 Mar 2020

[Redacted by agreement]

– removed 27 Mar 2020

9. Tabled items approved since last meeting or expired (>90 days)

Analysis of zebrafish embryonic development,

[Redacted by agreement]

10. Tabled items still pending but not expired

November Mtg.:

(b) (5)

11. Annual Reviews for the following Animal Study Proposals were reviewed and approved.

[Redacted by agreement]

[Redacted by agreement]

Approved: 4/1/2020
Approved: 3/19/2020
Approved: 3/30/2020
Approved: 3/30/2020
Approved: 3/26/2020
Approved: 3/19/2020
Approved: 3/19/2020

Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Animal Care and Use Committee
Wednesday April 15, 2020

The April meeting was held by Webex organized by [Redacted by agreement].

Members present:

1. [Redacted by agreement]
2. [Redacted by agreement]
3. [Redacted by agreement]
4. [Redacted by agreement]
5. Dr. Karl Pfeifer (NICHD ACUC Chair)
6. [Redacted by agreement]
7. Dr. Ruth Woodward (NICHD Attending Vet and APD)

Guest Present:

1. [Redacted by agreement]
2. [Redacted by agreement]

1. Review of minutes for the ACUC Meetings of February 19, 2020

APPROVED by unanimous committee vote.

- There was no March meeting but an ASP and several amendments were reviewed by designated review (after unanimous consent of committee members). Memos sent to the Principal Investigators were included for committee members to inspect.

2. Old and New Business

- List of behavior test that could be appropriately reviewed by APD (for VVC) – Dr. Woodward delegated this task to [Redacted by agreement], who has agreed to provide the ACUC a list of Behavior Tests (with standardized language for PIs to use in ASPs and Mods) every month for the ACUC to review and approve for VVC. This month we are reviewing the following tests:
 1. Rotarod Tests
 2. Wire Mesh Grip Strength Grip Test
 3. Elevated Plus Maze Test
- Behavioral tests: Dr. Woodward and Dr. [Redacted by agreement] had several comments and will work with [Redacted by agreement] to edit these protocols and we will review at a future ACUC meeting.
- Revised ASP template
 1. Added new check box for Experimental Endpoints (pg 5)
 2. Added new section in Section M (pg 8-9)
 3. Added statement to Section N. #8 (pg 9)
- ASP changes: [Redacted by agreement] suggested several changes with the goal of making it

easier for the ACUC and facility veterinarians to understand exactly when experimental endpoints apply. The committee agreed with the importance of these changes but suggested some wording changes so that investigators are clear what information is needed and where it should be located in the ASP. Dr. Pfeifer will work with [Redacted by agreement].

3. Animal Care and Use Program Issues

1. Report on Facility functions during pandemic by Dr. Woodward
 - Dr. Woodward reported on facility function during the pandemic. The contract staff has implemented multiple changes including staggered scheduling and expanded hours to maintain social distancing. Dr. Woodward indicated that worker safety is of maximum priority but that animals continue to receive full care. The committee expressed its enthusiastic appreciation of Dr. Woodward, of the entire RAMB staff ([Redacted by agreement]), and of the contract staff. They have been truly impressive!
 - Dr. Woodward indicated that research staff have been generally cooperative in regard to reducing their requests for research support. Therefore she does request any further interventions from the ACUC at this time. However, we should all recognize that this is a fluid situation and other changes may be needed in the future.
2. Semiannual review (see checklist)
 - The committee performed its semi-annual program review using the attached checklist. Here are some highlights of our discussion:
 1. We have had very significant changes regarding staffing. Dr. Woodward is now the Animal Program Director (APD/AV) while still functioning as the facility veterinarian for the Building [Redacted by agreement] and the NICHD Aquatics Facility. [Redacted by agreement] is now the [Redacted by agreement] Manager. [Redacted by agreement] is acting manager of the aquatics facility while providing mentoring to [Redacted by agreement] (b) (5)
 2. Dr. Pfeifer and Dr. Woodward reviewed comments from OLAW inspectors in regard to ACUC oversight. Positive comments include: 1) Our ASP is user-friendly, reviewer-friendly, and specialized for NICHD; 2) ACUC policies are organized, documented, and responsive to OLAW/PHS guidance; 3) minutes reflect robust oversight. Dr. Pfeifer noted that their review included minutes in which we discussed Dr. [Redacted by agreement] ASP. Since this review was based on new ARAC guidelines on ZF and new AVMA guidelines on euthanasia, their concurrence can be taken as tacit approval for our implementation of these new guidelines.
3. Summary of Facility inspections by Dr. Woodward
 - 3. Dr. Woodward clarified how facility inspections were accomplished during pandemic. These are detailed in the report but a quick summary is as follows: Aquatics facilities were inspected by normal processes; the [Redacted by agreement] facility was inspected as part of the recent OLAW inspection which included every room and procedure space in the facility; procedure spaces in Bldg [Redacted by agreement] and [Redacted by agreement] labs were inspected by normal processes; procedure spaces in other labs are considered currently closed (based on orders from SD) and will be inspected once reopened;

holding spaces in facilities run by other Institutes were inspected by ad hoc reviewers.

4. We noted that recent events have clearly demonstrated the excellent work done by RAMB in regard to disaster planning.
4. Review/approval of Semiannual Report.
 5. With these discussions, members present voted unanimously to approve the Semi-Annual Report. [Redacted by agreement] will plan for a method to obtain signatures.
5. OLAW Incident
 - o The OLAW response to the recent Fish mortality incident was included in the packet and is attached to these minutes. Dr. Pfeifer reported that there was another similar incident in February in one of the 4 water systems. Drs. Pfeifer and [Redacted by agreement] discussed this in great detail with [Redacted by agreement] and [Redacted by agreement] and clarified that this a longstanding problem in filtration capacity of the system. Dr. Pfeifer will ask [Redacted by agreement] and [Redacted by agreement] to join our full committee for a full discussion of this problem.

4. Animal Study Proposals – New

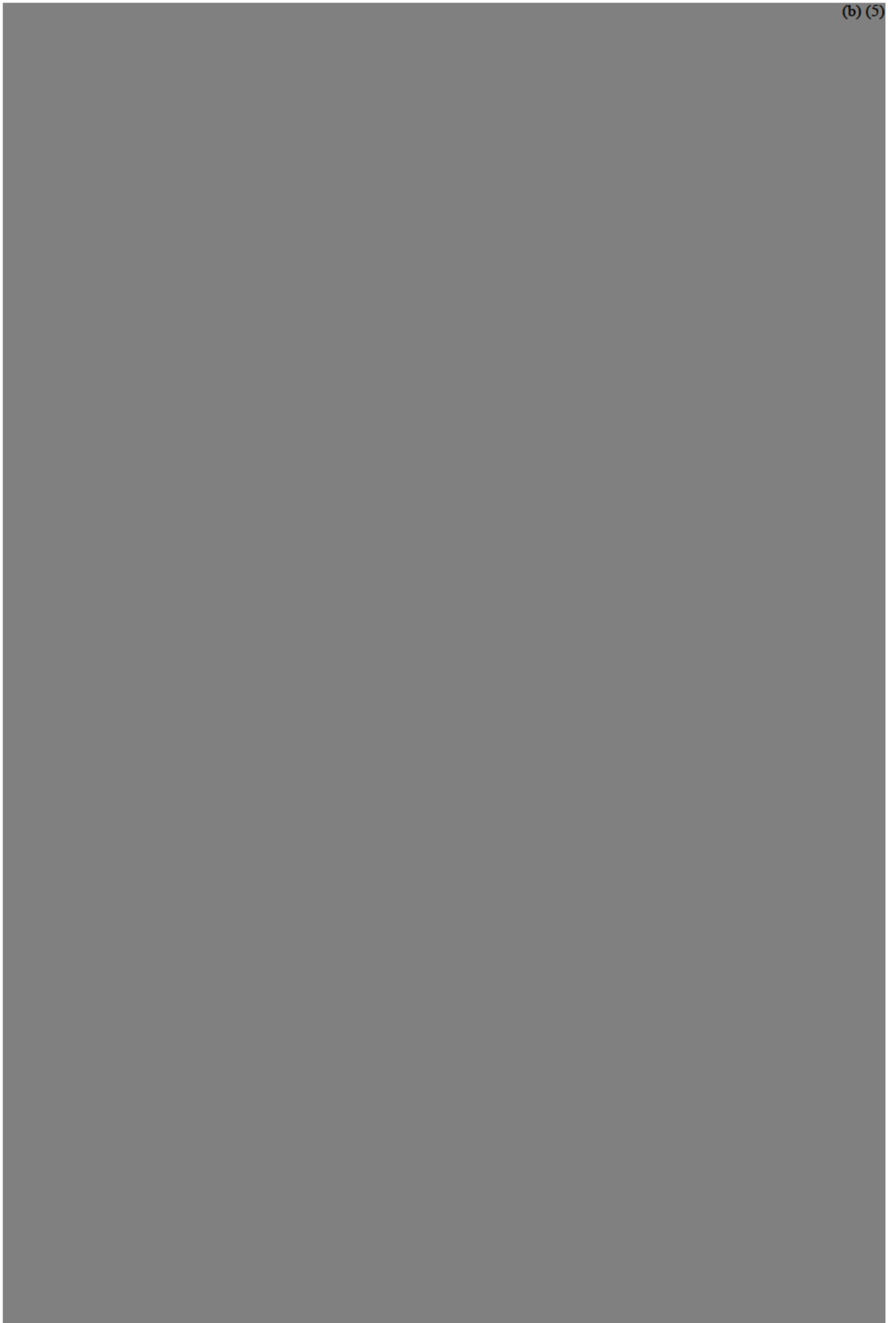
N/A

5. Animal Study Proposals – Renewals

(b) (5)

- o Dr. [Redacted by agreement] ASP underwent substantial pre-review but committee members still had several questions.
- o The committee unanimously voted to **TABLE** the ASP until the following issues have been addressed. The revised ASP will be reviewed by DMR subcommittee [Redacted by agreement], Woodward, Pfeifer):

(b) (5)



(b) (5)

(b) (5)

- [Redacted by agreement] was dismissed from the Webex meeting and Dr. [Redacted by agreement] took lead on reviewing this ASP with the remaining ACUC members. After the meeting, Dr. [Redacted by agreement] sent [Redacted by agreement] the following memo:

Dear [Redacted by agreement] on 4/15/20 the ACUC committee voted to approve your renewal pending the following administrative corrections.

(b) (5)

- The revised ASP will be reviewed by DMR subcommittee prior to final approval
Redacted by agreement, Woodward, Redacted by agreement to ensure the necessary administrative corrections were made.

6. Review of Proposed Modification to Animal Study Proposal

Genetic analysis of organ development in zebrafish (Danio rerio),

Redacted by agreement.

Redacted by agreement

- Mod – requests vital staining of the skull of adult zebrafish for imaging using Calcein and Alizarin Red
- Dr. Redacted by agreement will stain fish briefly with calcein and alizarin red before anesthesia and imaging. After imaging fish will be euthanized.
- Committee members present voted unanimously to **APPROVE** the amendment.

Roles of the melanocortin 3 receptor for energy balance of mice

Redacted by agreement.

Redacted by agreement

- Mod – requests to administer a type II activin receptor inhibitor to mice (BYM-338) and study the affects
- Dr. [Redacted by agreement] will treat mice with BYM-338 and follow effects as already described on the ASP.
- Committee members present voted unanimously to **APPROVE** the amendment.

(b) (5)

- [Redacted] (b) (5) and then monitor as already described on the ASP.
- Committee members present voted unanimously to **TABLE** the amendment so that Dr. [Redacted] could clarify one concern:

(b) (5)

(b) (5)

7. Proposed modifications to the following ASPs were approved using a designated review process.

Signals regulating thymocyte (T cell) development

[Redacted by agreement]

- Mod 4 – requests to have the Animal Care Staff change the sterile cage setup for room [Redacted] to sterile/nonsterile cage set up on alternating weeks

8. Proposed Personnel Modifications to the following ASPs were approved using a

designated review process.

Redacted by agreement.	
Redacted by agreement.	– removed 9 Apr 2020
Redacted by agreement.	– removed 10 Apr 2020
Redacted by agreement.	removed 10 Apr 2020
Redacted by agreement.	– removed 10 Apr 2020
Redacted by agreement.	– removed 13 Apr 2020
Redacted by agreement.	– added 17 Apr 2020
Redacted by agreement.	– removed 21 Apr 2020
Redacted by agreement.	Apr 2020
Redacted by agreement.	– removed 30 Apr 2020

9. Tabled items approved since last meeting or expired (>90 days)

Role of Ion Channels in Neuronal Development and Disease Redacted by agreement.

Role of carboxypeptidase E in neurodevelopment, neuroprotection and stress Redacted by agreement.

Dr. Redacted by agreement.

- Mod 5 – requests to add stereotaxic surgery and AAV injections

Genetic analysis of organ development in zebrafish (Danio rerio), Redacted by agreement.
Redacted by agreement.

- Mod 5 – requests to add treatment of Metronidazole (MTZ) for 3 – 18 mpf adult zebrafish

Analysis of developmental malformations in genetically altered mice Redacted by agreement.
Redacted by agreement.

- Mod 18 – requests to add treatment of Efavirenz
- Mod 19 - requests to amend humane endpoints
- Mod 20 - requests to add treatment of Perampanel

10. Tabled items still pending but not expired

March Mtg:

11. Annual Reviews for the following Animal Study Proposals were reviewed and approved.

Redacted by agreement.

Redacted by agreement.

Approved: 4/27/2020
Approved: 3/27/2020
Approved: 5/1/2020
Approved: 4/9/2020
Approved: 4/16/2020
Approved: 5/4/2020
Approved: 4/29/2020
Approved: 4/29/2020

Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Animal Care and Use Committee
Wednesday May 20, 2020

The May meeting was held by Webex organized by [Redacted by agreement].

Members present:

1. [Redacted by agreement]
2. [Redacted by agreement]
3. [Redacted by agreement]
4. [Redacted by agreement]
5. Dr. Karl Pfeifer (NICHD ACUC Chair)
6. [Redacted by agreement]
7. Dr. Ruth Woodward (NICHD Attending Vet and APD)

Guest Present:

1. [Redacted by agreement]
2. [Redacted by agreement]

1. Review of minutes for the ACUC Meetings of April 15, 2020

APPROVED by unanimous committee vote.

2. Old and New Business

- 2020 OLAW Audit of the IRP Bethesda Campus Report
 - This month's packet included the formal OLAW report from their inspection earlier this year. The report included some specific commendations for NICHD especially in regard to the ACUC coordinator, the ACUC committee, and the Aquatics facility and no specific requests for improvement. OLAW did request that across NIH, all ACUCs start keeping track of all rodent numbers. Right now NICHD ACUC counts weaned rodents. APDs and the OACU are working to implement policies that will allow us to accomplish this.
- 2 - OLAW Incident Closure Reports
 - OLAW responded to our recent reportable events and their report closure letters were included in the monthly packet.
- Bldg ^{Re}_{dac} Incident – animals FD without feed – inform and discuss event with committee
 - Committee members reviewed reports describing an incident from our Bldg. ^{Re}_{dac} facility in March 2020 where 3 animals were found dead after not providing food. The reports included a description of the facility's responses. Committee members agreed that the incident had been appropriately addressed and requested that Dr. Pfeifer report this incident to OACU and to Dr. Gottesman.
- VVC Behavior Tests – no new information for May Meeting
- Revised ASP template – no new information for May Meeting

- Finally, Dr. Woodward requested that the committee monitor Section B, age/weight/size more closely and that the Program needs to know when researchers intend to use older mice. Jax labs defines older mice as 18 months and assumes that these mice need to be handled and treated differently than other adults. Therefore, we will add a new question to Section B that asks the following: “Does this study require mice older than 18 months?” “If yes, please describe and justify in Section F, Part 2 (Experimental Design).
- Aquatics Filtration Project - no new information for May Meeting

3. Animal Care and Use Program Issues

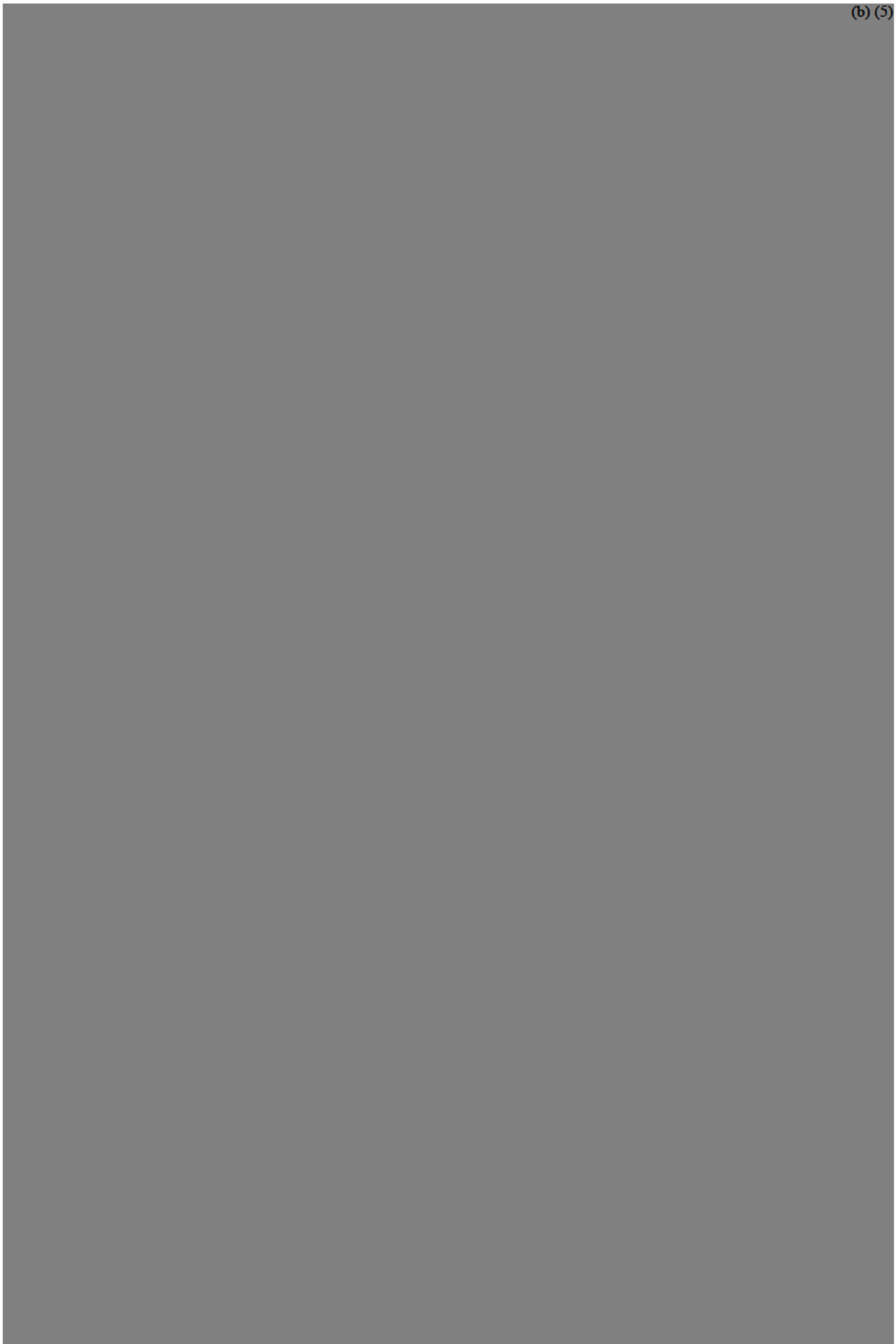
1. Report on Facility functions during pandemic by Dr. Woodward
 - Dr. Woodward reported on facility operations during the pandemic. Staff continue to work on staggered schedules (6 am to 5 pm/7 days per week) to allow for social distancing. Staffing levels remain adequate. OMS will provide testing for COVID-19 as needed.
 - Dr. Woodward is working with Dr. [Redacted] (NICHD SD) to develop plans to begin animal research activities. The solutions will likely include designated periods when investigators can enter the facility. Our committee appreciates that this new phase may put extra strain on facility resources and emphasized our appreciation that Dr. Woodward’s intentions and actions to put employee safety first.

4. Animal Study Proposals – New

N/A

5. Animal Study Proposals – Renewals

- [Redacted] (b) (5)
- [Redacted] (b) (5)
- Committee members voted unanimously to **TABLE** the ASP so that Dr. [Redacted] could address the following concerns:
- [Redacted] (b) (5)



(b) (5)

- The revised ASP can be reviewed by subcommittee
Redacted by agreement/Pfeifer/Woodward).

(b) (5)

- Committee members voted unanimously to **TABLE** the ASP so that Dr. Redacted by can clarify several issues. These changes are all minor and can be done administratively. If you agree to these changes, please respond by email to Redacted by agreement. and she will make the following changes:

(b) (5)

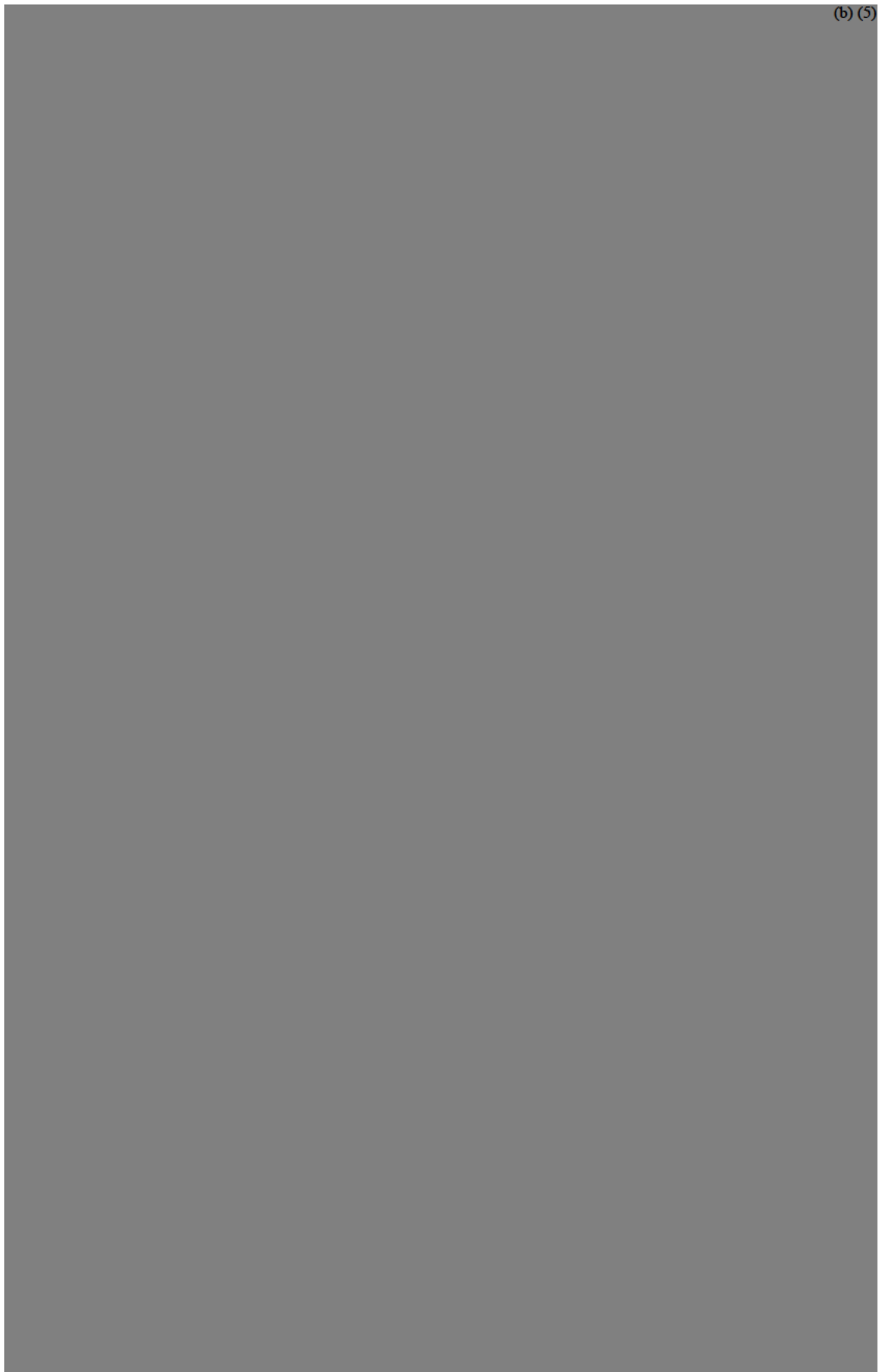
- Again, if you agree to these statements, just confirm that by email and Redacted by agreement.

- Redacted by will fix the ASP accordingly
- The revised ASP can be reviewed by subcommittee Redacted by agreement /Pfeifer/Woodward).

(b) (5)

- Committee members voted unanimously to **TABLE** the ASP so that Dr. Redacted by could address the following concerns:

(b) (5)



- The revised ASP can be reviewed by subcommittee [Redacted by agreement] /Pfeifer/Woodward).

6. Review of Proposed Modification to Animal Study Proposal

Genetic analysis of organ development in zebrafish (Danio rerio)

[Redacted by agreement]

[Redacted by agreement]

- Mod – requests to do adult zebrafish intubation for extended imaging
 - This amendment is to include intubation of zebrafish to permit long term anesthesia by tricaine. The committee concluded that fish would be unconscious and therefore not experiencing distress from the long-term restraint.
 - Committee members present voted unanimously to **APPROVE** the amendment.

7. Proposed modifications to the following ASPs were approved using a designated review process.

N/A

8. Proposed Personnel Modifications to the following ASPs were approved using a designated review process.

[Redacted by agreement]

PMod 12 – [Redacted by agreement] – removed 6 May 2020

PMod 13 – [Redacted by agreement] – removed 11 May 2020

9. Tabled items approved since last meeting or expired (>90 days)

Gene Regulation of the Immune System

[Redacted by agreement]

Genomic imprinting on distal mouse chromosome 7

Redacted by agreement.

Analysis of Developmental Malformations in Genetically Altered Mice

Redacted by agreement.

Redacted by agreement.

- Mod 21 – requests to add acetaminophen treatment

10. Tabled items still pending but not expired

March Mtg:

(b) (5)

11. Annual Reviews for the following Animal Study Proposals were reviewed and approved.

Redacted by agreement.

Redacted by agreement.

Approved:
Approved: 5/5/2020
Approved:

Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Animal Care and Use Committee
Thursday June 18, 2020

The June meeting was held by Webex organized by [Redacted by agreement].

Members present:

1. [Redacted by agreement]
2. [Redacted by agreement]
3. [Redacted by agreement]
4. [Redacted by agreement]
5. Dr. Karl Pfeifer (NICHD ACUC Chair)
6. [Redacted by agreement]
7. [Redacted by agreement]
8. Dr. Ruth Woodward (NICHD Attending Vet and APD)

Guest Present:

1. [Redacted by agreement]

1. Review of minutes for the ACUC Meetings of May 20, 2020

APPROVED by unanimous committee vote.

- During review of the minutes, Dr. Pfeifer discussed the review of Dr. [Redacted by agreement] revised ASP by designated member review (DMR). Dr. [Redacted by agreement] clarified that he was requesting authorization to use toe clips as his primary method for animal identification. By using toe clips, he could mark and biopsy younger animals for genotyping, avoid weaning animals with irrelevant genotypes, and therefore reduce cage numbers. However, given the need to distinguish 100s of animals, Dr. [Redacted by agreement] would not have been able to adhere to NIH recommendations for clipping a single digit, preferable from the hind paw. The DMR subcommittee therefore informed Dr. [Redacted by agreement] that this methodology could not be approved by DMR and instead would need to be discussed by the full committee at its June meeting. Dr. [Redacted by agreement] decided to revise his ASP submission so that toe clips would only be used as described in the NIH guidelines. His revised ASP was then approved by DMR. Committee members had no concerns with this process and agreed that there was no need to develop NICHD specific guidelines on toe clips.

2. Old and New Business

- Bldg [Redacted by agreement] Incident – Dr. Pfeifer sent report to OLAW
- VVC Behavior Tests – no new information yet
- Revised ASP template – no new information yet
- Aquatics Filtration Project - no new information yet
- Please note new function on Wiki – “ACUC MEMBER FILE SHARE”
 1. Dr. [Redacted by agreement] kindly uploaded the (Composite Phenotypic) Scoring System Test presentation, which any member can view
 2. If you have something you want to share with the committee, and the file size if

too big for email, please use this function and let me know so I can inform the group

3. Animal Care and Use Program Issues

- Photography and videography in animal facilities. (See ARAC guideline attachment on wiki)
 - Committee members reviewed the NIH ARAC Guidelines for Collecting and Releasing Animal Images and Audio Recordings (https://oacu.oir.nih.gov/sites/default/files/uploads/arac-guidelines/a3_collecting_and_releasing_animal_images_and_audio_recordings.pdf)
 - We agreed that this is an important issue for the NIH. Facilities holding NICHD animals all currently have policies requiring that researchers discuss any image acquisition with the facility manager and/or veterinarian as required by these policies. As described in the ARAC guideline, current NIH policies already clearly define and restrict mechanisms for making these images public.
 - We agreed that our ACUC does not have a role in enforcing these guidelines but we can play a helpful role by educating researchers. We requested that [Redacted by agreement] modify our ASP template to include a section on Collecting and Releasing Images and Audio Recordings. In this section, we would include 2 bits of information:
 1. A link to the ARAC guideline
 2. A reminder that researchers must discuss their recording plans with their facility manager and/or their facility veterinarian.
 - This section should include a place for the PI to sign to acknowledge that they read and understand these restrictions.
 - Based on this discussion we agreed that the [Redacted by agreement] amendment was not necessary. Dr. [Redacted by agreement] withdrew the amendment.

4. Animal Study Proposals – New

N/A

5. Animal Study Proposals – Renewals

N/A

6. Review of Proposed Modification to Animal Study Proposal

Role of adaptor protein complex 4 (AP-4) in trafficking of neuronal proteins

[Redacted by agreement]

[Redacted by agreement]

- Mod – requests 200 additional mice
 - Dr. [Redacted by agreement] amendment to increase animal numbers was **APPROVED** by unanimous vote.

Gene targeting and ablation of expression of IRE-BP1 and IRE-BP2 in mice

[Redacted by agreement]

[Redacted by agreement]

- Mod – requests to treat heart specific FXN knockout (FXN^{-/-}) mice with branched-chain amino acid (BCAA) supplementation.

- Dr. [Redacted by agreement] amendment for BCAA supplementation was **APPROVED** by unanimous vote.
- Mod – [Redacted by agreement] (b) (5)
- Dr. [Redacted by agreement] amendment [Redacted by agreement] (b) (5) was **TABLED** so that she could clarify th [Redacted by agreement] (b) (5)

[Redacted by agreement] (b) (5)

7. Proposed modifications to the following ASPs were approved using a designated review process.

N/A

8. Proposed Personnel Modifications to the following ASPs were approved using a designated review process.

[Redacted by agreement] – added 19 Jun 2020

9. Tabled items approved since last meeting or expired (>90 days)

Approved 1 Jun 2020:

1. *Investigation into the mechanisms regulating interneuron diversity and maturation* [Redacted by agreement]
Dr. [Redacted by agreement]
2. *Molecular genetics of glucose-6-phosphatase-beta deficiency* [Redacted by agreement]
[Redacted by agreement] agreeme
3. *The Role of Potassium Channels and Synaptic Plasticity in the Regulation of Excitability*^{nt}
[Redacted by agreement]

10. Tabled items still pending but not expired

March Mtg:

[Redacted by agreement] (b) (5)

11. Annual Reviews for the following Animal Study Proposals were reviewed and approved.

N/A

Guidelines for Collecting and Releasing Animal Images and Audio Recordings

This guideline provides details of the proper procedures for collecting and releasing of photographs, video and audio recordings of animals (alive and dead), in animal facilities and animal laboratories at the National Institutes of Health (NIH).

Background:

There are scientific and clinical reasons for obtaining photographs, videos and recordings of animals and animal procedures in animal facilities and laboratories. These materials are useful for documenting clinical care, research, teaching or test results. Public access to these recordings is authorized through the Federal Freedom of Information Act (FOIA) requests.

NIH Manual Chapter 3047 states the 'use of audio, photography and video recording devices for imaging animals (including but not limited to cell phone cameras, digital/cassette dictation devices, cameras and video recording equipment) in NIH owned or leased animal facilities is strictly prohibited except in performance of approved IC Animal Care and Use Committee activities in the animal facility or animal laboratory, or with prior approval by the IC Animal Program Director, or designee, responsible for that specific animal facility or animal laboratory.'

NIH Manual Chapter 1184 notes 'any presentation of information by an NIH employee on a work-related subject, . . . must be prepared according to accepted NIH standards; reviewed for substantive content . . . and administratively approved. This process both protects the public and the employee. The goal of review is to ensure that NIH releases the highest-quality information and to ensure the accuracy, validity, and appropriateness of materials and products for each intended audience.'

Compliance with the Use of Media in the Animal Program:

All digital images and recordings of animals and animal procedures must be transferred and stored onto a secure password protected government computer server. The original recording must be deleted from the recording device immediately following transfer.

The IC Animal Program Director can assist the IC Scientific Director by ensuring best practices were used during media collection, and animal image modifications required as a condition of release and distribution approval were completed. In general, when taking photographs or videos ensure:

- Personnel captured in images are wearing the facility-approved personal protective equipment (PPE) and modeling proper handling and restraint methods.
- Personnel and animal facility images do not show articles indicating the location and identity of the animal facility, personnel, or animals.
- Animal procedure recordings show clean surroundings; and any images of cages or pens show clean accessories, full water bottles and stocked feed containers.
- No extraneous comments or excessive background noises are recorded.
- Images of animal lesions or experimental research alterations only show the area of interest.

References

[NIH Manual Chapter 3047 Trans-NIH Animal Facility Security Program](#) Section G.4.

[NIH Manual Chapter 2809 - NIH Social and New Media Policy](#)

[NIH Manual Chapter 1184 – Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH](#)

[NIH Manual Chapter 1743 – Keeping and Destroying Records](#)

Approved: 12/19/19

Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Animal Care and Use Committee
Thursday July 23, 2020

The June meeting was held by Webex organized by [Redacted by agreement].

Members present:

1. [Redacted by agreement]
2. [Redacted by agreement]
3. [Redacted by agreement]
4. [Redacted by agreement]
5. [Redacted by agreement]
6. [Redacted by agreement]
7. [Redacted by agreement]
8. Dr. Ruth Woodward (NICHD Attending Vet and APD)

Guest Present:

1. [Redacted by agreement]
2. [Redacted by agreement]
3. [Redacted by agreement]
4. [Redacted by agreement]

1. Review of minutes for the ACUC Meetings of June 18, 2020

APPROVED by unanimous committee vote.

2. Old and New Business

- Bldg [Redacted] Incident – Discuss events with ACUC
 - The committee reviewed the June incident in Bldg. [Redacted] where an NICHD investigator set up new cages without adding food pellets. After three days animals were found dead. (Relevant documentation was listed on the Wiki)
 - The committee concluded that there were two important issues. First, the investigator made an easily preventable mistake. Dr. [Redacted] and Dr. [Redacted] (OACU) agreed to meet with the PI to discuss plans to prevent recurrence. Second, the facility care staff did not perform adequate daily health checks – a problem that had led to two other reportable events in the last year. In response to those reportable events, NICHD had planned several significant changes including increased staffing to allow more time per cage and increased oversight. However, staffing changes required by NIH's mandated response to the Covid19 pandemic prevented implementation of these changes. Therefore, we cannot conclude that these previously established plans were inadequate. Dr. Woodward did report that there were two personnel changes made in response to this latest problem. Dr. Pfeifer will prepare a report to OLAW once Dr. [Redacted] and Dr. [Redacted] finish their part of the investigation.

- Revised ASP template – ACUC Coordinator attended the annual PRIM&R’s IACUC Virtual Conference and with the new information learned here, made more revisions to the template for the committee to review
 - In the next month, members will receive [Redacted by agreement] revised ASP template. Please review very carefully. [Redacted by agreement] will present this template at the August meeting for our approval.
- Bldg [Redacted] Incident – see Dr. Pfeifer’s letter to OLAW
 - [Redacted by agreement] reported that the latest OLAW reportable event is closed. That is, OLAW has accepted our report.
- VVC Behavior Tests – no new information
- Aquatics Filtration Project - no new information
- Please note new function on Wiki – “ACUC MEMBER FILE SHARE”
 1. Dr. [Redacted by agreement] kindly uploaded the (Composite Phenotypic) Scoring System Test presentation, which any member can view
 2. If you have something you want to share with the committee, and the file size is too big for email, please use this function and let the ACUC Coordinator know to inform the committee of its addition

3. Animal Care and Use Program Issues

- OACU Guide on Meeting Minutes
- Discuss the designation of qualified individuals as Compliance Specialists to inspect IC labs and animal activity areas on the behalf of the ACUC. These designations have already been approved through DMR, but we would like to give committee members a chance to discuss this further at a fully convened meeting.
 - [Redacted by agreement] reported on his procedure room inspections. The committee was impressed with his work and would like to make use of his inspection template when we resume these inspections on our own. We asked [Redacted by agreement] to modify the template based on his experiences and forward to the committee for our approval [Redacted by agreement] pointed out some unusual features of inspections during the pandemic. Especially, staff are not available to answer questions labs are not being maintained by normal contract staff and so are often a bit untidy while research groups work out methods to perform their own custodial work.
 - Dr. [Redacted by agreement] will report back to Dr. Woodward on whether these July inspections will suffice for our semi-annual report due in October.

4. Animal Study Proposals – New

N/A

5. Animal Study Proposals – Renewals

- [Redacted by agreement] participated in our discussion.

(b) (5)

- We appreciate that this ASP was very carefully and precisely written. We were able to easily follow the experimental plans and understand the significance of the work.
- Committee members voted unanimously to table the proposal so that Dr. [Redacted] could address the following concerns. A revised ASP can be reviewed by subcommittee of [Redacted by agreement], Karl Pfeifer, and Ruth Woodward.

(b) (5)

(b) (5)

6. Review of Proposed Modification to Animal Study Proposal

Ribonuclease H Mutants

Redacted by agreement.

- Mod – wants to al [Redacted] xpected events and request supplemental provisions at weaning
 - Based on questions during pre-review, Dr. [Redacted by] edited his amendment to clarify his request to use food and transgel on the cage floor. This edited version was **APPROVED** by unanimous consent.

7. Proposed modifications to the following ASPs were approved using a designated review process.

Mechanisms of Mammalian Epigenome Reprogramming

Redacted by agreement.

- Mod – requests to add new room in Bldg [Redacted] – Room [Redacted by]
 - Approved through VVC

8. Proposed Personnel Modifications to the following ASPs were approved using a designated review process.

Redacted by agreement.

removed as of 15 Jul 2020

Redacted by agreement.

– removed as of 21 Jul 2020

Redacted by agreement.

added 16 Jul 2020

Redacted by agreement.

– added 27 Jul 2020

Redacted by agreement.

– removed as of last day 25 Aug 2020

Redacted by agreement.

– removed 30 Jul 2020

Redacted by agreement.

– added 31 Jul 2020

Redacted by agreement.

– removed as of last day 7 Aug 2020

9. Tabled items approved since last meeting or expired (>90 days)

Approved:

Gene targeting and ablation of expression of IRE-BP1 and IRE-BP2 in mice

Redacted by agreement.

Redacted by
agreement.

- Mod 13 – requests to treat heart specific FXN knockout (FXN^{-/-}) mice with the antioxidant idebenone

10. Tabled items still pending but not expired

N/A

11. Annual Reviews for the following Animal Study Proposals were reviewed and approved.

Redacted by agreement.

Redacted by agreement.

Approved: 7/30/2020

Approved: 7/2/2020

Approved: 7/16/2020

Approved: 7/2/2020

Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Animal Care and Use Committee
Wednesday August 19, 2020

The August meeting was held by Webex organized by [Redacted by agreement]

Members present:

1. [Redacted by agreement]
2. [Redacted by agreement]
3. [Redacted by agreement]
4. [Redacted by agreement]
5. Dr. Karl Pfeifer (NICHD ACUC Chair)
6. [Redacted by agreement]
7. [Redacted by agreement]
8. Dr. Ruth Woodward (NICHD Attending Vet and APD)

Guest Present:

1. [Redacted by agreement]
2. [Redacted by agreement]
3. [Redacted by agreement]
4. [Redacted by agreement]
5. [Redacted by agreement]
6. [Redacted by agreement]

1. Review of minutes for the ACUC Meetings of July 23, 2020

APPROVED by unanimous committee vote.

2. Old and New Business

A. Revised ASP template – Discuss revisions with ACUC

- [Redacted by agreement] has generated a modified ASP template with extensive revisions. The goals of revisions are as follows: 1) Make a form that is easier for the PI to complete, especially by including informational links, boiler-plate language, and making questions as precise as possible; 2) make a form that is easier for ACUC review; 3) make a form that is easier for research and facility staff to access and know exactly where to find information; 4) and make a form that is easier for veterinarians to use by providing more precise and complete information on endpoints, on phenotypes that might require special veterinary care.
- The committee reviewed the new ASP section by section and provided extensive comments to [Redacted by agreement]. She will prepare a revised ASP to send out to members.

B. Introduce new NICHD Veterinarians: [Redacted by agreement]

- Dr. Woodward summarized some major changes in RAMB staffing.
- Dr. Woodward will be leaving NICHD to oversee the animal program in the Vaccine Research Center (NIAID). We are very sorry to see Dr.

Woodward leave NICHD. She has been with our Institute more than 20 years. The committee especially appreciates and recognizes her accomplishments as acting APD and then as APD. Dr. Woodward has overseen the NICHD animal program under the extraordinarily difficult circumstances of the Covid-19 pandemic. We all agree that no one could have done a better job. However, we understand that these same extraordinary times require that Dr. Woodward move to the VCR. It is essential that NIAID have the very best staff supporting their vaccine research which is of the highest priority to our country and world.

- [Redacted by agreement] is now the facility veterinarian of the NICHD Aquatics program and will become acting APD as of August 30, 2020. [Redacted by agreement] and has extensive international experience in veterinary medicine and management of animal research programs.
- Dr. [Redacted by agreement] holds MS and DVM degrees from Cornell and has just completed her residency in Laboratory Animal Medicine. She is now the facility veterinarian of the NICHD rodent program.
- The committee enthusiastically welcomes [Redacted by agreement]

C. VVC Behavior Tests – no new information

D. Aquatics Filtration Project - no new information

E. SOP/Policy Review and/or Continuing Education (new standing item recommended by OACU)

1. ARAC Revised Guidelines

- Committee members have reviewed the pertinent ARAC Guidelines revised in February and June of 2020

F. Date of next NICHD ACUC Meeting (new standing item recommended by OACU) – Wednesday, September 16, 2020 @ 9am - Webex

3. Animal Care and Use Program Issues

A. Incident Reports (new standing item for all IC ACUCs to include in Minutes, as requested by OACU at ACUC Coordinators Meeting 8/27/2020)

1. Bldg [Redacted by agreement] Incident – Discuss investigation findings with ACUC

- [Redacted by agreement] improper mouse cage set up: As discussed last meeting, an NICHD researcher set up a cage without adding food. Dr. [Redacted by agreement] met with the PI and his research staff and reported her findings to the committee. She concluded that PI was genuinely interested in preventing recurrence and had developed detailed SOPs for both animal husbandry and for training. The committee was impressed with these plans but were concerned about one specific aspect: that his research staff report all new cage set-ups to animal care staff so that care staff would immediately double-check the cage set-up. We did not consider this to be practical, sustainable, or necessary to prevent recurrence and therefore we agreed to remove this item. Dr. [Redacted by agreement] summary of this modified plan is attached to the minutes. The committee requested that Dr. Pfeifer prepare a report to OLAW.

2. New Incident Investigated by NICHD Chair-

- Mouse injury during routine husbandry. On July 23 at 1 pm, an animal caretaker in Bldg ^{Redacted} found a dead animal trapped between a cage divider and the food hopper. The cage was marked as having received HCG injections (by an NEI Investigator) at 12:18. NEI has agreed to perform the investigation. OACU has been notified of these events.

4. Animal Study Proposals – New

(b) (5)

- Committee members voted unanimously to table so that the following concerns can be addressed:

(b) (5)

- **Disposition: Modifications required to secure approval. Revised submission is routed for DMR - Safety,** ^{Redacted by agreement.} **Pfeifer and either Woodward or** ^{Redacted by agreement.}

5. Animal Study Proposals – Renewals

(b) (5)

- The scientific value of the research is well documented, and the animal work is described carefully. Committee members present voted unanimously to table the proposal so that Redacted by agreement could clarify the following issues:

(b) (5)

- **Disposition: Modifications required to secure approval. Revised submission is routed for DMR - Safety, Drs. Pfeifer and either Woodward or Redacted by agreement.**

Production of Genetically Modified Mice for Electrophysiological and Histological Analyses
Redacted by agreement

- Dr. Redacted by agreement requests 6240 mice to understand the role of PV expressing neurons in brain function. He will collect tissues from wild type and mutant mice for histology and biochemistry and will also collect samples for electrophysiology.

- This ASP was written with great lucidity. During prereview, Dr. [Redacted by agreement] clarified that both ear tags and ear punches would be used to identify animals (dependent mostly on the age of the animals when identification was required). Isoflurane will be used only if the facility care staff performs the tail biopsies.
- At Dr. Woodward's request, Dr. [Redacted by agreement] agree to add [Redacted by agreement] as a potential holding space and agreed to follow standard procedures for transport. [Redacted by agreement] will verify these changes.
- With these clarifications, committee members present voted unanimously to approve the ASP.
- **Disposition: Approval**

(b) (5)

- **Disposition: N/A**

6. Review of Proposed Modification to Animal Study Proposal

Gene Function, Expression and Regulation in Zebrafish

Redacted by agreement.

- Mod – add room

Redacted by agreement.
- During discussion Dr.

Redacted by agreement.

 clarified that

Redacted by agreement.

 will be used as a procedure space and not as a holding space. He clarified that he will stop using this space for lab work once NIH removes Covid-19 restrictions on research. With these

clarifications, committee members present voted unanimously to approve the amendment.

- **Disposition: Approval**

(b) (5)

- **Disposition: Modifications required to secure approval. Revised submission is routed for DMR – Drs. Pfeifer and** Redacted by agreement.

Genetic analysis of organ development in zebrafish (Danio rerio)

Redacted by agreement.

agreement

- Mod - addition of oxazolone treatment
 - During prereview, Dr. Redacted by agreement. clarified that the shelf-life for oxazolone is 3 months and that the BCS scores used for endpoints run from 1 to 5 (and not 1-4). With these clarifications, committee members present voted unanimously to approve the amendment.

- **Disposition: Approval**

Retrograde axonal transport regulation in zebrafish larvae

Redacted by agreement.

- Mod - addition of NMDA treatment
 - During pre-review Dr Redacted by clarified that the treatments would last 30 minutes

and that animals will be euthanized upon completion of the experiments. She also clarified that NMDA will be added only to water and will not be injected. With these clarifications, committee members present voted unanimously to approve the amendment.

- **Disposition: Approval**

7. Proposed modifications to the following ASPs were approved using a designated review process.

N/A

8. Proposed Personnel Modifications to the following ASPs were approved using a designated review process.

Redacted by agreement.	– removed as of 4 Aug 2020
Redacted by agreement.	– added 10 Aug 2020
Redacted by agreement.	– added 10 Aug 2020
Redacted by agreement.	– added 13 Aug 2020
Redacted by agreement.	– added 13 Aug 2020
Redacted by agreement.	– removed 17 Aug 2020
Redacted by agreement.	– added 17 Aug 2020
Redacted by agreement.	– added 25 Aug 2020
Redacted by agreement.	– added 25 Aug 2020
Redacted by agreement.	– added 25 Aug 2020
Redacted by agreement.	– removed 31 Aug 2020
Redacted by agreement.	– added 31 Aug 2020

9. Tabled items approved since last meeting or expired (>90 days)

Approved 8/20/2020:

Activity-Dependent Nervous System Development Redacted by agreement.

10. Tabled items still pending but not expired

N/A

11. Annual Reviews for the following Animal Study Proposals were reviewed and approved.

Redacted by agreement.	Redacted by agreement.	Approved: 8/4/2020
		Approved: 8/17/2020
		Approved: 8/4/2020
		Approved: 8/3/2020