

NASA Institutional Animal Care and Use Committee

Meeting Minutes

5 June 2019

CONFIDENTIAL

MEMBERS PRESENT (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

SC: (b) (7)(F)

LifeSource (b) (7)(F)

LifeSource (b) (7)(F)

Community Member

DL: (b) (7)(F)

MEMBERS ABSENT

(b) (6), (b) (7)(C), (b) (7)(F)

SLR: (b) (7)(F)

GUESTS PRESENT

(b) (6), (b) (7)(C), (b) (7)(F)

DL: (b) (7)(F)

Meeting started at 9:11AM with a quorum present.

AGENDA

I. Old Business

- a. Next SemiAnnual Inspection 11 September 2019.

II. New Business

- a. The Chair indicated that the NASA Animal Policy Review Board (APRB) was tentatively planned to be held at Ames the 3rd week of September.
- b. Master Protocol Update: no work performed since the last meeting.
- c. Veterinary Update- a review of animals currently in-house and studies in progress was presented.
- d. DMR since last meeting:
 - (b) (4) new protocol reviewed via DMR was approved 20 May 2019.
 - (b) (4) protocol renewal reviewed at the April meeting was approved 24 May 2019.
 - (b) (4) amendment to add personnel was approved 22 May 2019.
 - (b) (4) amendment to add animals and personnel was approved 23 May 2019.
 - (b) (4) amendment to add a procedure and personnel was approved 31 May 2019.
 - (b) (4) protocol renewal reviewed at the May meeting was approved 31 May 2019.
 - NAS-19-001-Y1- new protocol reviewed at the April meeting was approved 31 May 2019.
 - NAS-19-001-Y1- amendment to change procedure was approved 31 May 2019.

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- (b) (4) amendment to add animals, procedures, and personnel was approved 3 June 2019.

III. Protocol/ Amendment Review

(b) (4)

- The following questions/ comments/ edits were presented from committee:
- Section 7- provide rationale for the request of extra animals.
- Section 8- arrange details into a narrative description of everything that will happen with the animals from arrival at the facility to euthanasia; provide maximum duration of study and endpoints; describe euthanasia.
- Section 9- there is no surgery, clear section answers.
- Section 14- add Isoflurane and antibodies to table.
- The ethical reviewer had no additional comments.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

- The following questions/ comments/ edits were presented from committee:
- Section 3- elaborate on progress made over the last year.
- Section 7- provide justification for all strains requested.
- Section 8- arrange details into a narrative description of everything that will happen with the animals from arrival at the facility to euthanasia; provide maximum duration of study and endpoints; need to add description of PK studies.
- The ethical reviewer had no additional comments.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

Meeting adjourned at 10:10AM. Submitted by IACUC Administrator.

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Meeting Minutes

14 August 2019

CONFIDENTIAL

MEMBERS PRESENT (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

SC: (b) (7)(F)

LifeSource (b) (7)(F)

Community Member

SLR: (b) (7)(F)

DL: (b) (7)(F)

MEMBERS ABSENT

(b) (6), (b) (7)(C), (b) (7)(F)

LifeSource (b) (7)(F)

GUESTS PRESENT

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

DL: (b) (7)(F)

Prospective Community Member

Meeting started at 9:10AM with a quorum present. The PI for the LifeSource protocols was not counted toward the quorum during review of their protocols.

AGENDA

I. Old Business

- a. Next SemiAnnual Inspection: 11 September 2019.

II. New Business

- a. Chair's Comments

- The Chair announced that the current Community Member is stepping down and introduced a prospective Community Member who attended part of the meeting via conference call. The prospective Community Member introduced himself and the rest of the committee members introduced themselves as well.
- The Chair indicated that the NASA Animal Policy Review Board (APRB) will be held at Ames the 3rd week of September.
- The Chair informed the committee that a Freedom of Information Act information request was received which requested the annual assurance documents and annual report.
- The Chair reported that the (b) (7)(F) will be opening sometime in the fall of 2019, and some Principal Investigators will move to that building which may make it part of the semi-annual review, depending on what activities are planned there.

- b. Master Protocol Update: no work performed since the last meeting.

- c. Veterinary Update- a review of animals currently in-house and studies in progress was presented.

- d. DMR since last meeting:

- (b) (4) amendment to add personnel was approved 3 July 2019.

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- (b) (4) amendment to add a procedure was approved 15 July 2019.
 - NAS-13-004-Y6- protocol renewal was approved 6 August 2019.
 - NAS-19-004-Y1- protocol was approved 6 August 2019.
 - (b) (4) protocol was approved 6 August 2019.
- e. Vote was taken to approve previous meeting minutes

III. Protocol/ Amendment Review

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 3- Clarify the species and the number of rodents used and the number of PIs the protocol supported during the last year
- Section 4A- Remove NHP, add if necessary via amendment
- Section 7: Remove NHP
- The ethical reviewer had no additional comments

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- The ethical reviewer had no additional comments.

This protocol was approved with minor grammatical corrections.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 4A- Remove NHP, add if necessary via amendment.
- Section 7: Remove NHP
- Section 14G: Change - Skin closures may not be removed in these animals
- A general discussion was held on how training would be assessed and it was recommended that this be added to the protocol
- The ethical reviewer had no additional comments.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 4A: Remove NHP
- Section 7A: A committee member asked if it was possible to reduce the number of mice used, remove NHP
- Section 7B: Reword the statistical data and include verbiage that the client's formula will be used

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- Section 7C: Add verbiage on skin closure in cannulated animals
- Section 8: Add that water will be given ad libitum
- Section 9B: Add formulary information
- The ethical reviewer had no additional comments.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 4A: Remove NHP
- Section 7A: Remove NHP
- Section 8: Add that restraint will be “non-prolonged”
- Section 9B: Add formulary information
- Section 9C: The Chair asked if water would be provided ad libitum for all species, confirmed by PI
- The ethical reviewer had no additional comments.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 4A: Remove NHP
- Section 7A: Remove NHP
- Section 8: Adjust maximum duration of study to be consistent throughout section (three months)
- Section 8: discussion on Category D versus E, it was decided to keep the protocol as a Category D and Category E studies can be added by amendment, suggested that 4th bullet point be deleted
- The ethical reviewer mentioned that the numbering of the protocol seems to be different from newest version, correct.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 7B: Add verbiage regarding how and who will determine statistical data, clarify animal numbers
- Section 8: Add information regarding weight loss and euthanasia, clarify blood draw information
- Section 14: Should the novel compound be added to the table?
- The ethical reviewer did not receive the protocol in time to conduct the ethical review.

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This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 7A: Clarify the use of both strains
- Section 7B: Correct numbers for subcutaneous implantation
- Section 8: Add body condition scoring information
- Section 10: Add loss of body condition information, explain why moribund animals must wait 48 hours vs. 24 hours for euthanasia
- Section 14: Add verbiage similar to that section in IVT-19-001-Y1
- The ethical reviewer did not receive the protocol in time to conduct the ethical review.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 6: Explain why a larger than standard volume injection is necessary
- Section 7B: Add verbiage on statistical data – how and who will determine?
- Section 8: Clarify if blood volumes adhere to the guidelines and explain if not
- Section 10: Do animals have to wait a full hour for euthanasia after injection if they do not return to normal? Could it be 45 minutes?
- The ethical reviewer did not receive the protocol in time to conduct the ethical review.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4)

The following questions/ comments/ edits were presented from committee:

- Section 4B: Is this actually a Pilot Study?
- Section 6: When was the LifeSource pilot study protocol used?
- Section 7B: Clarify the animal numbers
- Section 8: How many treatments will each animal receive? What treatment(s) exactly will each receive? Will each treatment be laser or biopsy or both? Will there be sequential wounds and treatments? Explain how wounds will be created. What are the test treatment dressings? What kind of analgesia is provided to human patients and can the animals receive the same? Clarify the number of treatment sites per animal and if the site will be used during the entire study? What is the criteria for not

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continuing the full wound/treatment course on an animal? Is the word “compound” used to mean multiple treatments or test substance? Clarify what kind of data can be captured from such a small wound as compared to a large wound on a human patient. Will the animals euthanized at 24 hours be used as baseline/control animals?

- Section 9A: Remove personnel information and move to Section 18
- The ethical reviewer did not receive the protocol in time to conduct the ethical review..

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

Meeting adjourned at 12:05 PM. Submitted by IACUC Administrator.

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11 September 2019

CONFIDENTIAL

MEMBERS PRESENT (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)
(b) (6), (b) (7)(C), (b) (7)(F)
(b) (6), (b) (7)(C), (b) (7)(F)
(b) (6), (b) (7)(C), (b) (7)(F)
(b) (6), (b) (7)(C), (b) (7)(F)

SC: (b) (7)(F)
LifeSource (b) (7)(F)
Community Member
SLR: (b) (7)(F)
DL: (b) (7)(F)

ALSO PRESENT (Non-Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

Administrator

GUESTS PRESENT

(b) (6), (b) (7)(C), (b) (7)(F)

DL: (b) (7)(F)

Meeting started at 9:30AM with a quorum present.

AGENDA

I. Old Business

- a. Next SemiAnnual Inspection: 11 March 2020.
- b. Meeting Minutes: 11 August 2019 meeting minutes were discussed and unanimously approved pending minor changes.

II. New Business

I. Chair's Comments

- The Chair announced that the NASA Animal Policy Review Board (APRB) meeting will be held on site on September 18 and 19. All committee members were invited to attend.
- The Chair reviewed that a recently approved protocol (NAS-19-004-Y1) will include work conducted on the centrifuge. It was not ready for inspection during the SemiAnnual review, but it will be inspected by members of the committee prior to any work being conducted on the protocol. The NASA Rodent Operations in the (b) (7)(F) SOP was sent to committee members prior to the meeting and reviewed during the meeting. The committee listed several additions and assurance that need to be made. When these changes are made, the document should be resubmitted to the committee for review.
 - A daily health checklist should be attached to the SOP.
 - The PI needs to confirm that the EKG tests listed in the SOP are the same as those in the protocol.
 - Does the PI understand the impact of transportation on the EKG results?
 - PI needs to clarify where the EKG tests will be conducted.

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- Appropriate training must be completed and documented by all personnel working under the protocol.
 - All personnel listed on the SOP must also be listed on the protocol.
 - The Chair announced that there is a new IO, (b) (6), (b) (7)(C), (b) (7)(F) He will replace (b) (6), (b) (7)(C), (b) (7)(F) who has retired (b) (6), (b) (7)(C), (b) (7)(F) will be invited to the APRB meeting and the IACUC meeting(s).
 - The Chair discussed that NASA is undergoing MAP, which is aimed at finding efficiencies in certain agency functions. This should not impact the IACUC.
- II. Master Protocol Update: no work performed since the last meeting.
- III. Veterinary Update- a review of animals currently in-house and studies in progress was presented.
- IV. DMR since last meeting:
- (b) (4) amendment to add personnel was approved 16 August 2019.
 - NAS-13-004-Y6 - amendment to change a procedure was approved 22 August 2019.
 - (b) (4) - protocol renewal was approved 30 August 2019.
 - (b) (4) - protocol renewal was approved 30 August 2019.
 - (b) (4) - protocol renewal was approved 30 August 2019.
 - (b) (4) - protocol renewal was approved 30 August 2019.
 - (b) (4) - protocol renewal was approved 30 August 2019.
 - (b) (4) - protocol renewal was approved 9 September 2019.
 - (b) (4) - protocol renewal was approved 10 September 2019.
- V. IACUC Member Training:
- (b) (6), (b) (7)(C), (b) (7)(F) discussed the upcoming changes to the AVMA Guidelines for euthanasia.

III. Protocol/ Amendment Review

NAS-19-005-Y1

The following questions/ comments/ edits were presented from committee:

- An overview of the entire four study should be included, but the protocol should focus on year one and should only include specifics related to those studies
- Section 7B: Adjust animal numbers to reflect only those needed for year one.
- Section 7C: Clarify if daily handling is to acclimate animals to handling or reduce aggression.
- Section 8:
 - While focusing on the first year of studies, add more detail regarding how and when single or multiple dosing will occur.
 - Are animals irradiated with or without HU?
 - Site source for age matching and explain calculation method

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- Add more detailed explanation to Experiment 1, including acclimation period, dosing, and number of exposures.
- Explain social hind limb unloading in more detail.
- Will retinal orbital bleeds be done under anesthesia, what is the volume and number of bleeds?
- Add timeline for studies.
- Explain why animals will be handled daily if daily handling causes undue stress
- Section 9: Remove Experiment 4 if it will not occur in year one
- Section 9C: Explain why food is withheld prior to surgery. Will water also be withheld? Why?
- Section 9E: Give detail about the datalogger or remove if this study will not occur in year one.
- Section 10: Add more study detail to Section 8 and address pain and distress in this section.
- The ethical reviewer had no addition issues beyond those listed above.

This protocol was not approved and will return to the full IACUC with revisions for review.

(b) (4)

This protocol was withdrawn, and the proposed study will be done under the
(b) (4)

NAS-15-007-Y5

The following questions/ comments/ edits were presented from committee:

- An investigator who is on site must be added at the Responsible Point of Contact for this protocol because the PI has moved and does not currently perform work on site at Ames.
- Section 3D: Remove portion of progress report that is not new and include information on studies listed in last year's protocol that are no longer listed in the proposed studies.
- Section 4A: "Check" box for Prolonged Restraint
- Section 7B: Correct animal numbers in explanation, add animal numbers for HU experiments and pregnant animals.
- Section 7C: List special care provided for HU.
- Section 8:
 - Account for missing Experiment 2 in explanation and Experiment 3 in table, adjust explanation to match the table of experiments
 - Correct animal numbers for experiments that use both male and female animals; add more animals in the text/table if necessary
 - Add Experiment 5.3 and 5.4 to the explanation
 - Phase 2: Correct animal numbers to match the table
 - Add Mechanical Loading animal numbers to the table

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- Remove redundant information for HU verbiage
- Add embryonic animals to the animal numbers
- Section 10: Discuss pain and distress for HU
- Section 12A:
 - Reduction: Text states that “several” means are used to reduce numbers, but only two are given
 - Refinement: Address HU
- Section 18: Remove “reviewer comments” from last year’s protocol
- Category E Explanation Form: Address HU in addition to “pain” in the verbiage
- The ethical reviewer agreed that the animal numbers need to be adjusted, but had no other comments.

This protocol was not approved and will return to the full IACUC with revisions for review.

IV. SemiAnnual Program Review and Inspection

(b) (6), (b) (7)(C), (b) (7)(F) SemiAnnual Program Review and Inspection was performed. (b) (6), (b) (7)(C), (b) (7)(F)
(b) (6), (b) (7)(C), (b) (7)(F) left prior to the review and inspection and did not participate in this portion of the meeting.

The next IACUC meeting will be held on October 9, 2019.

Meeting adjourned at 12:05 PM.

Submitted by IACUC Administrator.

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Meeting Minutes

9 October 2019

CONFIDENTIAL

MEMBERS PRESENT (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

SC: (b) (7)(F)

LifeSource (b) (7)(F)

Community Member (Call)

SLR: (b) (7)(F)

DL: (b) (7)(F)

Administrator

GUESTS PRESENT

(b) (6), (b) (7)(C), (b) (7)(F)

DL (b) (7)(F)

Meeting started at 9:06AM with a quorum present.

AGENDA

I. Old Business

a. Next SemiAnnual Inspection: 11 March 2020.

b. (b) (4)

(b) (4) The plan was reviewed, and the committee suggested a bit more detail be added, using the (b) (4) program as a guideline.

c. Rodents in the (b) (7)(F) SOP was briefly discussed. The PI on the associated protocol (NAS-19-004-Y1) was notified that the SOP had been reviewed by the committee and the committee has no further issues. The study has begun in the centrifuge.

d. Meeting Minutes: Approval of the September meeting minutes was deferred until the November meeting.

II. New Business

I. Chair's Comments

- The Chair requested the annual review is made available for all members to review when it is completed.
- The Chair reported that she had invited the new IO to attend this meeting.
- The Chair reported that an Animal Policy Review Board (APRB) meeting was held in September. Revision of the NASA Policy Requirements (NPR) was discussed, and a possible, new protocol template was presented. The Chair is reviewing this new version and comparing it to existing template for further discussion/refinement.
- The Chair discussed the possible retirement of (b) (6), (b) (7)(C), (b) (7)(F) which would necessitate amendments to add her replacement on her protocols.
- The Chair discussed the proper procedure (DMR) for review/approval of all study design outlines that are submitted under the (b) (4)

II. Master Protocol Update:

- (b) (4) was approved via DMR and will begin soon.

III. Veterinary Update- a review of animals currently in-house and studies in progress was presented.

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- The Chair requested that (b) (4) Manager's training of Investigator at the centrifuge be documented as (b) (4)

IV. DMR since last meeting:

- NAS-15-008-Y5: Renewal Protocol Approved on 9/12/19
- (b) (4) New Protocol reviewed at August meeting was approved on 9/12/19
- (b) (4) Amendment to add new personnel was approved administratively on 9/23/19
- (c) (4) approved on 10/2/19
- (b) (4) Amendment for add new personnel was approved administratively on 10/3/19

V. IACUC Member Training:

The Chair asked the committee members to view the OLAW webinar on Emergency Depopulation Using AVMA Guidelines. Documentation should be sent to IACUC Administrator for recording.

III. **Protocol/ Amendment Review**

NAS-19-005-Y1 – Second Review

The following questions/ comments/ edits were presented from committee:

- Section 6:
 - Explain antioxidant use
 - Move study details to Section 8
- Section 7A: Explain why the two strains of mice must be used
- Section 7B: Move animal number tables to this section
- Section 7C:
 - Clarify duration of irradiation
 - Explain methods for temperature controls of individually housed animals
- Section 8:
 - Create two separate timelines for Study 1 and 2
 - Add more information on and description of retro-orbital bleeds
 - Clarify duration of testing in both studies
 - Give more detail regarding the light-dark box
 - Elaborate on the exact test environment – home cage or other
 - List specific post IR tests
 - Clarify if all animals are subject to all tests
 - Explain the specifics of the “stranger mouse”
 - Discuss whether animals in the sociability test are able to contact each other
- Section 10:
 - Isoflurane Drop Method is not acceptable, revise to another method
 - Explain how will rectal thermometers be provided
 - List the criteria for euthanasia during/after irradiation
 - Include discussion of any other tests that could cause pain or distress
- Section 11: Ethical reviewer questioned if the extensive behavioral testing in addition to individual housing would be enough to change the protocol to Category E.
- Section 12:

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- Refinement: Address irradiation and any other test that might be painful or stressful
- Section 15: Confirm approved irradiation protocol is in place
- Section 18: For each person listed, add his/her specific role and experience that is related to this protocol. Also correct any mislabeling of participants.
- Ethical Reviewer questioned animal numbers and the correct category for the protocol as mentioned above.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4) Amendment to Add New Procedure and Animal Strains

The following questions/ comments/ edits were presented from committee:

- Section 3: Explain ascites protocol in lay terms.
- Section 5:
 - Explain why Pristane will be used versus another adjuvant and address any safety issues
 - Clarify the source of the retired mice to be used
 - Discuss how requested rats will be used
- Section 6:
 - Discuss whether ascites production will cause pain/distress
 - List humane endpoints
 - Explain how animals will be monitored
 - Clarify whether the new procedure changes the pain classification of the original protocol
- Section 7b: Explain why specific strains are used for hybridoma generation
- Section 7c: List new numbers of animal requested and new total number
- Section 7d: Clarify how candidates (compounds?) will be administered
- Ethical Reviewer questioned the clarity of the last sentence in Section 6 answer.

This amendment was not approved and will return to the IACUC office with revisions for review and approval via DMR.

The next IACUC meeting will be held on November 13, 2019.

Meeting adjourned at 10:40 AM.

Submitted by IACUC Administrator.

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15 January 2020

CONFIDENTIAL

MEMBERS PRESENT (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

SC: (b) (7)(F)

DL: (b) (7)(F)

Administrator

MEMBERS PRESENT VIA PHONE CONFERENCE (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

LifeSource (b) (7)(F)

Community Member

SLR: (b) (7)(F)

LifeSource (b) (7)(F)

GUESTS PRESENT

(b) (6), (b) (7)(C), (b) (7)(F)

DL: (b) (7)(F)

Meeting started at 9:12 AM with a quorum present.

AGENDA

I. Old Business

A. Next Semi-Annual Inspection: 11 March 2020.

B. September 2019 Semi-Annual Review: The SAR documents will be adjusted with the Chair's suggestions and transferred to the most updated template for resubmission to the IO.

C. (b) (4)

(b) (4) Several members were unable to review the plan prior to the meeting. The Chair's comments were reviewed, and the committee will review the revised plan at the next IACUC meeting.

D. Meeting Minutes: Both the September 2019 and October 2019 minutes were approved with minor amendments.

II. New Business

A. Chair's Comments

- The Chair reported that she had invited the IO to attend this meeting and the Semi-Annual Review in March.
- The Chair reported that an ad hoc subcommittee of the Animal Policy Review Board (APRB) reviewed and revised the NASA Policy Requirement (NPR). A draft of the revised NPR will be shared with the IACUC for comment when available. During the same meeting the best way to make sure that IACUC minutes are available to the Chief Veterinary Officer was discussed.
- The Chair reported that annual Animal Welfare Assurance document was submitted to OLAW (Office of Laboratory Animal Welfare) in December. No comments have been received as yet. Once approved, the document will be sent to the committee.

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- The Chair noted that the Animal Welfare Assurance document states that the IACUC meeting minutes will be distributed to the IO.
- The LifeSource Director of Operations reported that the AAALAC International annual report was submitted on January 14, 2020. The Chair requested a copy of the report for review at the February meeting. The Chair also requested that the IO receive a final copy, as required by the Assurance document.
- The Chair discussed the due dates for the annual reports that will be submitted to OLAW (Office of Laboratory Animal Welfare), USDA (United States Department of Agriculture), and AAALAC International.

B. Veterinary Update: A review of animals currently in-house and studies in progress was presented.

C. Master Protocol Update: No studies were performed on these protocols since last meeting as reported by the LifeSource Director of Operations

D. DMR and Administrative Approvals since last meeting:

- NAS-19-004-Y1: Amendment to add new personnel and study change was approved administratively on 10/18/19
- (b) (4) New protocol that was reviewed at the August 2019 meeting was approved via DMR on 10/21/19
- NAS-19-005-Y1: New protocol that was reviewed at the September and October meetings was approved via DMR on 11/8/19
- (b) (4) Amendment to add personnel was approved administratively on 11/14/19
- NAS-15-007-Y4: Renewal protocol that was reviewed at the September 2019 meeting was approved via DMR on 11/14/19
- (b) (4) Amendment to add new personnel and a new drug was approved administratively on 11/26/19
- (b) (4) Amendment to add new personnel was approved administratively on 12/2/19
- NAS-19-005-Y1: Amendment to add new personnel was approved administratively on 12/11/19
- (b) (4) Amendment to add a new species, new strain, and new procedure (DMR was approved at the October 2019 meeting) was approved via DMR on 12/11/19
- (b) (4) Amendment to add new personnel was approved administratively on 12/11/19
- (b) (4) Renewal protocol was approved via DMR on 12/18/19
- (b) (4) Amendment to add a new strain was approved via DMR on 12/23/19
- (b) (4) Amendment to add new personnel was approved administratively on 1/3/20

E. IACUC Member Training:

- The Chair reminded committee members to view the OLAW webinar on Emergency Depopulation Using AVMA Guidelines. The link will be emailed

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to all members, and documentation should be sent to IACUC Administrator for recording.

- The Chair provided a handout of the OLAW Guidance LabAnimal January 20, 2020 article, and committee discussed the role of the IACUC and authorities of the Attending Veterinarian in animal pain management. Members who attended the meeting via phone conference will be emailed the articles for review.
- Members were emailed a list of upcoming ICARE IACUC Training Seminars prior to the meeting which was reviewed.

F. 2020 IACUC Calendar: The November 2020 meeting was moved to November 18, 2020 to avoid a national holiday.

III. Protocol/ Amendment Review

NAS-16-007-Y4 – Renewal Protocol

The following questions/ comments/ edits were presented from committee:

- Section 3D: Clarify if any animals were transferred to other protocols
- Section 4C: An additional grant has been added to this year's protocol. Confirm that no additional animal numbers will be requested at this point to accommodate the second grant.
- Section 6: Minor verbiage changes are suggested for clarification.
- Section 7C: Explain why pregnant mice must be housed individually.
- Section 8:
 - Could ear punch tissue be used for genotyping, eliminating the need for tail snips?
 - Verbiage under the "Transfer Mice to Other Protocols" section does not relate to this topic. Remove or clarify.
- Section 10: Address pain and distress of tail snips if they will be used.
- Section 12A – Refinement: Explain how individually housing social animals will reduce stress.
- Section 18: (b) (6), (b) (7)(C), (b) (7)(F)
 - Explain (b) (6), (b) (7)(C), (b) (7)(F) role on this protocol since she will be retiring.
 - Remove experience that does not pertain to this protocol and list the specific duties under this protocol for each person listed in the table.
- The Ethical Reviewer had no additional comments and provided his comments for circulation among the other members via email from the Administrator.

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

The next IACUC meeting will be held on February 12, 2020.

Meeting adjourned at 10:17 AM.

Submitted by IACUC Administrator.

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MEMBERS PRESENT (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

(b) (6), (b) (7)(C), (b) (7)(F)

SC: (b) (7)(F)

LifeSource (b) (7)(F)

LifeSource (b) (7)(F)

DL: (b) (7)(F)

Administrator

MEMBERS PRESENT VIA PHONE CONFERENCE (Voting)

(b) (6), (b) (7)(C), (b) (7)(F)

Community Member

MEMBERS ABSENT

(b) (6), (b) (7)(C), (b) (7)(F)

SLR: (b) (7)(F)

GUESTS PRESENT

None

Meeting started at 9:05 AM with a quorum present.

AGENDA

I. Old Business

A. Next Semi-Annual Inspection: 11 March 2020

- All PI's will be notified of inspection date via email and asked to list the rooms/areas that are currently in use on their approved protocols to be sure all areas are inspected.
- Deficiencies from the September 2019 semi-annual facility inspection will be reviewed.

B. (b) (4)

(b) (4) The plan and some minor changes were discussed. The plan was approved pending the adjustments.

C. Meeting Minutes: The January Meeting Minutes were approved.

II. New Business

A. Chair's Comments

- The Chair reported that she had invited the IO to attend this meeting and the Semi-Annual Review in March.
- The Chair reported that the ad hoc subcommittee of the Animal Policy Review Board (APRB) has not yet released a revised draft of the NASA Policy Requirement (NPR).
- The Chair stated that the annual report was submitted to OLAW and some questions were sent back. They were discussed, and the Attending Veterinarian offered clarification.

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B. Veterinary Update: A review of animals currently in-house and studies in progress was presented.

C. Master Protocol Update:

- (b) (4)

D. DMR and Administrative Approvals since last meeting:

- NAS-19-005-Y1: Amendment to add a new study location was approved via DMR on 1-23-20.

E. IACUC Member Training:

- (b) (6), (b) (7)(C), (b) (7)(F) discussed the new AVMA Euthanasia Guidelines, listing the new additions/changes to this version and highlighting those that are pertinent to our program
- Clarification of the distinction between sedation and anesthesia
 - Change in guidelines for the use of CO2 in rodents
 - The committee discussed some important updates that need to be made to the program
 - Adjusting the wording of protocols to reflect new guidelines
 - Update IACUC Guidelines on Euthanasia
 - Update printed euthanasia instructions that are used for training
 - Ensure that the NASA Ames Research Center Vivarium Emergency Response Plan adheres to the new guidelines

F. IACUC Guideline Review

1. Policy on Protocol Submission and Review Process
 - The policy was discussed and some minor adjustments were suggested. The policy was approved pending the adjustments.
2. Guideline for Reporting Animal Care and Use Concerns
 - The policy was discussed, and the Chair offered some examples of other institution's policy. The Administrator will create a new draft that incorporates the committee's suggestion, and that version will be reviewed at the April meeting.

III. Protocol/ Amendment Review

(b) (4) Renewal Protocol

The following questions/ comments/ edits were presented by the committee:

- Section 4C: Answer "no" if no federal funding currently exists
- Section 7B: Define acronyms with first use in text
- Section 7C: Add "housing" to list of items to be autoclaved
- Section 8:
 - Add blood collection details
 - Add body conditioning score information
 - Clearly define humane endpoints

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- Add information on irradiation dose levels
 - Explain what will happen to mice that experience prolonged radiation sickness
- Section 9E: Explain scientific justification for not using the less invasive technique mentioned for the Orthotopic Pancreatic Tumor Model
- Section 10: Add verbiage stating that the NASA Humane Endpoints Guidelines will be followed.
- Category E Form: Discuss humane endpoints as requested by the Ethical Reviewer

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4) – Renewal Protocol

The following questions/ comments/ edits were presented by the committee:

- Section 7A: Include more detail on specific reasons mice will be used in this research
- Section 7B: Add further explanation of USDA requirements and confirm if the animal numbers will be increased to increase statistical power
- Section 8:
 - Explain calculation used to arrive at the number of 20 animals for the experiment set
 - Add body condition score information
 - Add administration route for fluid replacement
- Section 9: Remove information about procedures that are not actually surgical procedures and add to Section 8
- Section 10:
 - List and address any additional adverse events that may occur as animals reach the endpoints
 - Include any specific special monitoring that may be needed
 - Add verbiage stating that studies will adhere to the NASA Guidelines on Humane Endpoints
- Ethical Reviewer asked for additional information regarding justification of species and animal numbers as noted above

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR.

(b) (4) – Renewal Protocol

The following questions/ comments/ edits were presented by the committee:

- Section 3D: Add more detail on what was learned/accomplished from previous studies and why the studies need to continue in the progress report
- Section 7: Add animal number total row to the table
- Section 7A: Provide any known traits for the modified animals to be used that should be watched for during the study (e.g., excessive grooming leading to skin lesions).
- Section 7B:

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- Remove repetitive verbiage from paragraphs subsequent to first paragraph
 - Confirm if 30% is actually a failure or success rate
- Section 7C:
 - Add scientific rationale for individual housing after surgery
 - Explain reason for mentioning other institutions
 - Add more detail regarding how food will be provided in the modified cages. How often will it be changed? Will it be in a container?
 - Add verbiage regarding the addition of antibiotics to water
- Section 8:
 - Confirm whether animals in first paragraph are included in the animal numbers
 - Explain what happens to animals in which the microscopes have to be removed
 - Add information regarding the effects of LPS administration
 - Add information regarding the effects of maternal immune activation on dams and neonates
 - Confirm that animals to be shipped to offsite facilities are included in the requested animal numbers
 - Provide scientific justification for individually housing pregnant mice
- Section 9E: List any adverse outcomes that may occur
- Section 10: List any possible negative behaviors that may be seen in the modified strains
- Section 12B: List specific reasons that live animals must be used
- Section 14: List any biological materials to be used
- Section 18: List specific procedures each individual will perform
- Ethical Reviewer asked for a more specific explanation of why live animals must be used in Section 12B as noted above

This protocol was not approved and will return to the IACUC office with revisions for review and approval via DMR

IV. Final Comments

- The ethical/non-scientist committee member will be retiring in August. A replacement and alternate ethical/non-scientist committee member has been chosen.

The next IACUC meeting and semi-annual program review and inspection will be held on March 11, 2020.

Meeting adjourned at 11:05 AM.

Submitted by IACUC Administrator.