

NIDCR ANIMAL CARE AND USE COMMITTEE

Thursday April 16, 2020 Meeting Minutes

Location: WebEx meeting. Time: 2:15PM

1. ATTENDANCE

Members Present:

- [Redacted by agreement]
- [Redacted by agreement]
- Davidson, Attending Vet
- [Redacted by agreement]
- Hoon, Chair
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

- [Redacted by agreement]
- [Redacted by agreement]

Members Absent: None

Guests:

- [Redacted by agreement]
- [Redacted by agreement]

2. MINUTES

The March 19, 2020 meeting minutes were reviewed and approved (12 for, 0 against, 0 abstained).

3. SUBCOMMITTEE WORK

Review of business that occurred between ACUC meetings was noted. These include: tabled animal study proposals and significant amendments that were initially reviewed by Full Committee and designated for review by subcommittee; significant amendments reviewed by Veterinary Verification and Consultation (VVC); significant amendments reviewed by designated subcommittee; minor amendments reviewed by the ACUC Coordinator; and Annual Reviews reviewed by the ACUC Coordinator and ACUC Chair. Additional designated ACUC members, if any, are noted with each submission.

- a. **Tabled Animal Study Proposals:** tabled for review by designated subcommittee -- Attending Veterinarian, ACUC Coordinator, Safety & Health Specialist (for Safety issues), and other ACUC member/s if designated.

(b)(5)

- b. **Tabled Significant Amendments:** amendments reviewed by FCR and tabled for designated subcommittee review including the Attending Veterinarian, ACUC Coordinator, Safety and Health Specialist (for Safety issues), and other ACUC member/s if designated. NONE

c. **Significant Amendments** reviewed by the designated subcommittee including the ACUC Chair or Vice Chair, or Attending Veterinarian, and ACUC Coordinator. OR by Veterinary Verification and Consultation (VVC).

i. [Redacted by agreement] "Craniofacial and dental anomalies in mouse models of Loeys-Dietz Syndrome," Edits to amendment# A7, approved on 4/3/2020.

ii. [Redacted by agreement] "Ca²⁺ signaling and HCO₃⁻ secretion in exocrine glands," add strain, approved on 3/13/2020

d. **Minor Amendments** reviewed by the ACUC Coordinator.

i. [Redacted by agreement] "Murine Chronic Graft-versus-Host Disease," add user, approved on 3/17/2020

e. **Annual Reviews** reviewed by the ACUC Coordinator and ACUC Chair.

i. [Redacted by agreement] "Individual and shared functions of epidermal kallikreins," 2nd annual review, approved on 4/6/2020

4. DESIGNATED MEMBER REVIEW (DMR) IN LIEU OF FULL COMMITTEE REVIEW (FMR). NONE

5. PROTOCOLS FOR FULL COMMITTEE REVIEW.

a. [Redacted]
[Redacted] The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (11 for, 0 against, 1 abstain).

[Redacted]

(b)(5)

b.

(b)(5)

(b)(5)

The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (11 for, 0 against, 1 abstain).

(b)(5)

(b)(5)

6. SIGNIFICANT AMENDMENTS FOR FULL COMMITTEE REVIEW. NONE

7. NEW & OLD ACUC BUSINESS:

a. Spring 2020 semiannual program review – PART II.

- **ENVIRONMENT, HOUSING, AND MANAGEMENT**

- Terrestrial Animal Environment: Temp, Humidity, Ventilation, Air Quality, Illumination, Noise & Vibration.
 - No changes.
- Terrestrial Housing – Primary Enclosure, Enrichment, Outdoor Housing, Naturalistic Environments, Space.
- Terrestrial Management - Behavior & Social Management (Activity, Social Environment, Habituation, & Training), Husbandry (Food & Water), Bedding/Nesting Materials, Sanitation (Bedding Change, Waste Disposal, & Effectiveness), Pest Control, Emergency, Weekend, & Holiday Care, Population Management (Identification, Recordkeeping, Breeding, Nomenclature, & Genetics)
 - During Normal Operations (pre-COVID19) no significant changes in the managing of the facility. Holiday and weekend care is covered by VRC staff.
 - **COVID 19 Update** – there are changes to the way population management is handled. All the changes that are currently in place at the VRC fall within the Guide recommendations. Current changes are mainly applicable to animal care staffing. VRC Animal care staff are grouped in to two teams that alternate weekly. The VRC staffing plan was adopted by other NIH animal care and use programs.

VRC SOP on cage changes is followed. Cages housing up to 2 mice are changed every other week. Cages with 3 or more animals are changed weekly. This applies to cage bottoms and bedding.

Population management is being reviewed with PIs housing mice at the VRC. PIs were asked to review their mouse colonies in order to make plans for how to manage the animals that are housed in the VRC facility. Unless the mice are needed for aging studies or required as breeders, animals that will not be used in future experiments may be euthanized. As no experiments, other than those determined to be essential, are conducted at this time, breeders were separated to reduce the number of animals generated. Only keep breeders to maintain unique transgenic colonies, or those that will be used in essential studies.

Dr. Davidson continues to do rounds with some changes. Dr. Davidson is going into the facility every other week. Veterinary care is delegated to the veterinary technicians in conjunction with telemedicine practices. For

example, photos may be sent to Dr. Davidson when necessary, as well as other innovative means of communication used to assess sick animals. Adequate veterinary care is provided.

Currently not all NIH animal facilities are fully staffed. For example, one animal facility at the Bethesda campus has had staff diagnosed with COVID19 and is functioning with about 30% less staff than their regular number. There is stress, but they are managing with the available staff.

The OACU coordinates a call in meeting each weekday morning that includes members of the NIH Animal response team and other key staff from each animal care and use program. Issues that these programs face is discussed at this meeting. If staffing is needed, there are floaters. If shortage cannot be filled by floaters, then staff from other contracts may be considered.

The NIH APDs also have a weekly meeting. They have developed plans for different situations including worst case scenarios that can be activated when needed. OACU and [Redacted by agreement] are supportive of these plans. [Redacted by agreement] joins in the meetings whenever he can. All considerations are made to ensure the humane care of the research animals.

→ Aquatic Animal Environment, housing and management – Not applicable.

- **VETERINARY CARE**

→ Animal Procurement & Transportation – no changes.

→ Preventive Medicine –

- No major changes, quarterly sentinel testing have periodically come up MPV positive in various rooms, although we do not allow animals from MPV+ facilities into the VRC facility. Room [Redacted by agreement] has maintained continuous MPV negative status.
- Two new veterinary technicians, who started work at the VRC just before the pandemic, are doing very well. They have many years' experience at other NIH facilities and are able to function well.

→ Clinical Care & Management – There are no changes in clinical care and medical management. The SharePoint medical records system is still in use. The eSirius medical records system is not yet fully ready for use. SharePoint easier to use than eSirius.

→ Surgery (Training, Planning, Facilities, Procedures, Aseptic Technique, Intra-Op Monitoring, Post-Op Care) -

- No Changes in surgical training, planning or post op management.

- COVID19 update: currently, VRC training sessions are not offered due to the pandemic conditions. There have not been new animal users who require training. However, if any user requires training, the VRC will work with that person under the safety guidance.
- Pain & Distress – no changes in the assessment of pain/distress.
- Anesthesia & Analgesia – no changes/updates on anesthesia or analgesia usage.
- Euthanasia - No changes to the euthanasia equipment provided in the VRC animal facility. The updated AVMA Guidelines on Euthanasia has been published and adopted by the NIH ARAC. The ARAC Guidelines on Rodent euthanasia was updated with the 30-70% CO₂ flow rate replacing the 10-30% from the 2013 AVMA euthanasia guidance. All euthanasia signage and guidance for the VRC animal facility and NIDCR labs with euthanasia chambers, will be revised accordingly once the COVID 19 condition resolves.
- **PHYSICAL PLANT**
 - Functional Areas (Housing, Care, Sanitation, Receipt, Quarantine, Separation of Species, Storage) - No updates.
 - Construction Guidelines (Corridors, Doors, Windows, Floors, Drains, Walls/Ceilings, HVAC, Power, Lighting/Light Timer Override, Storage, Noise, Vibration, Sanitization Facilities, Environmental Monitoring) -
 - Construction of the new building (between Bldgs. Redacted by agreement) has caused minimal noise and vibration in the animal facility. There have been no reports of breeding issues or other animal related issues. We will continue to monitor with the assistance of ORF and the contracting PO.
 - Safety Devices (Showers, Eyewashes (flushing intervals & documentation), Escape for Cage/Rack Washers, Autoclaves & Instructional Safety Signage & Staff Training) –
 - All devices are tested regularly and are up to date on certifications.
 - Special Facilities (Surgery, Barriers, Imaging, Irradiators, Hazard Containment, Behavior Studies, Aquatics)
 - The biobubble is operational and in use by several investigator as is the X-irradiator. Non new equipment was added in the last 6 months.
 - Security & Access Control – no changes in the last 6 months.
- b. Spring 2020 semiannual program review and inspection report** – the Committee reviewed and unanimously approved the report. Members will email electronic signature following OACU/OLAW guidance.

Listed deficiencies that were discussed include:

- One of the discussed deficiencies was the modified waste anesthetic gas (WAG) scavenging system in the [Redacted by agreement] lab. [Redacted by agreement] said that the WAG Safety Manager was notified to verify the effectiveness of the method. This is DOHS responsibility.
- Leaking pipes in the VRC cage wash has been an issue for about 2 years now. This has been a continuing problem for the animal facility and awaits resolution by DOHS.
- The sharps' and MPW boxes in [Redacted by agreement] were full on the day of the site visit. The observed deficiency is VRC responsibility not GTC's; the lab does not have access to replacement sharps boxes. GTC will be removed from the deficiency table. The deficiency was corrected by VRC.

c. 2020 AAALAC site visit of the NIH IRP is postponed to a later date. TBD.

8. ACUC POLICIES/SOPs/FORMS FOR REVIEW: NONE

9. VRC SOPS FOR REVIEW: NONE

10.ACUC MEMBER TRAINING: NONE

11.INFORMATION / ANNOUNCEMENTS: Dr. Davidson provided VRC facility updates with the semiannual program review(see above).

12.DATE AND LOCATION OF NEXT MEETING: The next meeting is on Thursday May 21, 2020 at 1:00 PM, may be via WebEx if the NIH shutdown continues through May 2020.

NIDCR ANIMAL CARE AND USE COMMITTEE

Thursday May 21, 2020 Meeting Minutes

Location: WebEx meeting. Time: 2:15PM

1. ATTENDANCE

Members Present:

- [Redacted by agreement]
- [Redacted by agreement]
- Davidson, Attending Vet
- [Redacted by agreement]
- Hoon, Chair
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

- [Redacted by agreement]
- [Redacted by agreement]

Members Absent: None

Guests:

- [Redacted by agreement]
- [Redacted by agreement]

2. MINUTES

The April 16, 2020 meeting minutes were reviewed and approved (12 for, 0 against, 0 abstained).

3. SUBCOMMITTEE WORK

Review of business that occurred between ACUC meetings was noted. These include: tabled animal study proposals and significant amendments that were initially reviewed by Full Committee and designated for review by subcommittee; significant amendments reviewed by Veterinary Verification and Consultation (VVC); significant amendments reviewed by designated subcommittee; minor amendments reviewed by the ACUC Coordinator; and Annual Reviews reviewed by the ACUC Coordinator and ACUC Chair. Additional designated ACUC members, if any, are noted with each submission.

- a. **Tabled Animal Study Proposals:** tabled for review by designated subcommittee -- Attending Veterinarian, ACUC Coordinator, Safety & Health Specialist (for Safety issues), and other ACUC member/s if designated. NONE
- b. **Tabled Significant Amendments:** amendments reviewed by FCR and tabled for designated subcommittee review including the Attending Veterinarian, ACUC Coordinator, Safety and Health Specialist (for Safety issues), and other ACUC member/s if designated.
 - i. [Redacted by agreement] "Study of the periodontium in Bgn and Col6a2 deficient mice," add procedures, approved on 4/23/2020.

c. **Significant Amendments** reviewed by the designated subcommittee including the ACUC Chair or Vice Chair, or Attending Veterinarian, and ACUC Coordinator. OR by Veterinary Verification and Consultation (VVC).

- i. [Redacted by agreement] "Role of HAI-1, HAI-2, and prostasin in intestinal development in mice," increase animal number, approved on 4/27/2020
- ii. [Redacted by agreement] "Adeno-associated viral vector-mediated gene transfer to mice," add strain, approved on 4/29/2020.
- iii. [Redacted by agreement] "Investigating the role of mannose receptor and uPARAP in tumor-associated stromal cells," add toxin, approved on 5/1/2020.

d. **Minor Amendments** reviewed by the ACUC Coordinator. NONE

e. **Annual Reviews** reviewed by the ACUC Coordinator and ACUC Chair.

- i. [Redacted by agreement] "In vivo analysis of stromal cell osteogenic capacity in a murine model," 2nd annual review, approved on 5/7/2020.
- ii. [Redacted by agreement] "Craniofacial and dental anomalies in mouse models of Loeys-Dietz Syndrome," 1st annual review, approved on 4/29/2020.
- iii. [Redacted by agreement] "Adeno-associated viral vector-mediated gene transfer to mice," 2nd annual review, approved on 5/11/2020.
- iv. [Redacted by agreement] "Tropism and biodistribution of vector-mediated gene transfer to mice," 1st annual review, approved on 5/11/2020.
- v. [Redacted by agreement] "The effects of T-cells on tooth development," 1st annual review, approved on 5/7/2020.
- vi. [Redacted by agreement] "Ca²⁺ signaling and HCO₃⁻ secretion in exocrine glands," 1st annual review, approved on 4/29/2020.
- vii. [Redacted by agreement] "Role of regulatory T cells and TGFβ in experimental house dust mite-Induced asthma in mice," 1st annual review, approved on 5/7/2020.

4. DESIGNATED MEMBER REVIEW (DMR) IN LIEU OF FULL COMMITTEE REVIEW (FMR).

a. **Amendments:**

- i. [Redacted by agreement] "Adeno-associated viral vector-mediated gene transfer to mice," increase animal number, approved on 5/5/2020.
- ii. [Redacted by agreement] "Role of eIF5A and deoxyhypusine synthase in brain and global development in mice," increase animal number, approved on 5/6/2020.

5. PROTOCOLS FOR FULL COMMITTEE REVIEW.

- a. (b)(5)
(b)(5) The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (11 for, 0 against, 1 abstain). Dr. Hoon will be part of the designated subcommittee to review this ASP.

(b)(5)

- b. (b)(5)
(b)(5) The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (11 for, 0 against, 1 abstain). Redacted by agreement

Redacted by agreement Dr. Hoon will be part of the designated subcommittee to review this ASP.

(b)(5)

- c. (b)(5)
(b)(5) The Committee tabled the ASP for designated subcommittee

review after the ASP is revised addressing the Committee's comments/questions outlined below. (12 for, 0 against, 0 abstain).

(b)(5)

(b)(5)

6. SIGNIFICANT AMENDMENTS FOR FULL COMMITTEE REVIEW.

a.

(b)(5)

(b)(5)

The Committee tabled the amendment for designated subcommittee review (+ Dr. Hoon) after the ASP is revised addressing the Committee's comments/questions outlined below. (12 for, 0 against, 0 abstain).

(b)(5)

(b)(5)

7. NEW & OLD ACUC BUSINESS:

- a. 2020 AAALAC site visit of the NIH IRP is postponed to a later date. TBD.

8. ACUC POLICIES/SOPs/FORMS FOR REVIEW: NONE

- 9. VRC SOPS FOR REVIEW:** the ACUC reviewed and approved all four SOPs with recommended changes. Dr. Davidson remarked that the VRC is currently performing major revisions of all its SOPs. The four SOPs presented for Committee review are in the new format that is currently being instituted by the VRC. The SOPs have a new numbering system and the organizational structure as well as the contents of the SOPs are modified and updated. As currently revised, some of the SOPs may have been combined when applicable for ease of use by investigators. The SOPs will be uploaded to the VRC SharePoint site after they are reviewed and approved by the Committee.

- a. **VRC SOP 6.001**, tattoo procedures – no comments, approved as written.
- b. **VRC SOP 6.002**, euthanasia procedures – no comments, approved as written. The euthanasia SOP was updated with the recommendations in the 2020 edition of the AVMA Guidelines for the Euthanasia of Animals. In the 2020 edition, the use of CO₂ for rodent euthanasia have been changed from the previous recommendation of 10% - 30% to 30% - 70% of the chamber or cage volume/minute.
- c. **VRC SOP 6.003**, genotyping procedures. The Committee approved the SOP after it is revised addressing the following comments:

- The statement “at the time of genotyping, permanent identification of animals should be performed” should be optional, not a requirement.
- The statement “...all instruments should be sterilized between animals using a hot bead sterilizer...” should be optional, not a requirement.
- The use of chilled alcohol prior to tail snip should be optional, not a requirement. From the experience of Scientist members of the ACUC, rubbing chilled alcohol prior to tail snip would cause pain rather than prevent pain. But the use of chilled ethanol is recommended in the ARAC guidelines, and will be followed until there are changes in the ARAC guidance.
- Delete “at ages up to P7” in the statement “Anesthetic is not required for this procedure at ages up to P7.” No toe clip is performed on pups older than P7.
- Buccal swab procedure is included in this SOP. Currently, it is used by other animal programs at NIH (for example in [Redacted by agreement]). Currently, this method is not used by any labs at NIDCR. It is in the SOP as an option if any lab chooses to use the buccal swab method in the future.

d. **VRC SOP 6.004**, blood sampling procedures – no comments, approved as written. No changes to this version of the SOP, other than formatting. It is fully taken from the ARAC guidelines on blood sampling.

10.ACUC MEMBER TRAINING: NONE

11.INFORMATION / ANNOUNCEMENTS:

a. **VRC return to workplace plan:** Dr. Davidson provided a preliminary plan for the [Redacted by agreement] return to physical workplace. A copy of the plan was submitted to the ACUC prior to the meeting.

Dr. Davidson said that [Redacted by agreement] had requested all NIDCR labs and cores to submit a return to workplace guidance. This guidance is the VRC’s proposal on the plan to get the VRC to return to full capacity. It is aligned with the overall NIH plan, and specifically with that of the NIDCR IRP. The plan is based mainly on animal census, because staffing requirements for the husbandry care of the animals will be driven by animal census. The plan is flexible. It will be modified as needed when moving through the NIH Group phase in plan (Groups A-D correlates to VRC Phase 1 to 3) outlined in the plan. Below is the plan that was submitted to [Redacted by agreement]. This is preliminary and not yet finalized. Most of the work that is currently done by the VRC is as in Phase 1 described in the plan (see below). The final plan will be submitted to the ACUC when ready.

The standard of wearing a face mask while on the NIH campus shall continue to apply including upon entry into the animal facility. At the vivarium entrance (gowning station), the “street” mask/ face covering shall be removed, placed in a plastic bag (provided by VRC). A new facility supplied disposable surgical mask should then be donned, with the other required facility PPE, immediately prior to entrance into the vivarium. The bag containing the street mask will be labeled and left on the top shelf of

the gowning station to be reclaimed upon exit or maintained on the user's person in the vivarium.

During phases 2 and 3, how much time will the VRC animal care staff block off during the day for VRC work? Dr. Davidson said that the VRC is working on this right now and she will provide the actual plan when it is finalized. There will be flexibility on the planning. Users must use the calendar to schedule room and time to maintain required social distancing.

Phase 1 – Assumes that the cage census will remain at approximately 2400, with only critical breeding allowable. Social distancing, > 6ft. distance between two individuals as space allows, single room occupancy, minimal overall visitations. [Roughly a 10-25% user return to work.]

VRC staff remains split into weekly shifts.

The VRC staff will maintain a calendar on the Public VRC SharePoint website, with a schedule of when the VRC staff will require access to perform routine husbandry duties in all rooms. This calendar should be consulted prior to planning a visit to ensure the room will not be occupied by VRC staff or another researcher.

Researcher access during the workday, 7-3:30 PM, would be scheduled around the necessary husbandry duties. Researcher access at any time would be with advance approval, by VRC Technical Request with the times and the rooms requiring access specified. Such a Technical Request would act as a room reservation for a given researcher, at up to 1-hour blocks of time. Approved reservations would then be maintained on the calendar so that other users can see the dates/times available. As was the standard practice, if no other user has requested time in the room, and the VRC doesn't need to access the room, the user could extend their time. Coordination between labs with animals housed in each room is encouraged to allow for additional time.

Occupied rooms shall not be entered by more than one person at a time. Occupied rooms shall have signage indicating that another user is in the room. Signage shall be hung with Velcro tape so that when "Occupied" the sign will overhang the card reader for the room. When the room is not in use, the "Vacant" side of the sign shall be displayed above the card reader.

VRC staff will continue to implement all Covid-19 response procedures, including social distancing, disinfection of hi-touch surfaces, and receipt of supplies.

Phase 2 – Assumes that the cage census increases past 3000 cages, with moderate or unrestricted breeding. Social distancing, > 6ft. distance between two individuals as space allows, single room occupancy when possible, controlled visitations. [Roughly 25-50% user return to work.]

VRC will return to full weekly staffing. Arrival and departure times may be slightly staggered (<10 mins) to allow for social distancing of the VRC staff in the locker rooms. Lunch times may also be staggered to accommodate social distancing.

The VRC staff will maintain a calendar on the Public VRC Sharepoint website, with a schedule of when the VRC staff will require access to perform routine husbandry duties in all rooms. This calendar should be consulted prior to planning a visit to ensure the room will not be occupied by VRC staff.

Researcher access during the workday, 7-3:30 PM, would be scheduled around the necessary husbandry duties. Researcher access would be with advance approval, by VRC Technical Request with the times and the rooms requiring access specified. Such a technical request would act as a room reservation for a given researcher, at up to 1 hour blocks of time. As was the standard practice, if no other user has requested time in the room, and the VRC doesn't need to access the room, the user could extend their time.

Occupied rooms shall not be entered by more than one person at a time. Occupied rooms shall have signage indicating that another user is in the room. Signage shall be hung with velcro tape so that when "Occupied" the sign will overhang the card reader for the room. When the room is not in use, the "Vacant" side of the sign shall be displayed above the card reader.

VRC staff will continue to implement all Covid-19 response procedures, including social distancing, disinfection of hi-touch surfaces, and receipt of supplies.

Phase 3 – Assumes gradually increasing cage census back to maximum cage allocations, with unrestricted breeding. Social distancing, > 6ft. distance between two individuals as space allows, single room occupancy when possible. [Roughly >50% User return to work]

VRC will return to full weekly staffing. Arrival and departure times may be slightly (<10 mins. Staggered) to allow for social distancing of the VRC staff in the locker rooms. Lunch times may also be staggered to accommodate social distancing. Occupied rooms shall not be entered by more than one person at a time. Occupied rooms shall have signage indicating that another user is in the room. Signage shall be hung with velcro tape so that when "Occupied" the sign will overhang the card reader for the room. When the room is not in use, the "Vacant" side of the sign shall be displayed above the card reader.

VRC staff will continue to implement all Covid-19 response procedures, including social distancing, disinfection of hi-touch surfaces, and receipt of supplies.

12.DATE AND LOCATION OF NEXT MEETING: The next meeting will be held on Thursday June 18, 2020 at 2:15 PM, via WebEx.

NIDCR ANIMAL CARE AND USE COMMITTEE

Thursday June 18, 2020 Meeting Minutes

Location: WebEx meeting. Time: 2:15PM

1. ATTENDANCE

Members Present:

- [Redacted by agreement]
- [Redacted by agreement]
- Davidson, Attending Vet
- [Redacted by agreement]
- Hoon, Chair
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

Members Absent: None

Guests:

- [Redacted by agreement]

2. MINUTES

The May 21, 2020 meeting minutes were reviewed and approved (12 for, 0 against, 0 abstained).

3. SUBCOMMITTEE WORK

Review of business that occurred between ACUC meetings was noted. These include: tabled animal study proposals and significant amendments that were initially reviewed by Full Committee and designated for review by subcommittee; significant amendments reviewed by Veterinary Verification and Consultation (VVC); significant amendments reviewed by designated subcommittee; minor amendments reviewed by the ACUC Coordinator; and Annual Reviews reviewed by the ACUC Coordinator and ACUC Chair. Additional designated ACUC members, if any, are noted with each submission.

- a. **Tabled Animal Study Proposals:** tabled for review by designated subcommittee -- Attending Veterinarian, ACUC Coordinator, Safety & Health Specialist (for Safety issues), and other ACUC member/s if designated.
 - i. [Redacted by agreement] "Role of protease inhibitors HAI-1 and HAI-2 in mouse tissue development," renewal of [Redacted by agreement] approved 6/5/2020
- b. **Tabled Significant Amendments:** amendments reviewed by FCR and tabled for designated subcommittee review including the Attending Veterinarian, ACUC Coordinator, Safety and Health Specialist (for Safety issues), and other ACUC member/s if designated. **NONE**

c. **Significant Amendments** reviewed by the designated subcommittee including the ACUC Chair or Vice Chair, or Attending Veterinarian, and ACUC Coordinator. OR by Veterinary Verification and Consultation (VVC).

- i. [Redacted by agreement] "Somatosensation in mice," add strains, approved on 6/8/2020
- ii. [Redacted by agreement] "Generation of mouse models of somatosensation," add strains, approved on 6/8/2020
- iii. [Redacted by agreement] "Imaging extracellular matrix degradation," add strains and increase number, approved on 6/11/2020

d. **Minor Amendments** reviewed by the ACUC Coordinator.

- i. [Redacted by agreement] "Investigation of murine rib regeneration in the aging model," add user, approved on 5/19/2020
- ii. [Redacted by agreement] "The effects of T-cells on tooth development," add user, approved on 5/18/2020
- iii. [Redacted by agreement] "Induction of anemia by hemorrhage of mice with alteration of gene expression in connective tissues," add user, approved on 6/1/2020
- iv. [Redacted by agreement] "Transplantation of stem cells that heal mesenchymal tissue defects into mice (using guinea pigs)," edited sections F and M to add clarification on endpoints of SHC mice," approved on 6/9/2020
- v. [Redacted by agreement] "Molecular mechanisms of neural crest development in the mouse," edited/updated section J statement on embryo euthanasia; anesthesia is not used for euthanasia of embryos on this ASP, approved on 6/11/2020
- vi. [Redacted by agreement] "Immune subsets in knockout and reporter mice," add user, approved on 6/3/2020

e. **Annual Reviews** reviewed by the ACUC Coordinator and ACUC Chair.

- i. [Redacted by agreement] "Generation and acquisition of transgenic mice with alteration of gene expression in connective tissues," 1st annual review, approved on 6/5/2020

4. **DESIGNATED MEMBER REVIEW (DMR) IN LIEU OF FULL COMMITTEE REVIEW (FMR).** NONE.

5. **PROTOCOLS FOR FULL COMMITTEE REVIEW.**

- a. [Redacted by agreement]
[Redacted by agreement] The Committee

tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (10 for, 0 against, 2 abstain).

(b)(5)

(b)(5)

6. SIGNIFICANT AMENDMENTS FOR FULL COMMITTEE REVIEW. NONE

7. NEW & OLD ACUC BUSINESS:

- a.** 2020 AAALAC site visit of the NIH IRP is postponed to June 2021.

- b. **VRC return to work plan:** Dr. Davidson presented a summary of the power point presentation on the final return to work plan for the [Redacted by agreement] animal facility. A copy of the presentation was included in the agenda. It was presented to the NIDCR PIs, and it is similar to the preliminary plan that was presented at the May 21st ACUC meeting. A summary of the final plan for Group A returning to work was submitted and approved by the SD. The plan was also emailed to all investigators, which includes the information outlined below.

Staffing: The VRC Staff will maintain an alternate week split schedule in order to potential staffing reductions that may result from COVID related absenteeism. Facility staff will continue working in staggered shifts to minimize congestion near time clocks and in locker rooms.

PPE: Everyone (VRC staff, investigators, service personnel) is required to wear face masks in the facility at all times. Anyone observed without a mask will be asked to put one on. A “masking station” has been set up in the VRC lobby for facility users to change out of their personal face coverings into a facility provided disposable face mask. The personal face covering can be stored in a plastic bag on the user’s person or in the lab’s cage card box and retrieved once the user exits the facility. All other PPE requirements remain the same.

Facility Logistics and Social Distancing: Only 1 person is allowed in the gowning area at a time. Entrance to the facility is now ONE WAY. The new exit for the vivarium will be through the door formerly used as an emergency/ fire exit only, at the end of the main hallway by Room [Redacted by agreement]. Use the door windows to check if someone is in the animal holding or procedure rooms before entering. Use the signs (“VACANT”/ “OCCUPIED”) posted over the key card readers when you are entering and exiting a room. Floor and wall signage have been posted in several prominent locations in the facility as visual reminders of 6’ distancing requirements. Only one person may work in an animal holding or procedure room at one time.

Sanitation: Quatricide PV disinfectant is being used in the VRC facility in addition to Clidox. It has potential advantages over Clidox in that it’s less corrosive, requires less contact time for efficacy, is easy to dispose of and does not have to be replaced as often. Cleaning of the gowning areas will be conducted twice daily (morning and afternoon), to include mopping floors and wiping down doorknobs/handles/crash bars and benches. All walls, floors and ceilings in the facility, including locker rooms are decontaminated on a weekly basis. High touch surfaces are getting disinfected with Quatricide PV wipes frequently. High touch surfaces in animal holding rooms, marshalling areas, locker rooms, time clock areas & gowning areas are being cleaned throughout the day. The break room surfaces are cleaned between lunch groups. Animal holding room door handles and exit buttons and/or crash bars in corridors will be wiped down with disinfectant at the beginning of the day as staff passes through the facility, before they leave for lunch, when they return from lunch, and at the end of the day.

Animal Breeding and Ordering: VRC staffing is based on cage census. In an effort to maintain a split schedule for the time being, a slow ramp up of animal census is preferred. Group A may set up breeding cages and order animals from NIH Approved Vendors keeping in mind to limit ramp up. Strains that may not be needed or are not currently on study may be frozen down to reduce live animals on the rack.

Investigator Access: Investigators are still encouraged to work outside of normal VRC Staff working hours, 7:00am-3:30pm M-F and 8:00am -12pm noon on Saturdays. Procedure rooms should be scheduled by booking an appointment on the appropriate calendar on the VRC SharePoint site.

8. ACUC POLICIES/SOPs/FORMS FOR REVIEW: NONE

9. VRC SOPS FOR REVIEW: the ACUC reviewed and approved all three SOPs with recommended changes as outlined below.

- a. **VRC-16A, sentinel animal program**, approved with recommended edits.
 - There was a question about fighting injury among sentinel mice, and how often do sentinels die and are sent to DVR? Fighting is not a problem with sentinel mice since only females are used as sentinels. Over the years, several cases of sentinels are observed to develop lymphoma and are euthanized or may be found dead. These are also sent to DVR for testing.
 - Page 2, G.1. remove “Laboratory of Sensory Biology (LSB).” This is an old lab designation. Suggested to change to “NIDCR Labs in Redacted by agreement
 - Correct typographical errors.
- b. **VRC SOP 5.001**, anesthesia machine use – approved with the recommended edits.
 - Very useful photo/figure of the anesthesia machines.
 - On page 2, photo of COMPAC⁵ anesthesia setup, some of the labels used to indicate parts of the anesthesia machine are shifted away from the line pointers.
- c. **VRC SOP 5.002**, i-STAT® Blood Analyzer – approved with the suggested change.
 - It would be helpful to investigators if the specific volume of blood is given in this SOP; i.e., the amount that would be enough for the analysis.

10.ACUC MEMBER TRAINING: NONE

11.INFORMATION / ANNOUNCEMENTS: NONE.

12.DATE AND LOCATION OF NEXT MEETING: The next meeting is on Thursday July 16, 2020 at 2:15 PM, via WebEx.

NIDCR ANIMAL CARE AND USE COMMITTEE

Thursday July 16, 2020 Meeting Minutes

Location: WebEx meeting. Time: 2:15PM

1. ATTENDANCE

Members Present:

- [Redacted by agreement]
- [Redacted by agreement]
- Davidson, Attending Vet
- [Redacted by agreement]
- Hoon, Chair
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

- [Redacted by agreement]
- [Redacted by agreement]

Members Absent:

- [Redacted by agreement]

Guests:

- [Redacted by agreement]

2. MINUTES

The June 18, 2020 meeting minutes were reviewed and approved (12 for, 0 against, 0 abstained).

3. SUBCOMMITTEE WORK

Review of business that occurred between ACUC meetings was noted. These include: tabled animal study proposals and significant amendments that were initially reviewed by Full Committee and designated for review by subcommittee; significant amendments reviewed by Veterinary Verification and Consultation (VVC); significant amendments reviewed by designated subcommittee; minor amendments reviewed by the ACUC Coordinator; and Annual Reviews reviewed by the ACUC Coordinator and ACUC Chair. Additional designated ACUC members, if any, are noted with each submission.

- a. **Tabled Animal Study Proposals:** tabled for review by designated subcommittee -- Attending Veterinarian, ACUC Coordinator, Safety & Health Specialist (for Safety issues), and other ACUC member/s if designated.

- i. [Redacted by agreement] Fibroblast growth factor regulation of embryonic development in mice, renewal of [Redacted by agreement] approved on 7/9/2020
- ii. [Redacted by agreement] Generation of mouse models of somatosensation and pain, Initial submission, approved on 6/19/2020
- iii. [Redacted by agreement] Generation of transgenic mouse models for NIDCR, DIR investigators, renewal of [Redacted by agreement] approved on 7/1/2020

- iv. [Redacted by agreement] Generation of gene knockout mouse models for NIDCR, DIR investigators, renewal of [Redacted by agreement] approved on 7/1/2020
- v. [Redacted by agreement] Animal health surveillance program in mice, renewal of [Redacted by agreement] approved on 6/16/2020
- vi. [Redacted by agreement] Mouse and rat holding protocol and mouse technical procedure training, renewal of [Redacted by agreement] approved on 6/16/2020

b. **Tabled Significant Amendments:** amendments reviewed by FCR and tabled for designated subcommittee review including the Attending Veterinarian, ACUC Coordinator, Safety and Health Specialist (for Safety issues), and other ACUC member/s if designated. **NONE**

c. **Significant Amendments** reviewed by the designated subcommittee including the ACUC Chair or Vice Chair, or Attending Veterinarian, and ACUC Coordinator. OR by Veterinary Verification and Consultation (VVC).

- i. [Redacted by agreement] "Craniofacial and dental anomalies in mouse models of Loeys-Dietz syndrome," add euthanasia method - terminal perfusion. Approved 6/17/2020.
- ii. [Redacted by agreement] "Acquisition, generation, breeding and characterization of transgenic mice with alteration of gene expression in connective tissues," add strains and rDNA to generate strains, approved on 7/8/2020

d. **Minor Amendments** reviewed by the ACUC Coordinator. **NONE**

e. **Annual Reviews** reviewed by the ACUC Coordinator and ACUC Chair.

- i. [Redacted by agreement] "Apoptotic T-Cells induced tolerance in prevention and therapy of experimental autoimmune encephalomyelitis, inflammatory bowel disease, and diabetes in mice," 2nd annual review, approved on 6/25/2020
- ii. [Redacted by agreement] "Exploring connective tissue inflammation by high resolution imaging in mice: pilot study," 1st annual review, approved on 6/30/2020
- iii. [Redacted by agreement] "Immune factors related to periodontal disease susceptibility in mice," 1st annual review, approved on 6/30/2020

4. DESIGNATED MEMBER REVIEW (DMR) IN LIEU OF FULL COMMITTEE REVIEW (FMR). **NONE**.

5. PROTOCOLS FOR FULL COMMITTEE REVIEW.

- a. [Redacted by agreement]
[Redacted by agreement] The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (10 for, 0 against, 1 abstain).

(b)(5)

(b)(5)

- b. (b)(5) The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (10 for, 0 against, 1 abstain).

(b)(5)

(b)(5)

(b)(5)

c.

(b)(5)

(b)(5)

The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (11 for, 0 against, 0 abstain).

(b)(5)

6. SIGNIFICANT AMENDMENTS FOR FULL COMMITTEE REVIEW. NONE

7. NEW & OLD ACUC BUSINESS:

- a. **Fall 2020 Semiannual site visit:** The scheduled site visit dates and current OLAW guidance “Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees (IACUCs) Due to COVID-19,” (Notice Number: NOT-OD-20-088) was provided to members. The Committee discussed the current plan on how the Committee will conduct the site visits. The number of members to be assigned will follow current NIH/animal facility guidance on physical distancing. It will be limited to one member and/or an ad hoc consultant designated by the ACUC. The inspections will be limited to the animal facilities and procedure locations in these facilities, and labs where surgery and other in vivo procedures are performed. NIDCR labs, where only euthanasia is performed, were inspected during the last semiannual review, and will continue to be inspected at least once a year following the ARAC guidance on semiannual inspections.

The ACUC Coordinator will notify members of the site inspection plan and assignments.

- b. **ACUC POLICIES/SOPs/FORMS FOR REVIEW.** The NIDCR ACUC policy on significant changes to animal study protocols will be revised and reviewed by the Committee following the recent updates to the ARAC guidelines. The revised policy will be reviewed at the next ACUC meeting.

8. VRC SOPS FOR REVIEW: the ACUC reviewed and approved five VRC SOPs in the 4.000 series. The SOPs are well written and understandable. There were recommended edits, in which the edits include general typographical errors, and other minor edits that will not affect the procedures. Also, there were Committee requests that are outlined below.

- a. **VRC SOP 4.001, “ON-campus animal transport and transfers”** – no additional requests.

- b. **VRC SOP 4.003, “Transport of animals between [Redacted by agreement]”** – the Committee approved this SOP with a recommendation for review of the SOP by [Redacted by agreement] a member of [Redacted by agreement] lab, who uses the [Redacted by agreement] irradiator. The SOP will be revised incorporating any applicable suggested changes from [Redacted by agreement]. The revised SOP will be reviewed at the next Committee meeting.

- c. **VRC SOP 4.005, “Animal import/export”** - Committee suggested to provide a copy of the SOP to [Redacted by agreement] OTTIA, and get his input on current material transfer agreement (MTA) procedures. The Committee also recommended posting the SOP on

the NIDCR Intranet page where users submit a request for MTA services. It will be helpful to users since they will have easy access when initiating import/export. This will be in addition to posting the SOP on the VRC SharePoint site. [Redacted by agreement] will be consulted for the intranet postings.

d. **VRC SOP 4.008**, “Animal orders from approved vendors” - a request to make this SOP available on the animal order request page on the NIDCR intranet page. It will be helpful to users to know delivery and other ordering requirements outlined in the SOP when initiating animal order requests. This will be in addition to posting the SOP on the VRC SharePoint site. [Redacted by agreement] will be consulted for the intranet postings.

e. **VRC SOP 4.009**, “Moving animals on pancreatitis study”

9. ACUC MEMBER TRAINING: NONE

10. INFORMATION / ANNOUNCEMENTS: members were informed of recently revised and new ARAC guidelines. These are posted on the OACU website (see below). The NIDCR ACUC policy on significant changes, especially as it relates to VVC review, will be modified following the current ARAC guidance. The revised policy will be reviewed at the next Committee meeting.

a. Revised ARAC Guidelines:

- Changes to Animal Study Proposals - https://oacu.oir.nih.gov/sites/default/files/uploads/arac-guidelines/c3_asp-changes.pdf
- Review and Approval of Animal Study Proposals and Significant Changes - https://oacu.oir.nih.gov/sites/default/files/uploads/arac-guidelines/c6_review-asp-significant-changes.pdf

b. New ARAC Guideline:

- Example IC Policy for Changes to ASPs (including VVC) - https://oacu.oir.nih.gov/sites/default/files/uploads/information-for-acuc-members/example_acucpolicy_changes.pdf

11. DATE AND LOCATION OF NEXT MEETING: The next meeting is on Thursday August 20, 2020 via WebEx.

NIDCR ANIMAL CARE AND USE COMMITTEE

Thursday August 20, 2020 Meeting Minutes

Location: WebEx meeting. Time: 10:30AM

1. ATTENDANCE

Members Present:

- [Redacted by agreement]
- [Redacted by agreement]
- Davidson, Attending Vet
- [Redacted by agreement]
- Hoon, Chair
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

Members Absent:

- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

Guests:

- [Redacted by agreement]
- [Redacted by agreement]

2. MINUTES

The July 16, 2020 meeting minutes were reviewed and approved (9 for, 0 against, 0 abstained).

3. SUBCOMMITTEE WORK

Review of business that occurred between ACUC meetings was noted. These include: tabled animal study proposals and significant amendments that were initially reviewed by Full Committee and designated for review by subcommittee; significant amendments reviewed by Veterinary Verification and Consultation (VVC); significant amendments reviewed by designated subcommittee; minor amendments reviewed by the ACUC Coordinator; and Annual Reviews reviewed by the ACUC Coordinator and ACUC Chair. Additional designated ACUC members, if any, are noted with each submission.

- a. **Tabled Animal Study Proposals:** tabled for review by designated subcommittee -- Attending Veterinarian, ACUC Coordinator, Safety & Health Specialist (for Safety issues), and other ACUC member/s if designated.

- i. [Redacted by agreement] "Btbd7-Mediated Regulation of Organ Formation in Mice," renewal of [Redacted by agreement] approved on 8/3/2020

- ii. [Redacted by agreement] "Generation of Cre Transgenic Mice," renewal of [Redacted by agreement] approved on 8/12/2020

- b. **Tabled Significant Amendments:** amendments reviewed by FCR and tabled for designated subcommittee review including the Attending Veterinarian, ACUC Coordinator, Safety and Health Specialist (for Safety issues), and other ACUC member/s if designated.

- i. [Redacted by agreement] “Role of TGF-beta signaling in regulation of Septic Shock,” modify experimental design, approved on 7/20/2020
- c. **Significant Amendments** reviewed by the designated subcommittee including the ACUC Chair or Vice Chair, or Attending Veterinarian, and ACUC Coordinator. OR by Veterinary Verification and Consultation (VVC).
- i. [Redacted by agreement] “Apoptotic T cells induce tolerance in prevention and therapy of autoimmune disease via intrathymic injections and bone marrow transplants in mice,” add strains, approved on 7/27/2020
 - ii. [Redacted by agreement] “Apoptotic T cells induce tolerance in prevention and therapy of autoimmune disease via intrathymic injections and bone marrow transplants in mice,” add strains, approved on 8/6/2020
 - iii. [Redacted by agreement] “Apoptotic T cells induce tolerance in prevention and therapy of autoimmune disease via intrathymic injections and bone marrow transplants in mice,” add strain, approved on 8/6/2020
 - iv. [Redacted by agreement] “Role of eIF5A and deoxyhypusine synthase in brain and global development in mice,” add procedure and location, approved on 8/12/2020
 - v. [Redacted by agreement] “Role of eIF5A and deoxyhypusine synthase in brain and global development in mice,” add procedure, approved on 7/30/2020
 - vi. [Redacted by agreement] “Imaging extracellular matrix degradation,” add drug and treatment procedures, approved on 7/23/2020
- d. **Minor Amendments** reviewed by the ACUC Coordinator.
- i. [Redacted by agreement] “Role of eIF5A and deoxyhypusine synthase in brain and global development in mice,” add user, approved on 8/5/2020
 - ii. [Redacted by agreement] “Imaging extracellular matrix degradation,” add user, approved on 7/17/2020
 - iii. [Redacted by agreement] “Generating of cre transgenic mice,” edits, approved on 8/13/2020
- e. **Annual Reviews** reviewed by the ACUC Coordinator and ACUC Chair.
- i. [Redacted by agreement] “Apoptotic T cells induce tolerance in prevention and therapy of autoimmune disease via intrathymic injections and bone marrow transplants in mice,” 2nd annual review, approved on 7/17/2020
 - ii. [Redacted by agreement] “Skeletal analysis of mice with altered small proteoglycans and associated proteins,” 2nd annual review, approved on 8/3/2020

- iii. [Redacted by agreement] "Transcriptome-based evaluation of normal sensation and pain," 2nd annual review, 7/30/2020
- iv. [Redacted by agreement] "Collection of rat dental tissue for molecular analyses," 2nd annual review, 8/11/2020
- v. [Redacted by agreement] "Induction of anemia by hemorrhage of mice with alteration of gene expression in connective tissues," 1st annual review, approved on 8/11/2020
- vi. [Redacted by agreement] "Regeneration of a cartilage defect in mice and rats using induced pluripotent stem cells and post-natal stem cells," 1st annual review, approved on 8/11/2020
- vii. [Redacted by agreement] "Study of the periodontium in Col6a2 deficient mice," 1st annual review, approved on 8/11/2020
- viii. [Redacted by agreement] "Effect of dietary vitamin K2 on T-cell function in mice," 1st annual review, approved on 8/3/2020
- ix. [Redacted by agreement] "Role of cyclin-dependent kinase 5 (Cdk5) in the perception and sensitivity to orofacial inflammation and pain in mice," 1st annual review, approved on 8/11/2020

4. DESIGNATED MEMBER REVIEW (DMR) IN LIEU OF FULL COMMITTEE REVIEW (FCR).

- a. [Redacted by agreement] "Somatosensation in mice," add drugs and procedure, approved on 7/29/2020

5. PROTOCOLS FOR FULL COMMITTEE REVIEW.

- a. [Redacted by agreement] submitted as an initial submission. The Committee tabled the ASP for designated subcommittee review after the ASP is revised addressing the Committee's comments/questions outlined below. (9 for, 0 against, 0 abstain).

[Redacted by agreement]

(b)(5)

(b)(5)

(b)(5)

6. SIGNIFICANT AMENDMENTS FOR FULL COMMITTEE REVIEW.

a.

(b)(5)

(b)(5)

The Committee tabled the amendment for designated subcommittee review after the amendment is revised addressing the Committee's comments/questions outlined below. (9 for, 0 against, 0 abstain).

(b)(5)

7. NEW & OLD ACUC BUSINESS:

- a. **Fall 2020 Semiannual site visit:** The scheduled site visit dates and members assigned to perform the site visits were submitted to the Committee.
- b. **ACUC POLICIES/SOPs/FORMS FOR REVIEW.** The NIDCR ACUC policy on significant changes to animal study protocols is tabled for review. It will be revised following the recent updates to the ARAC guidelines.

8. VRC SOPS FOR REVIEW: NONE

9. ACUC MEMBER TRAINING: NONE

10. INFORMATION / ANNOUNCEMENTS:

- a. **VRC updates:** Dr. Davidson provided an update on VRC operations during the pandemic. More animal users are coming to campus and hence the need to train personnel by VRC or lab personnel. There are new trainees. DOHS has provided guidance regarding close contact, contact that is less than 6 feet distance. When conducting technical hands on training, it is difficult to keep 6 feet distance apart. This is being addressed by using additional PPE such as disposable face shield. VRC has face shields used for this type of interaction and will supply users when taking VRC training. It is preferable for the labs to supply face shields for training conducted by lab personnel in the VRC , but VRC has a limited number that may be requested when needed.

As requestd by DOHS, a sign in sheet is also available in the animal facility for when contact between VRC personnel and/or users is expected to be less than 6 feet, as during technical hands on training. This is to allow for contact tracing when necessary.

11.DATE AND LOCATION OF NEXT MEETING: The next meeting is on Thursday September 17, 2020, via WebEx.

NIDCR ANIMAL CARE AND USE COMMITTEE

Thursday September 17, 2020 Meeting Minutes

Location: WebEx meeting. Time: 10:00AM

1. ATTENDANCE

Members Present:

- [Redacted by agreement]
- [Redacted by agreement]
- Davidson, Attending Vet
- [Redacted by agreement]
- Hoon, Chair
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]
- [Redacted by agreement]

- [Redacted by agreement]

Members Absent:

- [Redacted by agreement]
- [Redacted by agreement]

Guests:

- [Redacted by agreement]
- [Redacted by agreement]

2. MINUTES

The August 20, 2020 meeting minutes were reviewed and approved (10 for, 0 against, 0 abstained).

3. SUBCOMMITTEE WORK

Review of business that occurred between ACUC meetings was noted. These include: tabled animal study proposals and significant amendments that were initially reviewed by Full Committee and designated for review by subcommittee; significant amendments reviewed by Veterinary Verification and Consultation (VVC); significant amendments reviewed by designated subcommittee; minor amendments reviewed by the ACUC Coordinator; and Annual Reviews reviewed by the ACUC Coordinator and ACUC Chair. Additional designated ACUC members, if any, are noted with each submission.

- a. **Tabled Animal Study Proposals:** tabled for review by designated subcommittee -- Attending Veterinarian, ACUC Coordinator, Safety & Health Specialist (for Safety issues), and other ACUC member/s if designated.

- i. [Redacted by agreement] "Studies of the trigeminal nerve as a potential pathway for pathogens connecting the oral cavity to the CNS," Initial submission, approved on 9/10/2020

- b. **Tabled Significant Amendments:** amendments reviewed by FCR and tabled for designated subcommittee review including the Attending Veterinarian, ACUC Coordinator, Safety and Health Specialist (for Safety issues), and other ACUC member/s if designated. **NONE**

c. **Significant Amendments** reviewed by the designated subcommittee including the ACUC Chair or Vice Chair, or Attending Veterinarian, and ACUC Coordinator. OR by Veterinary Verification and Consultation (VVC).

- i. [Redacted by agreement] "Somatosensation in mice," add strains, approved on 8/27/2020
- ii. [Redacted by agreement] "Generation of mouse models of somatosensation," add strains, approved on 8/27/2020
- iii. [Redacted by agreement] "Apoptotic T cells induce tolerance in prevention and therapy of autoimmune disease via intra-thymic injections and bone marrow transplants in mice," add strain, approved on 9/2/2020
- iv. [Redacted by agreement] "Role of TGF-beta signaling in regulation of septic shock," add strains, approved on 8/28/2020
- v. [Redacted by agreement] "Induce high efficiency tumor antigen-specific immunotherapy by inhibiting Tumor-infiltrating Treg cells in mice," add strains, approved on 8/28/2020
- vi. [Redacted by agreement] "Ca²⁺ and HCO₃⁻ signaling in exocrine glands add drug and treatment procedures," approved on 8/19/2020
- vii. [Redacted by agreement] "Generation and acquisition of transgenic mice with alteration of gene expression in connective tissues modify procedure 8/27/2020
- viii.

d. **Minor Amendments** reviewed by the ACUC Coordinator.

- i. [Redacted by agreement] "Plasmin and neutrophil elastase in hematopoietic recovery in mice," add user, approved on 8/18/2020
- ii. [Redacted by agreement] "Role of DESC/HAT-like proteases in mouse development," add user (1), approved on 8/18/2020
- iii. [Redacted by agreement] "Role of DESC/HAT-like proteases in mouse development," add user (2), approved on 9/4/2020
- iv. [Redacted by agreement] Individual and shared functions of epidermal kallikreins," add user (1), approved on 8/18/2020
- v. [Redacted by agreement] "Individual and shared functions of epidermal kallikreins add user (2), approved on 9/4/2020
- vi. [Redacted by agreement] "Genetic analysis of mice expressing catalytically inactive and zymogen-locked prostatic," add user, approved on 8/18/2020

- vii. [Redacted by agreement] “Investigating the role of mannose receptor and uPARAP in tumor-associated stromal cells,” add user, approved on 8/18/2020
- viii. [Redacted by agreement] “Role of protease inhibitors HAI-1 and HAI-2 in mouse tissue development,” add user, approved on 8/18/2020
- ix. [Redacted by agreement] “Role of protease inhibitors HAI-1 and HAI-2 in mouse tissue development,” add user, approved on 9/4/2020

e. Annual Reviews reviewed by the ACUC Coordinator and ACUC Chair.

- i. [Redacted by agreement] “Role of eIF5A and deoxyhypusine synthase in brain and global development in mouse,” 2nd annual review, approved on 9/10/2020
- ii. [Redacted by agreement] “Effect of stretching on tumor growth and metastasis,” 1st annual review, approved on 9/1/2020
- iii. [Redacted by agreement] “Identifying and characterizing salivary gland progenitors,” 1st annual review, approved on 8/27/2020

4. DESIGNATED MEMBER REVIEW (DMR) IN LIEU OF FULL COMMITTEE REVIEW (FCR). NONE

5. PROTOCOLS FOR FULL COMMITTEE REVIEW.

- a. (b)(5)
 (b)(5) The Committee approved the protocol as written. (8 for, 0 against, 1 abstain).

(b)(5)

6. SIGNIFICANT AMENDMENTS FOR FULL COMMITTEE REVIEW.

- a. (b)(5)
 (b)(5)
 (b)(5)
 (b)(5)). The Committee tabled the amendment for designated subcommittee review after the amendment is revised addressing the Committee’s comments/questions outlined below. (9 for, 0 against, 0 abstain). Designated subcommittee members include [Redacted by agreement] Davidson, [Redacted by agreement] and Hoon.

(b)(5)

(b)(5)

b)(5)

- b. [Redacted by agreement] *“Effect of stretching on tumor growth and metastasis,”* [Redacted by agreement]
Amendment is to modify experimental design: add MMTV-PyMT strain in tumor experiments, breeding in house, add 633 mice. (Column C). The Committee approved the amendment as written. (9 for, 0 against, 0 abstain).

7. NEW & OLD ACUC BUSINESS:

- a. Fall Semiannual program review – PART I (Based on the OACU checklist)
Dr. Davidson mentioned that she and [Redacted by agreement] (NIDCR Animal Program Coordinator) conducted the semiannual review of the VRC [Redacted by agreement] animal facility) on September 16th. [Redacted by agreement] participated as an ad hoc visitor to help minimize the number of persons performing the site visit.

- **Program Management & Responsibility**

- Key Management Personnel – no change
- VRC Collaborations – IAA with NINDS for eSirius software; ACUC functions and PI submission of protocols through eSirius continued.

The veterinary clinical care module of the application is currently taken out of the online system. The module required several changes to customize to a rodent facility. Cayuse has decided to pull it back to construct a new module better suited for rodent facilities. After the veterinarians spent many hours working on trying to adopt the module to the NINDS and NIDCR needs, they were told that it was not setup and will not work for small animals such as rodents. It was set up for large animals. Cayuse (parent company of eSirius) agreed to work on the development of the module. Implementation of this module is TBD.

- Training & Education – virtual training of the following
 - Veterinary CE: D.C. Academy of Veterinary Science monthly CE, ACLAM Forum, NCAB AALAS Seminar, AALAS National Meeting
 - VRC Staff CE: NCAB AALAS Seminar

- Occupational Health & Safety – VRC has established emergency operating procedures during the COVID 19 pandemic, which has been presented to the Committee at past meetings. In summary: split staffing schedule to reduce the number of animal care staff in the facility; a new foot pattern for getting in and out of the facility; limiting the number of persons in a room at a time, and scheduling of access to a room required in order to accommodate physical distancing of 6 feet between persons in a room; face mask stations, increased cleaning and disinfecting with disinfectants effective against SARS-CoV-2. A number of measures were taken along with the guidance from DOHS on occupational health and safety.

Split staffing will continue with continued assessment of animal census. To date, it has not been necessary to change the alternating schedule of staff.

- Personnel Security – no updates/changes. Not many users in the facility for most of the past 6 months. But, the number of users is now showing an increase.
- Investigating & Reporting Animal Concerns – no OLAW reportable incidents in the last 6 months.

- Program Oversight

- Animal Care and Use Committee – there are no changes in membership constitution or function. The change is in the OACU Observer assigned to the NIDCR ACUC. Redacted by agreement is the current OACU Observer.
- Standard Operating Procedure Review - The VRC Senior staff continues to review/revise and consolidate VRC SOPs. The revised SOPs, those requiring ACUC review, are being submitted and reviewed by the Committee as they become ready for review. In the last 6 months, the Committee has reviewed and approved the following SOPs:
 - 6.001 Tattoo procedures, 5/21/20
 - 6.002 Euthanasia procedures, 5/21/20
 - 6.003 genotyping procedures, 5/21/20
 - 6.004 blood sampling procedures, 5/21/20
 - 5.001 anesthesia machine use procedures, 6/18/20
 - 5.002 i-STAT® Blood Analyzer procedures, 6/18/20
 - 16A sentinel program, 6/18/20
 - 4.001 ON-campus animal transport and transfers, 7/16/20
 - 4.003 Transport of animals between Bldg. 30 and 14C, 7/16/20
 - 4.005 Animal import/export, 7/16/20
 - 4.008 Animal orders from approved vendors, 7/16/20
 - 4.009 Moving animals on pancreatitis study, 7/16/20
- Animal Study Proposal Review
 - Use-Benefit Analysis – in its review of ASPs, the Committee primarily relies on the Scientific reviewers of the ASP for assessing the scientific

merit of the study. The Committee also carefully considers the study's justification of the procedures to be performed on a protocol, emphasis on procedures that cause more than momentary or transient pain/distress.

- Protocol Endpoints – currently, there are no protocols with death as an endpoint. One of the ASPs, a sepsis study, that had death as an endpoint was amended and the study no longer requires death as an endpoint.
- Unexpected Outcomes – continue to report unexpected study outcomes (for example – adverse phenotypes) to the ACUC as they arise.
- Physical Restraint (Prolonged) – short term physical and chemical restraints are approved on a number of protocols. Prolonged restraint, however, is approved on one ASP, in which mice are potentially in the dolognawmeter for up to 8 hours.
- Multiple Survival Surgery Procedures (MSS) - currently, there are 4 ASPs approved to perform MSS (Hoon, Redacted by agreement).
- Fluid and/or feed restriction – a few ASPs are approved to restrict food and/or fluid. The purpose of the restrictions include: used as a means of training mice to perform in behavioral studies; measure fasting levels of blood glucose, or blood lipids, or blood phosphorous levels; or to observe drinking behavior; or chewing behavior; or maximize production of pancreatic enzymes. For example, the dolognawmeter procedure uses food and fluid restriction for the duration of the test; mice in the apparatus have immediate access to feed/water once they chew through the dowel. Additionally, a terminal acute pancreatitis experiment also has food restriction prior and during induction of pancreatitis.
- Non-Pharmaceutical Grade Compounds – no changes/update.
- Post-approval Monitoring – due to pandemic related procedural changes, there has been limited surgeries performed in the last 6 months. Continued monitoring of new surgical procedures and/or surgeons by Dr. Davidson is still in place, no changes.
- Disaster Planning & Emergency Preparedness – the VRC emergency plan is currently being revised/updated. The revised plan will be submitted for ACUC review.

- b. NIH animal disposition/adoption** – new OACU guidance to develop IC policy/memorandum on end of study adoption. Dr. Davidson summarized the guidance. The issue of adoption is mainly applicable to USDA regulated species (e.g. Guinea pigs, cats, dogs, etc.). Disposition of laboratory animals at the end of a study is currently a hot topic in Congressional discussions and OACU was asked to gather information from ICs on IC policy regarding transfer of ownership between different institutions or public

adoption of animals at the end of a study. OACU is putting together a document to submit for Congressional review. The call went out to all NIH IC animal programs to establish procedures for end of study adoption of laboratory animals if they currently do not have established IC adoption procedures. Each IC is expected to have a written policy/procedure on the disposition of animals addressing the issue of adoption.

A copy of Dr. Gottesman's memo, "Disposition of Laboratory Animals" (2014), was included in the agenda. The memo provides instructions to all NIH ICs on the approval process of animal transfers including public adoption of laboratory animals. The NIDCR will establish similar memorandum on the disposition of rodents using Dr. Gottesman's memo as a basis for the memorandum. The NIDCR uses mostly rodents and the institute has no plans to put out rodents for public adoption. The end of study disposition of rodents is euthanasia.

The ACUC Coordinator will draft the IC adoption memo and the memo will be reviewed by the Committee at a future meeting. The memo will then be submitted to the NIDCR Scientific Director (Institutional Official) for review/approval.

8. ACUC POLICIES/SOPs/FORMS FOR REVIEW.

- a. Revised policy on significant changes (Tabled)

9. VRC SOPS FOR REVIEW: NONE

10. INCIDENT REPORT: NONE

11. ARAC UPDATES:

- a. OLAW guidance/s update – [Redacted by agreement] is the currently assigned OACU observer on this Committee. After Dr. Hoon's introduction of [Redacted by agreement] she briefly introduced herself. She was the NIA ACUC Coordinator prior to joining the OACU. And prior to NIA, she worked for AAALACi. She said that regulatory compliance is an area of her interest and expertise.

[Redacted by agreement] had kindly agreed to the ACUC Coordinator's request to provide the Committee a summary update on current OLAW guidance. Her presentation focused on recent regulatory procedures that came about as a result of the March 2020 OLAW audit of the NIH IC animal programs. Topics included: ACUC review process, ACUC dispositions, and ACUC meeting minutes. Most NIH IC programs are doing these as expected, but some programs may not be documenting the practices accurately according to PHS policy.

- ACUC review process involves the review of animal study proposals and amendments. According to PHS policy, protocols are reviewed via Full Committee Review (FCR) or Designated Member Review (DMR). Amendments are reviewed via FCR, DMR, or administrative review. An administrative review includes different processes. VVC is one of those administrative processes. The OLAW auditors found inconsistencies and some confusion on how VVC was utilized by different IC ACUCs. There must be a policy defining VVC, including: the scope of acceptable changes approved for VVC; defining the approved guidance documents; designate the approved veterinarian/s who will do VVC; describe the VVC process including notification.

VVC is meant to help reduce the burden on the Committee by assigning specific types of the changes to protocols to be reviewed and approved by a veterinarian. The NIDCR ACUC has a policy on VVC for the review of some types of changes to protocols.

- OLAW auditors also reviewed the terms used when documenting ACUC dispositions. There are only three dispositions allowed by PHS policy. ACUC dispositions using FCR are as follows: approval, modification required to secure approval, and withhold approval. Some Committees have drifted away from the allowed terms of dispositions and are not in line with what is allowed. When the disposition is “modification required to secure approval,” it must be specified whether the revised submission will be routed to FCR or DMR. For example, if the disposition is modification required to secure approval, it is written as either tabled/routed for DMR with the names of members designated to review the protocol or amendment, or it is tabled/routed for FCR.

Additionally, when ACUC determines that a protocol or a significant change is approvable upon receipt of a very specific administrative modification or clarification (ex. Correction of typographical errors, misspellings, etc.), the Committee may handle the issue as an administrative detail that an individual (ex. ACUC Chair or Coordinator) may verify. The requested modifications should be specified in the minutes, as well as the person who will verify the modifications have occurred.

- OLAW auditors also identified issues in the minutes of some of the NIH ACUCs. The auditors felt that NIH ACUC are generally doing an excellent job of documenting committee deliberations regarding the review of protocols and significant changes to protocols. However, the auditors felt that a number of the IACUCs variably fall short on documenting full deliberations of other agenda items, such as: incident reports, semiannual program reviews, SOP/Policy reviews, or continuing training opportunities to members. This issue may not be applicable to this ACUC, but any business that the Committee conducts should be documented in the minutes to represent the full scope of the meeting deliberations.

One agenda item that OLAW recommends for inclusion as a standing agenda item, is incident reports. This agenda item can be used for Committee deliberations of either OLAW reportable or nonreportable adverse events, as applicable. Having it as a standing agenda items will be a cue signalling of events that occur

12.ACUC MEMBER TRAINING: NONE

13.INFORMATION / ANNOUNCEMENTS: NONE

14.DATE AND LOCATION OF NEXT MEETING: The next meeting is on Thursday October 15, 2020, via virtual platform.