

NIDDK IACUC Meeting Minutes
19 February 2020

- I. Constance T. Noguchi, Ph.D. NIDDK, Chair called the NIDDK IACUC to order at 1:30 P.M. in Redacted by agreement
Redacted by agreement

Members in attendance:

- ✓ Present Constance T. Noguchi, Ph.D., Chair, NIDDK, Senior Investigator, Molecular Medicine Branch
- ✓ Present Mark B. St. Claire, D.V.M., NIDDK, Animal Program Director
- ✓ Present Redacted by agreement
- ✓ Present
- ✓ Present
- ✓ Present
- ✓ Present
- ✓ Present
- ✓ Present

Other attendees:

- ✓ Present
- ☐ Present

Minutes from the 15 January 2020 NIDDK IACUC meeting were distributed. The minutes were unanimously approved.

Addendums from January 2020 NIDDK IACUC meeting were distributed. The addendums were unanimously approved.

II. **NIDDK Animal Study Proposal Amendment(s)/Annual Review(s)**

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the amendment to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

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Decision: Following convened deliberation the committee unanimously agreed to send the amendment to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

III. **NIDDK New Animal Study Proposal(s) and Three-Year Renewal(s) Review**

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

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Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

IV. **Old Business:**

NIDDK 2020 Spring Semi-Annual Animal Program Review

Comments: The animal program review will be done in the month of March and committee members are to send their schedules in to the ACUC manager.

V. **New Business:**

NIDDK 2020 OLAW Animal Program Review

Comments: The NIH Intramural animal program review will be done the week of March 2 – 6 , 2020. NIDDK is currently scheduled for visitation on March 5, and committee members are to make themselves available for questioning.

Review NIDDK Emergency Plan By: Dr. Mark St. Claire

Comments: SOPs were proofread and grammatical errors noted.

3.106A Recent update of the AVMA euthanasia policy necessitates alignment.

3.400A Note in point 6 position of rats for cage handling.

3.400B Note in C1b2 that Mark St. Claire is the Team Leader [Redacted by agreement] the primary alternate Team Leader and [Redacted by agreement] as the secondary alternate Team Leader.

Within the [Redacted by agreement] is the responsible party.

Updated ARAC guidelines are as follows:

Administrative:

Collecting and Releasing Animal Images and Audio Recordings, 12-19-19 **NEW**

Animal Care and Use Procedures:

Blood Collection in Mice and Rats, 10/23/19 **REVISED**

Euthanasia of Rodents Using Carbon Dioxide, 10/23/19 **REVISED**

Survival Rodent Surgery, 12/19/19 **REVISED**

Diet Control in Laboratory Animals, 10/23/19 **REVISED**

Animal Care and Use Committee:

Responding to Animal Care & Use Complaints from Outside NIH, 01/25/17

DDIR Policy Memo: Communicating Animal Care and Use Concerns within the NIH Intramural Research Program, 02/28/19 **REVISED**

Collaborative Animal Studies, 12/19/19 **REVISED**

Shared and Central Facilities, 10/23/19 **REVISED**

Review, Approval, & Post Approval Monitoring of Animal Study Proposals Including Designated Member Review, 01/22/20 **REVISED**

Facility Management:

Co-Housing Multiple Species of Laboratory Animals, 10/23/19 **REVISED**

Personnel Protection in Animal Facilities, 09/25/19 **REVISED**

General Species Environmental Enrichment, 12/19/19 **REVISED**

- a. Appendix 1: Environmental Enrichment of Rodents, 12/19/19 **REVISED**
- b. Appendix 2: Environmental Enrichment (Behavioral Management) of Nonhuman Primates, 12/19/19 **REVISED**

The ASPs to be reviewed for renewal at the March meeting are the following.

Redacted by agreement

Next ACUC meeting is scheduled for **Wednesday 18 March 2020** in Redacted by agreement on second floor at 1:30 pm.

There were no minority opinions expressed and the meeting adjourned at 2:20 pm.

Finalized Amendments & Annual ASPs

Administratively

February 2020

VCC

February 2020

Title: *Nuclear Receptors and Mammalian Development* By: [Redacted by agreement]

Amendment #2

Comments: Amendment #2 modifies the above protocol by adding mouse strains En2 ko and En2 cko from [Redacted by agreement] and 10 mice to year 1 and 20 to years 2 & 3 each for a total of 50 (Column C).

Title: *Mice Transgenic in Genes Expressed in the Gonad* By: [Redacted by agreement]

Amendment #15

Comments: Amendment #15 modifies the above protocol by adding camera documentation in [Redacted by agreement]

Title: *The Role of the Jak/Stat Signaling Pathways in the Mammary Gland, Salivary gland, Teeth and Kidney* By: [Redacted by agreement] Amendment #5

Comments: Amendment #5 modifies the above protocol by removing [Redacted by agreement]

[Redacted by agreement] ketamine/metomidine anesthesia, atipamezole hydrochloride anti-anesthesia and removing avertin.

Title: *Analysis of Initiation of Meiotic Recombination in Mammals* By: [Redacted by agreement]

[Redacted by agreement] Amendment #1

Comments: Amendment #1 modifies the above protocol by adding [Redacted by agreement] and mouse strain Stra8 (JAX#023805) from Whitehead Institute for Biomedical Research, [Redacted by agreement] and 84 mice to each years 1-3 for a total of 252 (Column C).

Title: *Analysis of G Protein-coupled Receptor Mutant Mice* By: [Redacted by agreement]

Amendment #19

Comments: Amendment #19 modifies the above protocol by adding S961 and procedure “Delivery of S961, an insulin receptor antagonist, via osmotic mini-pumps, to mice”.

Title: *Role of the GNB5/R7-RGS/R7BP Complex in Neuronal Cell Function and Behavior* By: [Redacted by agreement]

[Redacted by agreement] Amendment #15

Comments: Amendment #15 modifies the above protocol by adding mouse strain Rgs7-cKO from the [Redacted by agreement] and 78 mice for year 3 (Column C).

Title: *Metabolic Studies of Mouse Models of Obesity and Diabetes* By: [Redacted by agreement]

Amendment #5

Comments: Amendment #5 modifies the above protocol by removing animal procedure room 8/B2A12 and changing locations of procedures within already approved rooms and adding [Redacted by agreement] to the group of surgical investigators.

Title: *Tracer Studies of Metabolism in Mice* By: [Redacted by agreement] Amendment #3

Comments: Amendment #3 modifies the above protocol by adding animal procedure room [Redacted by agreement] and [Redacted by agreement] to the group of surgical investigators.

Title: *Analysis of G Protein-coupled Receptor Mutant Mice* By: [Redacted by agreement]
Amendment #20

Comments: Amendment #20 modifies the above protocol by adding mouse strain Gna12^{-/-}; Gna13 fl/fl mice from [Redacted by agreement] and 4 mice to year 2 (Column C).

Approved at ACUC Meeting
February 2020

Expedited Review
February 2020

Annual Reviews

Title: *In Vivo Activity of Small Ligands for G-Protein-coupled Receptors* By: [Redacted by agreement]
[Redacted by agreement]

Title: *O-GlcNAcase & O-linked GlcNAc Transferase in Diabetes and Neurodegenerative Disease* By: [Redacted by agreement]
[Redacted by agreement]

Title: *Metabolic Studies of Mouse Models of Obesity and Diabetes* By: [Redacted by agreement]

Title: *Ascorbic Acid, Dehydroascorbic Acid, and Glucose Transport in Xenopus Laevis Oocytes* By: [Redacted by agreement]
[Redacted by agreement]

Title: *Mouse Models for Erythropoietin Signaling* By: [Redacted by agreement]

Title: *Development of Mouse Model for the Trinucleotide Repeat Expansion Disorders* By: [Redacted by agreement]
[Redacted by agreement]

Finalized ASPs & Three Year Renewals

Designated Review
February 2020

Title: *Treatment of Sepsis and Sepsis-induced Acute Kidney Injury* By: [Redacted by agreement]
18 Amendment #10

Comments: Amendment #10 modifies the above protocol by adding animal procedure location [Redacted by agreement] for fluorescent imaging to all experimental protocols, add heart failure model, alternative coagulated cecal contents for CLP, and major surgery for transverse aortic constriction.

[Redacted by agreement] addressed all issues from 20 November, 2019 meeting. The ASP was presented for Designated Review and approval was given on 13 February, 2020.

Title: *Effect of Environment, Nutrients and Pharmacologic Agents on Mouse Energy Homeostasis and Body Temperature* By: [Redacted by agreement] Amendment #16

Comments: Amendment #16 modifies the above protocol by adding procedures; “Part 31, recording electroencephalograms (EEG)”, “Part 32, measurement of body temperature in different places”, and “Part 33, a new method for measuring tail temperature”.

[Redacted by agreement] addressed all issues from 15 January, 2020 meeting. The ASP was presented for Designated Review and approval was given on 03 February, 2020.

Three year renewal
February 2020

Initial Submission
February 2020

Title: *Potential Antineoplastic Effects of Small Molecule TSHR Ligands in a Mouse model of Thyroid Cancer* By: [Redacted by agreement]

Comments: The above protocol is an initial submission. [Redacted by agreement] addressed all issues from 20 November, 2019 meeting. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 06 January, 2020.
Final Approval letter sent 02/03/2020.

Tabled Amendment Not Yet Re-Submitted

Deactivation of Animal Study Protocol
February 2020

(b)(5) [Redacted]

Deactivation 02/26/2020.

NIDDK IACUC Meeting Minutes
18 March 2020

- I. Constance T. Noguchi, Ph.D. NIDDK, Chair called the NIDDK IACUC to order at 1:35 P.M. in Building 3, Rm. 2E04. Majority of members attended via teleconference.

Members in attendance:

- | | | |
|-------------------------------------|---------|---|
| <input checked="" type="checkbox"/> | Present | Constance T. Noguchi, Ph.D., Chair, NIDDK, Senior Investigator, Molecular Medicine Branch |
| <input type="checkbox"/> | Present | Mark B. St. Claire, D.V.M., NIDDK, Animal Program Director |
| <input checked="" type="checkbox"/> | Present | <div style="border: 1px solid black; padding: 5px;">Redacted by agreement</div> |
| <input checked="" type="checkbox"/> | Present | |
| <input checked="" type="checkbox"/> | Present | |
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| <input checked="" type="checkbox"/> | Present | |
| <input checked="" type="checkbox"/> | Present | |
| <input type="checkbox"/> | Present | |
| <input type="checkbox"/> | Present | |

Other attendees:

- | | |
|-------------------------------------|---------|
| <input checked="" type="checkbox"/> | Present |
| <input type="checkbox"/> | Present |

Minutes from the 19 February 2020 NIDDK IACUC meeting were distributed. The minutes were unanimously approved.

Addendums from February 2020 NIDDK IACUC meeting were distributed. The addendums were unanimously approved.

II. **NIDDK Animal Study Proposal Amendment(s)/Annual Review(s)**

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the amendment to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the amendment to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

Title: *The Role of the Jak/Stat Signaling Pathways in the Mammary Gland, Salivary gland, Teeth and Kidney* By: Redacted by agreement Amendment #6

Comments: A fully convened IACUC reviewed the above protocol.

Decision: Following convened deliberation the committee unanimously agreed to approve the amendment.

III. **NIDDK New Animal Study Proposal(s) and Three-Year Renewal(s) Review**

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol back to the Principal Investigator for revision and then to come before Full Committee Review (FCR) once the Principal Investigator responds to questions and comments.

(b)(5)

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

IV. Old Business:

Review 2017 AAALACi site visit

Comments: The safety officer is in the process of generating computer code to generate formulations from previous publications that have addressed the chemical and pharmacological properties of Non-Pharmaceutical Grade Compounds (NPGC).

Discuss OLAW site visit

Comments: The safety officer and veterinarian will compose a table of common pharmaceutical compounds with dosages to be reviewed at the April meeting for Veterinarian Verification and Consultation (VVC), Category 2: *NIDDK Policy on Changes to Animal Study Protocols*.

V. New Business:

Animal Welfare Concern

Title: *Mouse Models of Liver Diseases* By: [Redacted by agreement]

Comments: A fully convened IACUC reviewed the above incident. The committee wants the following addressed. The IACUC chairperson will correspond with [Redacted by agreement] and request a letter to be submitted by March 25, 2020 detailing the following:

1. Provide an explanation for the unapproved use of retrorsine in mice which also resulted in several deaths.

2. What action has been or will be taken to address this immediate situation?
3. What action will be taken in effort to prevent this from happening in the future?

After the receipt of the letter from [Redacted by agreement] additional review will be discussed via email. All personnel on the ASP will retake the OACU online training, Using Animals in NIH Intramural Research: Guidelines for Principal Investigators. The attending veterinarian will write a letter to OACU outlining the changes made and make the final report to OLAW.

Review

(b)(5)

Comments: It was unanimously agreed to review this at the April meeting due to time constraints.

Title: *NIDDK LASS Rodent Survival Surgery Checklist Draft* By [Redacted by agreement]

Comments: Following convened deliberation the committee unanimously agreed to approve the checklist to be added for surgical procedures.

Updated ARAC guidelines are as follows:

Administrative: None

Animal Care and Use Procedures: None

Animal Care and Use Committee: None

Facility Management: None

The ASPs to be reviewed for renewal at the April meeting are the following.

[Redacted by agreement]

Next ACUC meeting is scheduled for **Wednesday 15 April 2020** in [Redacted by agreement] on second floor at 1:30 pm.

There were no minority opinions expressed and the meeting adjourned at 3:00 pm.

Amendment/Annual Reviews NIDDK March, 2020

Finalized Amendments & Annual ASPs

Administratively

March 2020

Title: *Epigenetic Regulation of PPAR γ and Adipogenesis* By: [Redacted by agreement] Amendment #15

Comments: Amendment #15 modifies the above protocol by adding [Redacted by agreement] and removing [Redacted by agreement]
[Redacted by agreement]

VCC

March 2020

Title: *Central Nervous System G Protein Signaling in Metabolic Regulation* By: [Redacted by agreement]

[Redacted by agreement] Amendment #6

Comments: Amendment #6 modifies the above protocol by modifying the cage wire and water for mice with cranial implants to prevent getting caught and for single housing the mice due to chewing on the implants.

Title: *Role of Cell Cycle Regulators in Diabetes and Obesity* By: [Redacted by agreement]

Amendment #5

Comments: Amendment #5 modifies the above protocol by adding mouse strain 129S-Pitx2^{tm4(cre)Jfm}/Mmucd from MMRRC and 30 mice to years 2 & 3 each for a total of 60 (Column C).

Approved at ACUC Meeting

March 2020

Title: *The Role of the Jak/Stat Signaling Pathways in the Mammary Gland, Salivary gland, Teeth and Kidney* By: [Redacted by agreement] Amendment #6

Comments: Amendment #6 modifies the above protocol by adding Buprenorphine SR.

[Redacted by agreement] addressed all issues from 18 March, 2020 meeting.

Expedited Review

March 2020

Annual Reviews

Title: *Mouse Models of Disordered Sphingolipid Metabolism: Characterization and Therapy* By: [Redacted by agreement]

[Redacted by agreement]

Title: *Molecular Mechanisms of Endocrine Tumorigenesis in Mouse Model of Multiple Endocrine Neoplasia Type 1 (MEN1)* By: [Redacted by agreement]

Title: *The Role of TSH receptors in Bone Homeostasis* By: [Redacted by agreement]

Title: *NIDDK Transgenic Rodent Core Facility: Production of Transgenic Rodents, Embryo and Sperm Cryopreservation, Rederivation, Intracytoplasmic Sperm Injection (ICSI), In vitro fertilization (IVF)* By: [Redacted by agreement]

[Redacted by agreement]

Title: *NIDDK Rodent Holding and Breeding Protocol* By: [Redacted by agreement]

Title: *Embryonic and Fetal Globin gene expression* By: [Redacted by agreement]

Finalized ASPs & Three Year Renewals

Designated Review

March 2020

Title: *Nitrate/nitrite/nitric oxide metabolic pathway in relation to classical nitric oxide pathway and the effect of diet, exercise and oxygen variations on NO metabolite fluxes in mammalian body* By: Dr.

Redacted by agreement

Amendment # 7

Comments: Amendment #7 modifies the above protocol by adding procedures “*Intraocular pressure (IOP) measurements*” and “*Bolus administration of ¹⁵N-nitrate and ¹⁵N-nitrite to rats and mice by oral gavage.*”.

Dr. Noguchi addressed all issues from 19 February, 2020 meeting. The ASP was presented for Designated Review and approval was given on 02 March, 2020.

Title: *Analysis of G Protein-coupled Receptor Mutant Mice* By: Redacted by agreement

Amendment #18

Comments: Amendment #18 modifies the above protocol by adding 48 mice (16 Column C & 32 Column D) and procedures “*Treatment of WT mice with N-methyl Leukotriene C4 (NMLC4)*” and “*Intraperitoneal Implantation of ALZET osmotic mini-pumps*”.

Redacted by agreement

Redacted by agreement addressed all issues from 19 February, 2020 meeting. The ASP was presented for Designated Review and approval was given on 06 March, 2020.

Title: *Unravelling Immunoregulatory Circuits of T cells in Kidney Diseases* By: Redacted by agreement

Redacted by agreement

Amendment #5

Comments: Amendment #5 modifies the above protocol by adding NHLBI MPC behavioral tests; Hole Board Test, Reverse Light Cycle, Running Wheel, Sucrose Consumption Test, Sociability Test, Contextual Learning, Pre-pulse Inhibition and Phenotyper Home Cage Monitoring.

Redacted by agreement

Redacted by agreement addressed all issues from 19 February, 2020 meeting. The ASP was presented for Designated Review and approval was given on 11 March, 2020.

Title: *Transgenesis for Investigations of Germ Cell Development and Fertilization* By: Redacted by agreement

Redacted by agreement

Amendment # 7

Comments: Amendment #7 modifies the above protocol by adding procedure “*In vivo Mouse Testis Microinjection and Electroporation*”.

Redacted by agreement

Redacted by agreement addressed all issues from 19 February, 2020 meeting. The ASP was presented for Designated Review and approval was given on 16 March, 2020.

Three year renewal

March 2020

Title: *Anti-cancer Effects and Mechanisms of Ascorbic Acid* By: Redacted by agreement

Comments: Redacted by agreement addressed all issues from 19 February, 2020 meeting. The ASP was presented for Designated Review and approval was given on 20 March, 2020.

Final Approval letter sent 03/20/2020.

Initial Submission

March 2020

Tabled Amendment Not Yet Re-Submitted

Deactivation of Animal Study Protocol

March 2020

NIDDK IACUC Meeting Minutes
15 April 2020

- I. Constance T. Noguchi, Ph.D. NIDDK, Chair called the NIDDK IACUC to order at 1:30 P.M. Members attended via WebEx.

Members in attendance:

- ✓ Present Constance T. Noguchi, Ph.D., Chair, NIDDK, Senior Investigator, Molecular Medicine Branch
- ✓ Present Mark B. St. Claire, D.V.M., NIDDK, Animal Program Director
- ✓ Present
- ✓ Present
- ✓ Present
- ✓ Present
- ✓ Present
- ✓ Present
- ✓ Present

Other attendees:

- ✓ Present
- ✓ Present

Redacted by agreement

Minutes from the 18 March 2020 NIDDK IACUC meeting were distributed. The minutes were unanimously approved.

Addendums from March 2020 NIDDK IACUC meeting were distributed. The addendums were unanimously approved.

II. **NIDDK Animal Study Proposal Amendment(s)/Annual Review(s)**

Title: *Mouse Models of Liver Diseases* By: Redacted by agreement Amendment #3

Comments: A fully convened IACUC reviewed the above protocol.

Decision: Following convened deliberation the committee unanimously agreed to approve the amendment.

III. **NIDDK New Animal Study Proposal(s) and Three-Year Renewal(s) Review**

(b)(5)

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

IV. **Old Business:**

Animal Welfare Concern: Follow-up

Title: *Mouse Models of Liver Diseases* By [Redacted by agreement]

Comments: A fully convened IACUC reviewed the above incident response and corresponding letter to Dr. Gottsman. All personnel on the ASP will retake the OACU online training, Using Animals in NIH Intramural Research: Guidelines for Principal Investigators. [Redacted by agreement] will submit a TSR for injections and be supervised by DVR staff for the next 3 occasions. The committee wants the letter to be submitted to OACU, OLAW and Dr. Gottsman with the actions submitted to rectify the situation and retrain personnel.

V. **New Business:**

Review: 2019 Spring Semi-annual inspection with ad hocs.

Comments: A fully convened IACUC reviewed the above semi-annual inspection report. We accept the following DVR and NIAID as qualified ad hoc team members via email sent out on March 31, 2020. [Redacted by agreement]

[Redacted by agreement]

Following convened deliberation the committee unanimously agreed to approve the report. The signature page will be sent out after meeting.

Review: NIDDK Review Process for Significant Changes (Modifications) to Animal Study Proposals Guideline.

Comments: The safety officer and veterinarian will compose a table of common pharmaceutical compounds with dosages to be reviewed at the May meeting for Veterinarian Verification and Consultation (VVC), Category 2. It was unanimously agreed to approve the update in terminology.

Review: *Behavior test Policy 1.02* By: Dr. Mark St. Claire, updated with new NHLBI MPC tests.

Comments: It was unanimously agreed to approve the updates.

SOP Review:

- 3.502 Animal Identification and Completion of Cage Cards
- 3.600 Sample Collection to Genotype Mice by Tail Biopsy
- 3.601 Rodent Enrichment
- 4.000 Decontamination of Used Equipment of Animal Caging upon Entry into the Animal Facility
- 4.101 Sanitation of Corridors
- 4.102 Sanitation of Cage Wash Area and Supporting Areas
- 4.103 Sanitation-Storage Rooms
- 4.104 Sanitation of Racks
- 4.105 Sanitation of Procedure Rooms
- 4.105.1 Daily, Weekly and Monthly Procedures for Redacted by agreement
- 4.106 Cleaning and Maintenance of Building 8 Animal Facility Dock and Dock Hallway
- 4.107 Cleaning of Refrigerators and Freezers
- 4.308 Operation, Cleaning, and Maintenance of the Stay-Clean Workbench Unit
- 4.402A Autoclave Technique for Rodent Chow, Micro-Isolator Cages, and Drinking Water
- 4.501 Operation of the Two-Station Anesthesia Unit
- 4.504 Operation, Cleaning, and Maintenance of the ThermoCare Unit
- 6.003 Husbandry Procedures for African Clawed Frogs (*Xenopus laevis*)
- 6.003A *Xenopus laevis* Daily Observation Log

Comments: It was unanimously agreed to approve the SOPs with minor typo corrections.

Updated ARAC guidelines are as follows:

Administrative: None
Animal Care and Use Procedures: None
Animal Care and Use Committee: None
Facility Management: None

The ASPs to be reviewed for renewal at the May meeting are the following.

Redacted by agreement

Next ACUC meeting is scheduled for **Wednesday 20 May 2020** in Redacted by agreement on second floor at 1:30 pm or via WebEx.

There were no minority opinions expressed and the meeting adjourned at 2:30 pm.

Amendment/Annual Reviews NIDDK April, 2020

Finalized Amendments & Annual ASPs

Administratively

April 2020

Title: *Mouse Models for Erythropoietin Signaling* By: [Redacted by agreement]

Amendment #4

Comments: Amendment #4 modifies the above protocol by removing [Redacted by agreement]

Title: *Nitrate/nitrite/nitric oxide metabolic pathway in relation to classical nitric oxide pathway and the effect of diet, exercise and oxygen variations on NO metabolite fluxes in mammalian body* By: Dr.

[Redacted by agreement] Amendment # 8

Comments: Amendment #8 modifies the above protocol by removing [Redacted by agreement]

Title: *Protective Activity of Erythropoietin/Erythropoietin Receptor in Progenitor Cells* By: [Redacted by agreement]

[Redacted by agreement] Amendment #5

Comments: Amendment #5 modifies the above protocol by removing [Redacted by agreement]

VVC

Approved at ACUC Meeting

April 2020

Title: *Mouse Models of Liver Diseases* By: [Redacted by agreement] Amendment #3

Comments: Amendment #3 modifies the above protocol by limiting cage changing by 1-2 weeks for newly born litters and gravid dams that are about to deliver to reduce stress and increase survivability. Adding mouse strain C57BL/6J-Tg(SLC10A1)39Mvw/J, for Fah^{-/-} mice, uPA adenovirus (CuRx™ uPA Liver Tx Enhancer, Yecuris) is pretreated one day before engraftment by retro-orbital injection to induce liver injury, increasing Nitisinone stock solution to 4mg/mL and NTBC cycling schedule.

Expedited Review

Annual Reviews

Title: *Understanding the Pathogenesis of Nonalcoholic Fatty Liver Disease (NAFLD)* By: [Redacted by agreement]

[Redacted by agreement]

Finalized ASPs & Three Year Renewals

Designated Review

April 2020

Title: *Unravelling Immunoregulatory Circuits of T cells in Kidney Diseases* By: [Redacted by agreement]

[Redacted by agreement] Amendment #6

Comments: Amendment #6 modifies the above protocol by adding euthanasia by exsanguination for rapid tissue fixation.

[Redacted by agreement] addressed all issues from 18 March, 2020 meeting. The ASP was presented for Designated Review and approval was given on 13 April, 2020.

Three year renewal

Initial Submission

Tabled Amendment Not Yet Re-Submitted

Deactivation of Animal Study Protocol

April 2020

(b)(5)

Deactivation 04/08/2020.

NIDDK IACUC Meeting Minutes
20 May 2020

- I. Constance T. Noguchi, Ph.D. NIDDK, Chair called the NIDDK IACUC to order at 1:30 P.M. Members attended via WebEx.

Members in attendance:

- ✓ Present Constance T. Noguchi, Ph.D., Chair, NIDDK, Senior Investigator, Molecular Medicine Branch
- ✓ Present Mark B. St. Claire, D.V.M., NIDDK, Animal Program Director
- ✓ Present Redacted by agreement
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- ✓ Present
- Present
- ✓ Present
- ✓ Present
- ✓ Present

Other attendees:

- ✓ Present
- ✓ Present

Minutes from the 15 April 2020 NIDDK IACUC meeting were distributed. The minutes were unanimously approved.

Addendums from April 2020 NIDDK IACUC meeting were distributed. The addendums were unanimously approved.

II. **NIDDK Animal Study Proposal Amendment(s)/Annual Review(s)**

III. **NIDDK New Animal Study Proposal(s) and Three-Year Renewal(s) Review**

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

Title: *Studies of Purinergic Receptors (P2Y₆ and P2Y₁₄) mutant mice* By: [Redacted by agreement]
[Redacted by agreement] **(THREE YEAR RENEWAL)**

Comments: A fully convened IACUC reviewed the above protocol.

Decision: Following convened deliberation the committee unanimously agreed to approve the protocol.

IV. **Old Business:**

V. **New Business:**

Animal Facility Scheduling:

Comments: A fully convened IACUC discussed the easing of telework restrictions on campus and the return of personnel to labs and animal facilities. Concern was expressed over; status of PPE, COVID-19 personnel contamination of facilities, keeping social distancing, cleaning of animal rooms and common areas in the animal facilities. It was suggested to post a schedule for rooms with sign up to prevent overlapping of room usage. Additional concerns were; how to make sure personnel only work the time and place scheduled, how to distribute the schedule. The Animal Program Manager will follow up on this including facility staff and the APD. Outlook calendar for rooms is a possible format.

SOP Review:

- 3.103 Quarantine for Disease Control
- 3.104 Small Animal Laboratory Clinical Records
- 3.105 Handling of Dead Animal Carcasses
- 3.107 Procedures in Sentinelization of Sentinel Records
- 3.107.1 Guidelines for the Sentinel QA Program
- 3.108 Animal Caretaker Daily Responsibilities
- 3.108.1 Guidelines for Checking Pest Management Rodent Traps
- 3.110 Storage and Handling of Feed in Animal Rooms

- 3.111 Bedding
- 3.113 Packing Rodents for Extramural Shipment
- 3.200 Animal Husbandry Procedures
- 3.201 Animal Husbandry Procedures – Immune Competent Mice
- 3.202 Labeling of cages for Fasting, Feed Intake Studies, Special Diets and Surgery
- 3.202A Weekend and Holiday Observation of Mice housed in Metabolic Core in Redacted by agreement
Redacted by agreement
- 3.203 Housing and Care of Immune Compromised Mice
- 3.204 Animal Husbandry Procedure for Rats
- 3.213 Use of Wavicide 01
- 3.213.1 Preparation of Trimethoprim-Sulfa treated water
- 3.214 Preparation of Avertin

Comments: It was unanimously agreed to approve the SOPs with minor typo corrections.

Updated ARAC guidelines are as follows:

Administrative: None

Animal Care and Use Procedures: None

Animal Care and Use Committee: None

Facility Management: None

The ASPs to be reviewed for renewal at the June meeting are the following.

Redacted by agreement

Next ACUC meeting is scheduled for **Wednesday 17 June 2020** in Redacted by agreement on second floor at 1:30 pm or via WebEx.

There were no minority opinions expressed and the meeting adjourned at 2:30 pm.

Finalized Amendments & Annual ASPs

Administratively

May 2020

Title: *Nitrate/nitrite/nitric oxide metabolic pathway in relation to classical nitric oxide pathway and the effect of diet, exercise and oxygen variations on NO metabolite fluxes in mammalian body* By: Dr.

Redacted by agreement

Amendment # 9

Comments: Amendment #9 modifies the above protocol by removing Redacted by agreement

Redacted by agreement

VVC

May 2020

Approved at ACUC Meeting

May 2020

Title: *Studies of Purinergic Receptors (P2Y₆ and P2Y₁₄) mutant mice* By: Redacted by agreement

Redacted by agreement

(THREE YEAR RENEWAL)

Expedited Review

May 2020

Annual Reviews

Title: *Gnas Gene Regulation and Physiological Roles of G Proteins* By: Redacted by agreement

Title: *Analysis of the Molecular Targets for Therapy in Endocrine Tumors* By: Redacted by agreement

Redacted by agreement

Finalized ASPs & Three Year Renewals

Designated Review

May 2020

Title: *Mouse Models of Disordered Sphingolipid Metabolism: Characterization and Therapy* By: Redacted by agreement

Redacted by agreement

Amendment #5

Comments: Amendment #5 modifies the above protocol by removing Redacted by agreement

Redacted by agreement 40 mice to year 3 (Col C) for procedure "Hematopoietic stem cell transplantation" and RD-20-IV-10.

Redacted by agreement addressed all issues from 18 March, 2020 meeting. The ASP was presented for Designated Review and approval was given on 07 May, 2020.

Three year renewal

May 2020

Title: *Study of Mice Lacking the Na⁺ Dependent Ascorbic Acid Transporter – SVCT1* By: Redacted by agreement

Redacted by agreement

(THREE YEAR RENEWAL)

Comments: Redacted by agreement addressed all issues from 18 March, 2020 meeting. The ASP was presented for Designated Review and approval was given on 22 April, 2020.

Final Approval letter sent 05/08/2020.

Title: *Diagnosis and Treatment of Acute Kidney Injury* By: Redacted by agreement

(THREE YEAR RENEWAL)

Comments: [Redacted by agreement] addressed all issues from 18 March, 2020 meeting. The ASP was presented for Designated Review and approval was given on 27 April, 2020.
Final Approval letter sent 05/11/2020.

Title: *Rodent Models of Glomerulosclerosis* By: [Redacted by agreement] **(THREE YEAR RENEWAL)**

Comments: [Redacted by agreement] addressed all issues from 15 April, 2020 meeting. The ASP was presented for Designated Review and approval was given on 30 April, 2020.
Final Approval letter sent 05/15/2020.

Initial Submission

May 2020

Tabled Amendment Not Yet Re-Submitted

Deactivation of Animal Study Protocol

May 2020

(b)(5)

Deactivation 05/26/2020.

NIDDK IACUC Meeting Minutes

17 June 2020

- I. Constance T. Noguchi, Ph.D. NIDDK, Chair called the NIDDK IACUC to order at 1:39 P.M. Members attended via WebEx.

Members in attendance:

- ✓ Present Constance T. Noguchi, Ph.D., Chair, NIDDK, Senior Investigator, Molecular Medicine Branch
- ✓ Present Mark B. St. Claire, D.V.M., NIDDK, Animal Program Director
- ✓ Present Redacted by agreement
- ✓ Present
- ✓ Present
- ✓ Present
- Present
- ✓ Present
- ✓ Present
- ✓ Present

Other attendees:

- ✓ Present
- ✓ Present

Minutes from the 20 May 2020 NIDDK IACUC meeting were distributed. The minutes were unanimously approved.

Addendums from May 2020 NIDDK IACUC meeting were distributed. The addendums were unanimously approved.

II. NIDDK Animal Study Proposal Amendment(s)/Annual Review(s)

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the amendment to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

III. NIDDK New Animal Study Proposal(s) and Three-Year Renewal(s) Review

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

Title: *Regulation of Systemic and Hepatic Immune Responses by the Microbiome* By: [Redacted by agreement]
[Redacted by agreement] **THREE YEAR RENEWAL)**

Comments: A fully convened IACUC reviewed the above protocol. It was noted that the ASP is beautifully written and very clear. Sect B, pg 2 “Wildling/Balb/c mice: C57BL/6 mice” correct typo to Balb/c. Sect K, it was noted that 4018 is active but doesn’t show in the HealthRx. The safety officer suggested to update the PRD with the new ASP so it will show up.

Decision: Following convened deliberation the committee unanimously agreed to approve the protocol.

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

IV. **Old Business:**

V. **New Business:**

In order to follow OLAWs requirement for Semi-annual inspection report, the inspection of [Redacted by agreement] needs to be completed by 07/30/2020.

Comments: A fully convened IACUC unanimously agreed to accept [Redacted by agreement] NIAID as qualified ad hoc team members to inspect NIDDK animal rooms on June 18, 2020. The 2020 Fall semi-annual inspection will occur in the fall and it will be notated that [Redacted by agreement] was inspected by qualified ad hoc team members

in June 2020 and will be again inspected during the Fall semi-annual inspection in September to maintain our normal inspection schedule.

Updated ARAC guidelines are as follows:

Administrative: None

Animal Care and Use Procedures: None

Animal Care and Use Committee: None

Facility Management: None

The ASPs to be reviewed for renewal at the July meeting are the following.

Redacted by agreement

Next ACUC meeting is scheduled for **Wednesday 15 July 2020** in Redacted by agreement on second floor at 1:30 pm or via WebEx.

There were no minority opinions expressed and the meeting adjourned at 2:35 pm.

Finalized Amendments & Annual ASPs

Administratively

June 2020

VVC

June 2020

Title: *Small Molecule TSHR Antagonists in a Mouse Model of Autoimmune Graves' Disease* By: [Redacted by agreement]

[Redacted by agreement] Amendment #1

Comments: Amendment #1 modifies the above protocol by adding CO2 as a method of euthanasia per DVR SOP.

Approved at ACUC Meeting

June 2020

Title: *Regulation of Systemic and Hepatic Immune Responses by the Microbiome* By: [Redacted by agreement]

[Redacted by agreement] (THREE YEAR RENEWAL)

Expedited Review

June 2020

Annual Reviews

Title: *Genetic Manipulation of the Murine Pkd1 Gene and Analysis of its Effects* By: [Redacted by agreement]

[Redacted by agreement]

Title: *NIDDK Mouse CRISPR/Cas9 Genome Editing Facility: Production of Genome Modified Mice* By:

[Redacted by agreement]

Title: *Unraveling Functional Circuits Modulating Food Intake* By: [Redacted by agreement]

[Redacted by agreement]

Finalized ASPs & Three Year Renewals

Designated Review

June 2020

Title: *In Vivo Activity of Small Ligands for G-Protein-coupled Receptors* By: [Redacted by agreement]

[Redacted by agreement] Amendment #5

Comments: Amendment #5 modifies the above protocol by adding [Redacted by agreement] 284 mice (Column C) to years 2 & 3, humanized TSHR knock-in mice on Balb/c background, Protocols 5 & 6, VGD040; 9-cyclohexylmethyl-1-(p-toluenesulfonyl)-3-methylene-1,5,9-triazacyclododecane, and CO2 as a method of euthanasia per DVR SOP.

[Redacted by agreement] addressed all issues from 20 May, 2020 meeting. The ASP was presented for Designated Review and approval was given on 30 June, 2020.

Three year renewal

June 2020

Title: *Small Molecule TSHR Antagonists in a Mouse Model of Autoimmune Graves' Disease* By: [Redacted by agreement]

[Redacted by agreement] (THREE YEAR RENEWAL)

Comments: [Redacted by agreement] addressed all issues from 15 April, 2020 meeting. The ASP was presented for Designated Review and approval was given on 12 May, 2020.
Final Approval letter sent 06/26/2020.

Initial Submission
June 2020

Tabled Amendment Not Yet Re-Submitted

Deactivation of Animal Study Protocol
June 2020

NIDDK IACUC Meeting Minutes

15 July 2020

- I. Constance T. Noguchi, Ph.D. NIDDK, Chair called the NIDDK IACUC to order at 1:30 P.M. Members attended via WebEx.

Members in attendance:

- ✓ Present Constance T. Noguchi, Ph.D., Chair, NIDDK, Senior Investigator, Molecular Medicine Branch
- ✓ Present Mark B. St. Claire, D.V.M., NIDDK, Animal Program Director
- ✓ Present [Redacted by agreement]
- ✓ Present [Redacted by agreement]
- ✓ Present [Redacted by agreement]
- ✓ Present [Redacted by agreement]
- ✓ Present [Redacted by agreement]
- Present [Redacted by agreement]

Other attendees:

- ✓ Present [Redacted by agreement]
- Present [Redacted by agreement]
- ✓ Present [Redacted by agreement]
- ✓ Present [Redacted by agreement]

Minutes from the 17 June 2020 NIDDK IACUC meeting were distributed. The minutes were unanimously approved.

Addendums from June 2020 NIDDK IACUC meeting were distributed. The addendums were unanimously approved.

II. NIDDK Animal Study Proposal Amendment(s)/Annual Review(s)

Title: *Understanding the Pathogenesis of Nonalcoholic Fatty Liver Disease (NAFLD)* By: [Redacted by agreement]
[Redacted by agreement] Amendment #6

Comments: A fully convened IACUC reviewed the above protocol.

Decision: Following convened deliberation the committee unanimously agreed to approve the amendment.

Title: *Nuclear Receptors and Mammalian Development* By: [Redacted by agreement]
Amendment #3

Comments: A fully convened IACUC reviewed the above protocol.

Decision: Following convened deliberation the committee unanimously agreed to approve the amendment.

(b)(5)

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the amendment to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

III. NIDDK New Animal Study Proposal(s) and Three-Year Renewal(s) Review

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol to the Designated Member Review (DMR) process once the Principal Investigator responds to questions and comments.

(b)(5)

Decision: Following convened deliberation the committee unanimously agreed to send the protocol back to the Principal Investigator for revision and then to come before Full Committee Review (FCR) once the Principal Investigator responds to questions and comments.

IV. **Old Business:**

V. **New Business:**

Updated ARAC guidelines are as follows: As of 07/06/2020

Administrative: None

Animal Care and Use Procedures:

Investigator-Managed, Small-Scale Zebrafish Facilities, 06/24/2020 NEW

Animal Care and Use Committee:

Changes to Animal Study Proposals, 06/24/2020 REVISED

Review and Approval of Animal Study Proposals and Significant Changes, 06/24/2020 REVISED

Facility Management: None

The ASPs to be reviewed for renewal at the August meeting are the following.

None

Next ACUC meeting is scheduled for **Wednesday 19 August 2020** in Redacted by agreement on second floor at 1:30 pm or via WebEx.

The ASPs to be reviewed for renewal at the September meeting are the following.

Redacted by agreement

Next ACUC meeting is scheduled for **Wednesday 16 September 2020** in Redacted by agreement on second floor at 1:30 pm or via WebEx.

There were no minority opinions expressed and the meeting adjourned at 2:30 pm.

Amendment/Annual Reviews NIDDK July-August, 2020

Finalized Amendments & Annual ASPs

Administratively

July 2020

Title: *Central Nervous System G Protein Signaling in Metabolic Regulation* By: [Redacted by agreement]
[Redacted by agreement] Amendment #7

Comments: Amendment #7 modifies the above protocol by removing [Redacted by agreement]
[Redacted by agreement]

Title: *Mouse Models for Erythropoietin Signaling* By: [Redacted by agreement]
Amendment #5

Comments: Amendment #5 modifies the above protocol by adding [Redacted by agreement]

Title: *Protective Activity of Erythropoietin/Erythropoietin Receptor in Progenitor Cells* By: [Redacted by agreement]
[Redacted by agreement] Amendment #6

Comments: Amendment #6 modifies the above protocol by adding [Redacted by agreement]

Title: *Mouse Models for Erythropoietin Signaling* By: [Redacted by agreement]
Amendment #7

Comments: Amendment #7 modifies the above protocol by adding [Redacted by agreement]

Title: *Analysis of G Protein-coupled Receptor Mutant Mice* By: [Redacted by agreement]
Amendment #21

Comments: Amendment #21 modifies the above protocol by adding [Redacted by agreement]

Title: *Mice Transgenic in Genes Expressed in the Gonad* By: [Redacted by agreement]
Amendment #16

Comments: Amendment #16 modifies the above protocol by adding [Redacted by agreement]

Title: *Transgenesis for Investigations of Germ Cell Development and Fertilization* By: [Redacted by agreement]
[Redacted by agreement] Amendment # 8

Comments: Amendment #8 modifies the above protocol by adding [Redacted by agreement]

Title: *Gnas Gene Regulation and Physiological Roles of G Proteins* By: [Redacted by agreement]
[Redacted by agreement] Amendment #3

Comments: Amendment #3 modifies the above protocol by adding [Redacted by agreement]

Title: *Central Nervous System G Protein Signaling in Metabolic Regulation* By: [Redacted by agreement]
[Redacted by agreement] Amendment #8

Comments: Amendment #8 modifies the above protocol by adding [Redacted by agreement]

August 2020

Title: *Mouse Models of Disordered Sphingolipid Metabolism: Characterization and Therapy* By: [Redacted by agreement]
[Redacted by agreement] Amendment #6

Comments: Amendment #6 modifies the above protocol by removing [Redacted by agreement]
and adding [Redacted by agreement]

Title: *Mouse Models of Disordered Sphingolipid Metabolism: Characterization and Therapy* By: [Redacted by agreement]
[Redacted by agreement] Amendment #7

Comments: Amendment #7 modifies the above protocol by removing [Redacted by agreement]
[Redacted by agreement]

Title: *Studies of Adenosine Receptors (A₁ and A₃) and Purinergic Receptors (P2Y₆ and P2Y₁₄) mutant mice*
By: [Redacted by agreement] Amendment #3

Comments: Amendment #3 modifies the above protocol by adding [Redacted by agreement]

Title: *Gnas Gene Regulation and Physiological Roles of G Proteins* By: [Redacted by agreement]
[Redacted by agreement] Amendment #4

Comments: Amendment #4 modifies the above protocol by removing [Redacted by agreement] and adding
[Redacted by agreement]

Title: *Central Nervous System G Protein Signaling in Metabolic Regulation* By: [Redacted by agreement]
[Redacted by agreement] Amendment #9

Comments: Amendment #9 modifies the above protocol by removing [Redacted by agreement] and adding
[Redacted by agreement]

Title: *Unraveling Functional Circuits Modulating Food Intake* By: [Redacted by agreement]
[Redacted by agreement] Amendment #8

Comments: Amendment #8 modifies the above protocol by adding [Redacted by agreement]

VVC

July 2020

Title: *Treatment of Sepsis and Sepsis-induced Acute Kidney Injury* By: [Redacted by agreement]
[Redacted by agreement] Amendment #11

Comments: Amendment #11 modifies the above protocol by adding [Redacted by agreement]
[Redacted by agreement] 2 mouse strains from [Redacted by agreement] (NIDDK) Lad1ko/+;Pkd1cko/+;Cre+ and
Lad1ko/+;Pkd1cko/+;Cre-.

Title: *Gnas Gene Regulation and Physiological Roles of G Proteins* By: [Redacted by agreement]
[Redacted by agreement] Amendment #2

Comments: Amendment #2 modifies the above protocol by removing [Redacted by agreement]
[Redacted by agreement] mouse strain Nu-TRAP from [Redacted by agreement] and 320 mice
to year 2 & 3 each for a total of 640 (Column C), procedure *Cell lineage tracing*.

Title: *Mouse Models for Erythropoietin Signaling* By: [Redacted by agreement]
Amendment #6

Comments: Amendment #6 modifies the above protocol by adding mouse strain B6.129S4-
Gt(ROSA)26Sortm1Sor/J [Redacted by agreement] #003474).

Title: *Nuclear Receptors and Mammalian Development* By: [Redacted by agreement]
Amendment #4

Comments: Amendment #4 modifies the above protocol by adding mouse strains Tyrosinase-CreErT2
from [Redacted by agreement] (NEI).

Title: *Role of Cell Cycle Regulators in Diabetes and Obesity* By: [Redacted by agreement]

[Redacted] Amendment #7

Comments: Amendment #7 modifies the above protocol by adding animal holding location [Redacted by agreement]

August 2020

Title: *NIDDK Rodent Holding and Breeding Protocol* By: [Redacted by agreement]

Amendment #9

Comments: Amendment #9 modifies the above protocol by adding mouse strains; HAS-P2Y6 ko, A1 F/F, WB-P2Y6 ko from K083-LBC-17 and 30 per strain for each year for a total of 270 (Column C).

Title: *Analysis of G Protein-coupled Receptor Mutant Mice* By: [Redacted by agreement]

Amendment #23

Comments: Amendment #23 modifies the above protocol by adding mouse strain Brs3-loxTB from [Redacted by agreement] (NIDDK) and 4 mice to year 2 (Column C).

Title: *Analysis of G Protein-coupled Receptor Mutant Mice* By: [Redacted by agreement]

Amendment #24

Comments: Amendment #24 modifies the above protocol by adding mouse strain Avpr1b-cre/cre from [Redacted by agreement] (NIMH) and 4 mice to year 2 (Column C).

Title: *The Role of the PCBP family of Iron Chaperones in Mice* By: [Redacted by agreement]

[Redacted by agreement] Amendment #1

Comments: Amendment #1 modifies the above protocol by adding mouse strains C57BL6-Rfr1 fl/fl & Stab2-Cre from [Redacted by agreement] and 76 mice for each year for a total of 228 (Column C).

Approved at ACUC Meeting

July 2020

Title: *Nuclear Receptors and Mammalian Development* By: [Redacted by agreement]

Amendment #3

Comments: Amendment #3 modifies the above protocol by adding procedure “Fasting Procedure” for 12-16 hours (overnight).

Title: *Understanding the Pathogenesis of Nonalcoholic Fatty Liver Disease (NAFLD)* By: [Redacted by agreement]

[Redacted by agreement] Amendment #6

Comments: Amendment #6 modifies the above protocol by adding [Redacted by agreement] 176 mice to year 3 (Column C) and procedures Experiment 5 & 6 in Aim 5.

Expedited Review

July 2020

Title: *Role of Cell Cycle Regulators in Diabetes and Obesity* By: [Redacted by agreement]

Amendment #6

Comments: Amendment #6 modifies the above protocol by adding [Redacted by agreement] 6 mouse strains [Cart-IRES2-Cre-D (JAX: 028533); R26^{floxstop-TenT} (MGI:3839913); Fos^{2A-iCreER} (TRAP2) (JAX: 030323); Ai75D (JAX: 025106); Ai96(RCL-GCaMP6s) (C57BL/6J) (JAX: 028866); Gcg^{iCre} (JAX:

030663)], animal procedure location(s) [Redacted by agreement] (surgeries) [Redacted by agreement] Nodose ganglion AAV injections: AAV9 CBA.FLEX-TetTox (RD-13-IV-08 amend 200812, ABSL=1), and 5 chemicals [4-Hydroxytamoxifen, 2-deoxy-D-glucose, Phlorizin, Retrobeads, Fast Green dye].

The ASP was presented to the Full Committee on 30 June, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 16 July, 2020.

Title: *Regulation of Immune Responses to Viral Infection* By: [Redacted by agreement]
17 Amendment #17

Comments: Amendment #17 modifies the above protocol by adding 100 mice to year 3 (Column C) and procedure *Aim 3, Experiment 7b*; sub-therapeutic dose of low-dose penicillin.

The ASP was presented to the Full Committee on 01 July, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 10 July, 2020.

Title: *Regulation of Immune Responses to Viral Infection* By: [Redacted by agreement]
17 Amendment #18

Comments: Amendment #18 modifies the above protocol by adding [Redacted by agreement] Oxytocin and procedure Milking mice.

The ASP was presented to the Full Committee on 22 July, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 29 July, 2020.

Title: *Development of Mouse Model for the Trinucleotide Repeat Expansion Disorders* By: [Redacted by agreement]
[Redacted by agreement] Amendment #6

August 2020

Comments: Amendment #6 modifies the above protocol by removing Inbal Gazy, adding mouse strain FancJ KO (C57BL/6NJ-Brip1^{em1J}/Mmjax) from JAX and procedure *Fresh Stool Collection*.

The ASP was presented to the Full Committee on 27 July, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 11 August, 2020.

Title: *Mice Transgenic in Genes Expressed in the Gonad* By: [Redacted by agreement]
Amendment #17

Comments: Amendment #17 modifies the above protocol by adding PFI3, Chicago blue B dye and E2 Progesterone.

The ASP was presented to the Full Committee on 29 July, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 18 August, 2020.

Title: *Protective Activity of Erythropoietin/Erythropoietin Receptor in Progenitor Cells* By: [Redacted by agreement]

[Redacted by agreement]

Amendment #7

Comments: Amendment #7 modifies the above protocol by adding [Redacted by agreement] animal holding location [Redacted by agreement] procedure location [Redacted by agreement] 24 mice to years 2 & 3 for a total of 48 (Column C), additional 0.5-5% isoflurane dosage and procedure *Ultrasound*.

The ASP was presented to the Full Committee on 31 July, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 11 August, 2020.

Title: *Role of Cell Cycle Regulators in Diabetes and Obesity* By: [Redacted by agreement]

[Redacted] Amendment #8

Comments: Amendment #8 modifies the above protocol by adding 60 mice to year 3 (Column D) for surgical intercranial injection of AAV.

The ASP was presented to the Full Committee on 11 August, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 19 August, 2020.

Title: *Analysis of G Protein-coupled Receptor Mutant Mice* By: [Redacted by agreement]

Amendment #22

Comments: Amendment #22 modifies the above protocol by adding procedures for treatment of mice with V1b vasopressin receptor (V1bR) and bombesin 3 receptor (BB3R) agonists {d[Leu4,Lys8]-VP & MK5046} and 32 mice to year 3 (Column C).

The ASP was presented to the Full Committee on 12 August, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 25 August, 2020.

Title: *Mouse Models of Disordered Sphingolipid Metabolism: Characterization and Therapy* By: [Redacted by agreement]

[Redacted by agreement]

Amendment #8

Comments: Amendment #8 modifies the above protocol by adding mouse strain Hexa269/Neu3, modifying the study objectives to include newly developed base editors for point mutations *in vivo*, “*Intracerebroventricular AAV9 injection of neonatal mice for base editing*” procedure, transferring 90 mice from Column C to Column D, hypothermia anesthesia, AAV9 PRD# 8019 and RD-20-VIII-04 (ABSL-1).

The ASP was presented to the Full Committee on 17 August, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 25 August, 2020.

Title: *Effect of Environment, Nutrients and Pharmacologic Agents on Mouse Energy Homeostasis and Body Temperature* By: [Redacted by agreement] Amendment #1

Comments: Amendment #1 modifies the above protocol by adding 2 Aldj1a1 inhibitor drugs (NCGC00386123, NCATS novel compound), 48 mice per year totaling 144 (Column C) and 2 procedures (*Part 35. Effect of novel ALDH1A1 inhibitors on energy and glucose homeostasis. & Part 36. Single housing of male and female mice.*)

The ASP was presented to the Full Committee on 19 August, 2020 via email and was unanimously approved for Designated Review without a fully convened committee review requested. The ASP was presented for Designated Review after comments from the ACUC committee were addressed and approval was given on 28 August, 2020.

Annual Reviews

Title: *Training Protocol for NIDDK Investigators* By: [Redacted by agreement]

Title: *Role of Cell Cycle Regulators in Diabetes and Obesity* By: [Redacted by agreement]

Title: *Mice Transgenic in Genes Expressed in the Gonad* By: [Redacted by agreement]

Title: *Regulation of the Development of the Small Intestine and Study of Neuroendocrine Tumorigenesis* By: [Redacted by agreement]

Title: *Central Nervous System G Protein Signaling in Metabolic Regulation* By: [Redacted by agreement]

[Redacted by agreement]

Finalized ASPs & Three Year Renewals

Designated Review

July 2020

Title: *Potential Antineoplastic Effects of Small Molecule TSHR Ligands in a Mouse model of Thyroid Cancer* By: [Redacted by agreement] Amendment #1

Comments: Amendment #1 modifies the above protocol by adding [Redacted by agreement], blood draws for evaluating cancer biomarkers, use of suture for wound closure, use of a BSC for injection of cells and tumor grafts, CO2 as a method of euthanasia and updated the [Redacted by agreement] facility manager to [Redacted by agreement] [Redacted by agreement] addressed all issues from 15 July, 2020 meeting. The ASP was presented for Designated Review and approval was given on 28 July, 2020.

Three year renewal

July 2020

Title: *Fat soluble Vitamins Supplementation to Prevent Non-Alcoholic Fatty Liver (NAFLD) and/or Nonalcoholic Steatohepatitis (NASH)* By: [Redacted by agreement] **(THREE YEAR RENEWAL)**

Comments: [Redacted by agreement] addressed all issues from 20 May, 2020 meeting. The ASP was presented for Designated Review and approval was given on 14 June, 2020.

Final Approval letter sent 07/14/2020.

Title: Mechanisms of *alpha-Synuclein Intercellular Transmission* By: [Redacted by agreement]

Redacted (THREE YEAR RENEWAL)

Comments: [Redacted by agreement] addressed all issues from 20 May, 2020 meeting. The ASP was presented for Designated Review and approval was given on 09 July, 2020.

Final Approval letter sent 08/14/2020.

Title: *Effect of Environment, Nutrients and Pharmacologic Agents on Mouse Energy Homeostasis and Body Temperature* By: [Redacted by agreement]

(THREE YEAR RENEWAL)

Comments: [Redacted by agreement] addressed all issues from 17 June, 2020 meeting. The ASP was presented for Designated Review and approval was given on 28 July, 2020.

Final Approval letter sent 08/19/2020.

Initial Submission

July 2020

Tabled Amendment Not Yet Re-Submitted

Deactivation of Animal Study Protocol

July 2020