

NATIONAL INSTITUTES OF HEALTH  
NATIONAL CANCER INSTITUTE

Redacted by agreement.

Frederick, Maryland 21702-1201  
National Cancer Institute at Frederick

## MEMORANDUM

February 26, 2020

TO: Distribution

Redacted by agreement.

Through: Melinda Hollingshead, DVM, PhD  
Chair, NCI at Frederick Animal Care and Use Committee

FROM: Redacted by agreement.

NCI at Frederick Animal Care and Use Committee

SUBJECT: Minutes of the February 20, 2020, NCI at Frederick Animal Care and Use Committee Meeting

The meeting of the NCI at Frederick Animal Care and Use Committee [ACUC] was called to order at 10:03 a.m. on Thursday, February 20, 2020, by Dr. Melinda Hollingshead. Those in attendance were:

Redacted by agreement.

Redacted by agreement.

Dr. Jatinder Gulani, Dr. Melinda Hollingshead,

Redacted by agreement.

Not present:

Redacted by agreement.

1. The minutes of the January 16, 2020, meeting were unanimously approved as written. **Motion: Approved as written. Vote: 8 in favor and no minority opinions expressed.**
2. Redacted by agreement. was introduced as the LASP representative.
3. Dr. Sara Hook was introduced as the Institutional Official.
4. The following annual review statements were reported to the ACUC:

Redacted by agreement.

5. All issues were resolved for proposals designated as approved/pending or deferred at previous ACUC meetings unless indicated below:

Redacted by agreement.

Pending IBC  
Pending MTBM  
Pending IBC

6. The following modifications were reviewed and unanimously approved by the ACUC using the designated member review process:

Redacted by agreement.

7. A spreadsheet for LAM post-approval monitoring (PAM) was distributed to members. Dr. Gulani provided an update on the ammonia odor issue in [Redacted by agreement]. An ammonia meter has been purchased and has consistently recorded ammonia levels at 0 [Redacted by agreement], LAM will continue to take readings for a month. Additionally, LAM also provided documentation regarding a PAM performed per ACUC Guideline 53.00. There were no issues with ASP [Redacted by agreement].
8. Members reviewed several revised ACUC guidelines. ACUC 5, 10, 11, and 19 were approved as submitted. The following guidelines required additional changes:
  - ACUC 9 – Add individual responsible for monitoring, change title, and add EAE as a potential source of paralysis
  - ACUC 18 – LAM and facility management will continue to revise
9. The following proposals were reviewed and discussed:

[Redacted by agreement.]

Tabled pending clarifications. LAM presented the committee with their observations. Members reviewed and discussed this information extensively to determine whether the animals required Category 2 or 3 classification. Histopathology data will be sent to members via email once received for review and additional discussion. ***Vote: 8 in favor and no minority opinions expressed.***

Approved as a pilot study with clarifications: [1] clarify if the *C. albicans* can be irradiated, [2] injection site clarification, and [3] additional monitoring details. ***Vote: 7 in favor and no minority opinions expressed.***

Approved with procedure verification and minor clarifications: [1] clarify clinical endpoints and [2] clarify superovulation age and purpose. ***Vote: 7 in favor and no minority opinions expressed.***

Approved with minor clarification: [1] recommend adding DT as a mod to the tumor protocol. ***Vote: 7 in favor and no minority opinions expressed.***

The meeting was adjourned at 11:56 a.m. The next meeting of the NCI at Frederick ACUC will be held on March 19, 2020, at 10:00 a.m. in Building [Redacted by agreement].

Distribution: NCI at Frederick ACUC Members and Guests

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National Cancer Institute at Frederick

## MEMORANDUM

March 20, 2020

**TO:** Distribution

Redacted by agreement

**Through:** Melinda Hollingshead, DVM, PhD  
Chair, NCI at Frederick Animal Care and Use Committee**FROM:** Redacted by agreement  
NCI at Frederick Animal Care and Use Committee**SUBJECT:** Minutes of the March 19, 2020, NCI at Frederick Animal Care and Use Committee Meeting

The meeting of the NCI at Frederick Animal Care and Use Committee [ACUC] was called to order at 10:03 a.m. on Thursday, March 19, 2020 via teleconference, by Dr. Melinda Hollingshead. Those in attendance were

Redacted by agreement

Dr. Melinda Hollingshead,

Redacted by agreement

Not present: Redacted by agreement, Dr. Jatinder Gulani, Redacted by agreement

1. The minutes of the February 20, 2020, meeting were unanimously approved as written. **Motion:** *Approved as written. Vote: 8 in favor and no minority opinions expressed.*

2. Redacted by agreement was introduced as the LASP representative.

3. The following annual review statements were reported to the ACUC:

Redacted by agreement

4. All issues were resolved for proposals designated as approved/pending or deferred at previous ACUC meetings unless indicated below:

Redacted by agreement

Pending IBC  
Pending MTBM  
Pending IBC  
Pending IBC

5. The following modifications were reviewed and unanimously approved by the ACUC using the designated member review process:

Redacted by agreement

6. A spreadsheet for LAM post-approval monitoring (PAM) was distributed to members. Additionally, LAM also provided documentation regarding a PAM performed per ACUC Guideline 53.00. There were no issues with ASP Redacted by agreement.
7. Members reviewed several revised ACUC guidelines. ACUC 21, 22, and 45 were approved as submitted.
8. The following proposals were reviewed and discussed:

Redacted by agreement.

Approved with minor clarifications: [1] receipt of pre-review responses and [2] correction of math in animal number justification. ***Vote: 8 in favor and no minority opinions expressed.***

Approved with minor clarification: receipt of pre-review responses. ***Vote: 8 in favor and no minority opinions expressed.***

Approved with minor clarifications: [1] receipt of pre-review responses and [2] deletion of frog sources. ***Vote: 8 in favor and no minority opinions expressed.***

Approved with minor clarification: receipt of pre-review responses. ***Vote: 7 in favor, 1 abstained due to conflict of interest, and no minority opinions expressed.***

Approved with minor clarifications: receipt of pre-review responses. ***Vote: 8 in favor and no minority opinions expressed.***

Approved with minor clarifications: [1] verify MTBM, [2] PI signature on ASP, and [3] receipt of tumor endpoints. ***Vote: 8 in favor and no minority opinions expressed.***

The meeting was adjourned at 11:04 a.m. The next meeting of the NCI at Frederick ACUC will be held on April 16, 2020, at 10:00 a.m. via teleconference.

Distribution: NCI at Frederick ACUC Members and Guests



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Frederick, Maryland 21702-1201  
National Cancer Institute at Frederick

## MEMORANDUM

May 12, 2020

**TO:** Distribution

Redacted by agreement.

**Through:** Melinda Hollingshead, DVM, PhD  
Chair, NCI at Frederick Animal Care and Use Committee

**FROM:** Redacted by agreement.

NCI at Frederick Animal Care and Use Committee

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**SUBJECT:** Minutes of the April 16, 2020, NCI at Frederick Animal Care and Use Committee Meeting

The meeting of the NCI at Frederick Animal Care and Use Committee [ACUC] was called to order at 10:01 a.m. on Thursday, April 16, 2020 via teleconference, by Dr. Melinda Hollingshead. Those in attendance were:

Redacted by agreement.

Dr. Jatinder Gulani,  
Redacted by agreement.

Dr. Melinda Hollingshead,

Redacted by agreement.

1. The minutes of the March 19, 2020, meeting were unanimously approved as written. **Motion: Approved as written. Vote: 11 in favor and no minority opinions expressed.**

2. Redacted by agreement was introduced as the LASP representative.

3. The following annual review statements were reported to the ACUC:

Redacted by agreement.

4. All issues were resolved for proposals designated as approved/pending or deferred at previous ACUC meetings unless indicated below:

Redacted by agreement.

Pending IBC  
Pending MTBM  
Pending IBC  
Pending IBC  
Pending IBC

5. The following modifications were reviewed and unanimously approved by the ACUC using the designated member review process:

Redacted by agreement.

6. A spreadsheet for LAM post-approval monitoring (PAM) was distributed to members. No new updates were highlighted this month.
7. Dr. Gulani provided an update to the committee on LAMP's COVID-19 efforts. An SOP has been developed in conjunction with EHS and OHS, which outlines the steps to take in the event of a positive test. Additionally, caretaking staff in the larger animal facilities are now working split shifts in an effort to minimize the number of staff in the facilities. In the smaller facilities, staff are working 7-hour shifts with no lunch breaks to minimize the number of individuals in the lunchroom. ADL has developed a COVID-19 environmental test to be used in the event of a positive case in an animal facility.
8. Members reviewed a subcommittee memorandum regarding noncompliance issues within the [Redacted] lab. This has been an ongoing issue and a repeat reportable for the staff scientist involved in the [Redacted] incident. His access to the animal facility has been revoked pending a 6-month retraining period; however, the PI and the staff scientist were notified that his access will be permanently revoked if there are any future incidents. After discussion, the committee agreed with the subcommittee's recommendation to report the incident to OLAW. **Motion: Report to OLAW. Vote: 11 in favor and no minority opinions expressed.**
9. Members reviewed the following revised ACUC guidelines and were approved with the following changes:
  - [1] ACUC 49 – add pest control manager's title and change number to current 10-digit dialing.
  - [2] ACUC 51 – add LAM statements regarding endpoints and consultation.
  - [3] ACUC 52 – add verbiage from LAMP SOP regarding secondary container labeling.
  - [4] ACUC 53 – no changes
10. Members reviewed a Deleterious Phenotype Reporting form for ASPs [Redacted by agreement]. LAM will work with the lab to find the cause of the phenotype and more details on the antibiotics and dosage will be added. The form will be submitted after LAM consultation.
11. The following proposals were reviewed and discussed:
 

[Redacted by agreement.]

Approved with minor clarifications: [1] change genotyping to 21 days for reclaims and [2] receipt of branch chief signature. **Vote: 10 in favor, 1 abstained due to conflict of interest, and no minority opinions expressed.**

Approved with minor clarification: receipt of branch chief signature. **Vote: 9 in favor, 2 abstained due to conflict of interest, and no minority opinions expressed.**

Approved as submitted. **Vote: Vote: 10 in favor, 1 abstained due to conflict of interest, and no minority opinions expressed. Note:** [Redacted by agreement]. **served as Chair during the discussion of this ASP.**

The meeting was adjourned at 11:10 a.m. The next meeting of the NCI at Frederick ACUC will be held on May 21, 2020, at 10:00 a.m. via teleconference.

Distribution: NCI at Frederick ACUC Members and Guests

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## MEMORANDUM

May 27, 2020

TO: Distribution

Redacted by agreement.

Through: Melinda Hollingshead, DVM, PhD  
Chair, NCI at Frederick Animal Care and Use CommitteeFROM: Redacted by agreement.  
NCI at Frederick Animal Care and Use Committee

SUBJECT: Minutes of the May 21, 2020, NCI at Frederick Animal Care and Use Committee Meeting

The meeting of the NCI at Frederick Animal Care and Use Committee [ACUC] was called to order at 10:03 a.m. on Thursday, May 21, 2020 via teleconference, by Dr. Melinda Hollingshead. Those in attendance were:

Redacted by agreement. Dr. Jatinder Gulani,  
Dr. Melinda Hollingshead, Redacted by agreement.  
Redacted by agreement.1. The minutes of the April 16, 2020, meeting were unanimously approved as written. *Motion: Approved as written. Vote: 11 in favor and no minority opinions expressed.*

2. Redacted by agreement. was introduced as the LASP representative.

3. The following annual review statements were reported to the ACUC:

Redacted by agreement.

4. All issues were resolved for proposals designated as approved/pending or deferred at previous ACUC meetings unless indicated below:

Redacted by agreement.

Pending IBC  
Pending MTBM  
Pending IBC  
Pending IBC  
Pending IBC, MTBM

5. The following modifications were reviewed and unanimously approved by the ACUC using the designated member review process:

Redacted by agreement.



6. A spreadsheet for LAM post-approval monitoring (PAM) was distributed to members. LAM performed a training verification for c-section. The procedure was performed proficiently, and the pups survived. Additionally, rack and cage changing stations have been purchased for the [Redacted by agreement] animal facility, with an estimated delivery time of six months. Racks have also been purchased for CAPR, which recently moved into its new renovated space in [Redacted by agreement].
7. Members reviewed a Deleterious Phenotype Reporting form for ASP [Redacted by agreement]. The document was approved as written.
8. Dr. Gulani updated the committee on the status for the semiannual inspections and upcoming AAALAC site visit. A waiver has been approved by OLAW to delay the semiannual inspections for up to six months. It is anticipated the inspections will take place in late August/early September with modifications to maintain social distancing. The AAALAC site visit, which was originally scheduled for Fall 2020, has been moved so Winter 2021.
9. Members reviewed the following revised ACUC guidelines and were approved with the following changes:
  - [1] ACUC 7 – no additional changes
  - [2] ACUC 34 – Safety to add verbiage for DMSO
  - [3] ACUC 47 – add 10-digit EHS phone number
  - [4] ACUC 15 and 40 – tabled
10. The following proposals were reviewed and discussed:
 

Redacted by agreement.

Approved with minor clarifications: [1] clarify buprenorphine injection site, [2] receipt of Safety questions, [3] IBC clarification, and [4] receipt of branch chief signature. ***Vote: 11 in favor and no minority opinions expressed.***

Approved with minor clarifications: [1] change to analgesia in Section 9, [2] correction to IBC reference in hazards table, and [3] receipt of branch chief signature. ***Vote: 11 in favor and no minority opinions expressed.***

Deferred pending clarifications. ***Vote: 11 in favor and no minority opinions expressed.***

Approved with minor clarifications: [1] remove xenograft distribution text, [2] delete tumor endpoint references, and [3] receipt of branch chief signature. ***Vote: 11 in favor and no minority opinions expressed.***

Deferred pending clarifications. ***Vote: 11 in favor and no minority opinions expressed.***

The meeting was adjourned at 11:25 a.m. The next meeting of the NCI at Frederick ACUC will be held on June 18, 2020, at 10:00 a.m. via teleconference.

Distribution: NCI at Frederick ACUC Members and Guests



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## MEMORANDUM

June 23, 2020

TO: Distribution

Redacted by agreement.

Through: Melinda Hollingshead, DVM, PhD  
Chair, NCI at Frederick Animal Care and Use Committee

FROM:

Redacted by agreement.

NCI at Frederick Animal Care and Use Committee

SUBJECT: Minutes of the June 18, 2020, NCI at Frederick Animal Care and Use Committee Meeting

The meeting of the NCI at Frederick Animal Care and Use Committee [ACUC] was called to order at 10:05 a.m. on Thursday, June 18, 2020 via teleconference, by Dr. Melinda Hollingshead. Those in attendance were:

Dr. Melinda Hollingshead,

Redacted by agreement.

Dr. Jatinder Gulani,

Redacted by agreement.

Redacted by agreement.

Not present:

Redacted by agreement.

1. The minutes of the May 21, 2020, meeting were unanimously approved as written. **Motion: Approved as written. Vote: 9 in favor and no minority opinions expressed.**

2. Redacted by agreement was introduced as the LASP representative.

3. The following annual review statements were reported to the ACUC:

Redacted by agreement.

4. All issues were resolved for proposals designated as approved/pending or deferred at previous ACUC meetings unless indicated below:

Redacted by agreement.

Pending IBC  
Pending IBC  
Pending IBC

5. The following modifications were reviewed and unanimously approved by the ACUC using the designated member review process:

Redacted by agreement.

6. A spreadsheet for LAM post-approval monitoring (PAM) was distributed to members. LAM performed Animal Health Overview and ACUC guideline training via Webex. They also practiced intrafemoral injections per a recent PI modification and recommended modifications to the procedure.

7. Members reviewed a Deleterious Phenotype Reporting form for ASP Redacted by agreement. The document was approved as written.
8. Members reviewed a revised Deleterious Phenotype Reporting form for ASP Redacted by agreement. The document was approved as written. LAM recommended sending one animal to MHL for kidney histology.
9. Members completed the semiannual program review. All items were deemed acceptable. It was noted that pandemic information has been added to the Disaster Plan. Additionally, a target date of August 1, 2020, has been set by LAM to complete training on the new euthanasia guidelines.
10. Members reviewed the following revised ACUC guidelines and were approved with the following changes:
- [1] ACUC 15 – add an asterisk to C. bovis and MKPV to denote that they are excluded in some facilities, change pathogen registration verbiage and update link
  - [2] ACUC 16 – table pending review with PI performing ascites production
  - [3] ACUC 22 – table pending LAM revisions
  - [4] ACUC 39, 40, 48, and 54 – no additional changes
11. Several LASP SOPs were revised with minor changes since the last ACUC review. The following SOPs were approved as written:
- [1] Policy 7
  - [2] SOP 3.010
  - [3] SOP 3.021F
  - [4] SOP 5.026
12. The following proposals were reviewed and discussed:
- Redacted by agreement.

Approved as written. ***Vote: 9 in favor and no minority opinions expressed.***

Approved with minor clarification: revision to Section 11.1.1.3. ***Vote: 9 in favor and no minority opinions expressed.***

Approved with minor clarifications: [1] additional pre-review questions, [2] clarification for blind dosing, [3] update to biological table in Section 11, and [4] receipt of branch chief signature. ***Vote: 9 in favor and no minority opinions expressed.***

Approved with minor clarifications: [1] additional pre-review questions, [2] change “starvation” verbiage, [3] add ascites check, and [4] receipt of branch chief signature. ***Vote: 9 in favor and no minority opinions expressed.***

Approve with minor clarifications: [1] additional pre-review questions, [2] clarify why imaging must occur in Frederick, and [3] receipt of branch chief signature. ***Vote: 9 in favor and no minority opinions expressed.***

Approve with minor clarifications: clarify tumor measurement and receipt of branch chief signature. ***Vote: 8 in favor, 1 abstained due to conflict of interest, and no minority opinions expressed.***

Approve with minor clarifications: additional pre-review questions and receipt of branch chief signature. ***Vote: 8 in favor, 1 abstained due to conflict of interest, and no minority opinions expressed.***

The meeting was adjourned at 11:30 a.m. The next meeting of the NCI at Frederick ACUC will be held on July 16, 2020, at 10:00 a.m. via teleconference.

Distribution: NCI at Frederick ACUC Members and Guests



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## MEMORANDUM

August 13, 2020

**TO:** Distribution

Redacted by agreement.

**Through:** Melinda Hollingshead, DVM, PhD  
Chair, NCI at Frederick Animal Care and Use Committee

**FROM:** Redacted by agreement.  
NCI at Frederick Animal Care and Use Committee

**SUBJECT:** Minutes of the July 16, 2020, NCI at Frederick Animal Care and Use Committee Meeting

The meeting of the NCI at Frederick Animal Care and Use Committee [ACUC] was called to order at 10:02 a.m. on Thursday, June 18, 2020 via teleconference, by Dr. Melinda Hollingshead. Those in attendance were:

Redacted by agreement. Dr.

Jatinder Gulani, Dr. Melinda Hollingshead,

Redacted by agreement.

Redacted by agreement.

1. The minutes of the June 18, 2020, meeting were unanimously approved as written. *Motion: Approved as written. Vote: 9 in favor and no minority opinions expressed.*
2. Redacted by agreement was introduced as the LASP representative.
3. Redacted by agreement was introduced as the new LAM fellow.
4. It was announced that Redacted by agreement is resigning from her position. The ACUC would like to thank Redacted by agreement for her hard work and service to the committee.
5. The following annual review statements were reported to the ACUC:

Redacted by agreement.

6. All issues were resolved for proposals designated as approved/pending or deferred at previous ACUC meetings unless indicated below:

Redacted by agreement.

Pending IBC  
Pending IBC

7. The following modifications were reviewed and unanimously approved by the ACUC using the designated member review process:

Redacted by agreement.

8. A spreadsheet for LAM post-approval monitoring (PAM) was distributed to members. LAM has performed several training verifications for new employees. Additionally, retraining for a staff scientist has started.
9. Dr. Gulani updated the committee on updates for the semiannual inspection and AAALAC site visit. The AAALAC site visit has been postponed for one year and will now occur in Fall 2021, with the Program Description due August 1, 2021. The NCI at Frederick has an exemption from OLAW regarding the timing of the semiannual inspections, which allows flexibility in performing the inspections once it is deemed safe to do so. The recommendation is to keep the semiannual inspection on the same schedule (October/November). Members also suggested utilizing facility managers in order to minimize exposure. ***Motion: Perform semiannual inspections October/November 2020. Vote: 11 in favor, and no minority opinions expressed.***
10. Members reviewed the following revised ACUC guidelines and were approved with the following changes:
  - [1] ACUC 20 – Table pending updates to blood volume table
  - [2] ACUC 23, 33 – no additional changes
11. Several LASP SOPs were revised with minor changes since the last ACUC review. The following SOPs were approved as written:
  - [1] SOP 5.001
  - [2] SOP 5.003
  - [3] SOP 5.025
  - [4] SOP 5.028 \*Note – QA will ensure this matches the final version of ACUC 20
  - [5] SOP 5.033
12. The following proposals were reviewed and discussed:
 

Redacted by agreement.

Approved with procedure verification and minor clarifications: [1] add LASP SOPs in Section 7.1, [2] addition of supportive care, and [3] clarification of animal numbers. ***Vote: 11 in favor and no minority opinions expressed.***

Approved with minor clarifications: [1] add frog use identification information and [2] receipt of additional pre-review responses. ***Vote: 11 in favor and no minority opinions expressed.***

Defer with procedure verification pending receipt of pre-review responses. ***Vote: 11 in favor and no minority opinions expressed. Final approval via Designated Member Review.***

Approved with minor clarifications: [1] clarification from staff scientist regarding the need for the protocol and [2] receipt of pre-review responses. ***Vote: 11 in favor and no minority opinions expressed.***

Approve with minor clarifications: [1] clarify animal numbers and [2] removal of unused cell line in Section 11. ***Vote: 11 in favor and no minority opinions expressed.***

The meeting was adjourned at 11:35 a.m. The next meeting of the NCI at Frederick ACUC will be held on August 20, 2020, at 10:00 a.m. via teleconference.

Distribution: NCI at Frederick ACUC Members and Guests