

AGENDA

NIH ANIMAL RESEARCH ADVISORY COMMITTEE

11:00 a.m., Wednesday, January 23, 2019

Building 1, 3rd Floor, Wilson Hall

Teleconference#: (b) (5), (b) (6) – Passcode: (b) (5), (b) (6)
GoToMeeting URL: (b) (5), (b) (6)

Call Meeting to Order/Approval of Minutes

Roll Call: Teleconference Attendees

Agreement

Review of November 28, 2018 Meeting Minutes

Agreement

Follow-up

GAO Study: 'Alternatives to the Use of Animals in Research, Testing, and Training' (102874)

Agreement

Agreement

Agreement

New Business:

ARAC Guideline Reviews:

Pain and Distress in Laboratory Animals:
Responsibilities, Recognition and Alleviation

Agreement

Classifying Deficiencies Identified during
Semiannual Reviews

Agreement

Monoclonal Antibody Production in Mice

Agreement

Animal Incident Summary (September-December 2018)

Agreement

Emergency Response in the Animal Facility

Agreement

Guidelines for Photography in the Animal Facility

Agreement

Topic Update

Federal Animal Use Legislation Proposals

S.3773 – Primate Protection and Research Modernization Act of 2018. To require review and approval for future research on nonhuman primates, and for other purposes. **(Archived)**

H.R. 7268 – “The Humane Retirement Act”. An amendment to the Public Health Service Act to ensure that healthy research dogs and cats are adopted into suitable homes. **(Archived)**

21st Century Cures Act Sec. 2034(d) Working Group:
Draft Report on Reducing Administrative Burden to Researchers
– Animal Care and Use in Research, November 2018.

Animal Awareness Poster: 'Culture of Care and Compassion Starts Here'

Agreement

Adjournment

Agreement

Next Meeting: February 27, 2019; 11:00 AM; Building 1, Wilson Hall

**** Teleconference Attendees:** To confirm your attendance, please send an e-mail to

Agreement

Minutes of the January 23, 2019 ARAC Meeting

Meeting Called to Order: Agreement, ARAC Chair, called the meeting to order at 11:00 a.m.

Discussion: Agreement reviewed the focus and status of the ongoing GAO Study - 'Alternatives to the Use of Animals in Research, Testing, and Training'. He explained the GAO investigators interviewed NIH three times requesting information on how NIH ensures alternatives to animal use are addressed in its research programs. He noted that while the first two interviews were conducted on conference calls with other federal agencies involved in biomedical research, the last interview was conducted in person with Agreement followed Agreement with a short report on the interview which was conducted in December.

Review and Approval of Meeting Minutes: The November 28, 2018 ARAC meeting minutes were reviewed and approved with no changes.

New Business:

- a. **Guidelines on Pain and Distress in Laboratory Animals: Responsibilities, Recognition, and Alleviation.** Agreement thanked the individuals on the review subcommittee and presented their revision recommendations. A discussion ensued over the utility of Table 2 (Post Procedural Pain Potential). The committee decided that Table 2 should be used as a listing of how other individuals assessed the general level of pain associated with particular procedures, and reiterated that individual ACUCs were responsible for determining pain scores for their studies according to their own ACUC policies or processes. The proposed revisions were approved as presented.
- b. **Guidelines for Classifying Deficiencies Identified during Semiannual Reviews.** Agreement thanked the individuals on the review subcommittee and presented the minor changes to these guidelines the subcommittee recommended. After a short discussion, the proposed revisions were approved as presented.
- c. **Guidelines on Monoclonal Antibody Production in Mice.** Agreement thanked the individuals on the review subcommittee and presented their recommendation to archive these guidelines. She addressed the changes the subcommittee recommended should the Committee prefer to adopt the revisions, then followed with their argument for archiving them. She stated one IC reported they have an ASP approved for monoclonal antibody production, but that it was not being performed; and another IC reported they have cancer studies using pristane as an adjuvant in their murine models, but not for the production of monoclonal antibodies. After discussion, the Committee voted to not change the 2016 version of these guidelines and to place them in an archive.
- d. **Animal Incident Summary.** Agreement presented the summaries of IRP animal incidents closed by OLAW from September through December 2018. The Committee accepted the report.
- e. **Photography in Animal Facilities.** Agreement led a brief discussion on current NIH policies addressing photography in animal facilities. The Committee asked Agreement appoint a subcommittee of APDs to review current NIH and IC policies on this topic for presentation to the ARAC in the future.

Information Items:

- a. **Emergency Response.** Agreement gave a presentation on the key elements of the NIH Animal Program's Emergency and Disaster Response Program.
- b. **Animal Use Legislation Proposal.** Agreement gave a report on two recent legislation proposals which expired with the close of the 115th Congress in December 2018. One proposed to require review and approval for future research on nonhuman primates, and other purposes; and the other proposed an amendment to the PHS Act to ensure healthy research dogs and cats are adopted into suitable homes.
- c. **21st Century Cures Act.** Agreement announced that the Draft Report on Reducing Administrative Burden to Researchers - Animal Care and Use in Research, November 2018 was posted on the web for public comment until mid-February.

Poster: Don Bordine reported that the 'Culture of Care and Compassion Starts Here' poster should go on display by the end of next week.

Adjournment: The meeting adjourned at 11:50 pm. The next meeting will be held February 27, 2018 in Building 1, Wilson Hall.

AGENDA

NIH ANIMAL RESEARCH ADVISORY COMMITTEE

11:00 a.m., Wednesday, February 27, 2019

Building 1, 3rd Floor, Wilson Hall

Teleconference#: (b) (5), (b) (6) – Passcode: (b) (5), (b) (6)

GoToMeeting URL: (b) (5), (b) (6)

Call Meeting to Order/Approval of Minutes

Roll Call: Teleconference Attendees

Agreement

Review of January 23, 2019 Meeting

Agreement

Minutes **New Business:**

Management Controls Survey Question:

Agreement

*D.6. ANIMAL CARE AND USE (answer with assistance of ACUC chair)
'Does an SD or SD designated individual confirm that all animal studies are statistically valid by signing off on the ASP?'*

ARAC Guideline Reviews:

Rodent Toe Clipping

Agreement

Establishment and Use of Mouse Breeding Groups
Semiannual Reviews

Agreement

Egg and Oocyte Harvesting in *Xenopus* Species

Agreement

An NIH Basic Mouse Users Course Proposal

Agreement

Old Business:

Photography in the Animal Facility – Update

Agreement

Rules for Rodent Transfers between NIH Buildings-Update

Agreement

For Your Information:

GAO Study: 'Alternatives to the Use of Animals in Research, Testing, and Training' (102874)

FOIA Requests: NEAVS, February 8, 2019.

Animal Use Legislation: H.R. 1209, 116th Congress (2019-2020) HEARTS Bill - Humane and Existing Alternatives in Research and Testing Sciences Act of 2019. To amend the Public Health Service Act to ensure that non-animal methods are prioritized, where applicable and feasible, in proposals for all research to be conducted or supported by the National Institutes.

Animal Awareness Poster: None to present.

Adjournment

Agreement

Next Meeting: March 27, 2019; 11:00 AM; Building 1, Wilson Hall

**** Teleconference Attendees:** To confirm your attendance, please send an e-mail to

Agreement

Minutes of the February 27, 2019 ARAC Meeting

Call to Order: Agreement, ARAC Chair, called the meeting to order at 11:00 a.m.

Discussion: Agreement reviewed the IRP Disposition of Laboratory Animals policy dated June 5, 2014. The policy was written to provide guidance to scientists, veterinarians and facility managers who may receive requests to “adopt” animals following completion of research studies. He outlined the key elements of the animal transfer policy: (1) Science Director approval of the transaction and (2) completion of a transfer of ownership agreement with the assistance of the Office of General Council identifying the terms of transfer, health of the animal, and relinquishment of NIH responsibility for the animal after the transfer. He stressed the policy applies to all IRP animal programs who plan to transfer federally owned animals to private parties. Agreement described the ORS/DVR animal program’s transfer of ownership policy, and offered to share her policy with other ICs considering adopting animal to private parties or developing their program’s transfer of ownership policy.

Meeting Minutes Approval: The January 23, 2019 ARAC meeting minutes were reviewed and approved with no changes.

New Business:

- a. **Management Controls Survey Question # D.6.** Agreement explained the NIH Management Controls Program and its Scientific Directors Survey. He presented survey question D.6. He proposed the ARAC consider language to amend survey question D.6 to read *‘Does an SD or SD designated individual confirm that whenever practical and applicable all animal studies are statistically valid by signing off on the ASP?’* After several points were discussed arguing against the ACUCs being responsible for ensuring statistical validity, the ARAC decided to postpone the topic to a future meeting. Agreement to lead the ARAC effort to shape their position on this ‘ensuring statistical validity’ issue.
- b. **Guidelines for Toe Clipping of Rodents.** Agreement, NIEHS, stated there were no new relevant publications addressing toe clipping in rodents, and her subcommittee recommended a only few edits. The ARAC approved the revisions and Guidelines as presented.
- c. **Guidelines for the Establishment and Use of Mouse Breeding Groups.** Agreement, NIDA, explained the subcommittee’s rationale for inserting specific breeding cage weaning guidance in the Guideline revision. After discussion, the ARAC approved the Guidelines with the following revisions:
 - 1) The first sentence of the Guideline should read: ‘These ARAC Guidelines are intended to provide consideration for the establishment ...’.
 - 2) “AAALAC” to be changed to “AAALAC International”.
 - 3) The last sentence of the Guideline should read: ‘Many programs separate litters in the same cage that are born more than 7-10 days apart, with a mother or their respective mother, to prevent the older pups from injuring the ‘younger pups.’
- d. **Guidelines for Egg and Oocyte Harvesting in *Xenopus* Species.** Agreement, NINDS, presented the subcommittee’s revisions to this Guideline which included updating the references, separating *X. laevis* and *X. tropicalis* oocyte priming protocols, and expanding descriptions of skin preparation and surgical techniques. The revisions were approved as presented.
- e. **NIH Basic Mouse Handling Course Proposal.** Agreement presented a plan to develop a central Rodent Handling Training Course and Program. He addressed the proposed target audience, resource requirements, and expected outcomes.
- f. **Photography in Animal Facilities - Update.** The Photography subcommittee has developed a draft policy. The draft will be refined over the next few weeks and reviewed by the APD Committee prior to its presentation to the ARAC.
- g. **Rules for Rodent Transfers between NIH Buildings - Update.** Agreement announced the members of the subcommittee to review the Campus Rodent Transfer Policy and stated their first meeting was scheduled for March.

Information Items: Agreement briefly commented on the status of the GAO Study on Research Animal Alternatives Use, a FOIA request for IC NHP usage, and the HEARTS bill proposal to amend the Public Health Service Act to ensure that non-animal methods are prioritized, *where applicable and feasible*, in proposals for all research to be conducted or supported by the National Institutes.

Adjournment: The meeting adjourned at 11:50 pm. The next meeting is scheduled for March 27, 2018 in Building 1.

AGENDA

NIH ANIMAL RESEARCH ADVISORY COMMITTEE

11:00 a.m., Wednesday, July 24, 2019

Building 1, 3rd Floor, Wilson Hall

Teleconference #: (b) (5), (b) (6) – Passcode: (b) (5), (b) (6)

Call Meeting to Order/Approval of Minutes:

Agreement

Teleconference Attendees: contact OACU @ bordined@od.nih.gov to confirm your attendance

Review of June 26, 2019 Meeting Minutes

Presentations:

Perspectives of Animal Research at NIH

Agreement

The Impact of Implementing the Sex as a Biological Variable Policy on Enhancing Research Reproducibility through Increased Rigor and Transparency

Agreement

New Business:

ARAC Animal Care and Use Guidelines Reviews

Personal Protective Equipment

Agreement

Co-Housing Multiple Species of Laboratory Animals

Agreement

Photography and Videotaping in Animal Labs and Facilities

Agreement

Proposed Animal Use Awareness Poster for Display Sep-Nov 2019

Agreement

Diseases are Not Conquered by People Alone

Animal Incident Summaries – March through June 2019

Agreement

Old Business:

GAO Review of Federal Efforts to Discover and Implement Alternatives to the Use of Animals in Research

Agreement

The May 2019 Animal Bite RCA and Action Plan Summary

Agreement

Topics for Future ARAC Meeting Presentations or Discussions

Agreement

For Your Information:

--August ARAC Meeting Cancelled – Next ARAC Meeting, 25 Sep

--2019 Animal Program Reflection and Celebration Ceremony

Animal Tribute Garden, 2:45 pm, Thursday, Sep 12, 2019

--NIH PHS Animal Welfare Assurance – Accepted by OLAW 6/10/19

Effective 6/30/19 to 6/30/23

--IRP Animal Use Forum – 10/18/19, 08:30 a.m. - 12:00 p.m., Bldg 50

Adjournment: Next Meeting: 25Sep19; 11:00 a.m., Bldg 1, Wilson Hall

Agreement

Minutes of the July 24, 2019 ARAC Meeting

Call to Order: [Agreement], ARAC Chair, called the meeting to order at 11:00 a.m.

Meeting Minutes Approval: The July 24, 2019 ARAC meeting minutes were reviewed and approved.

Presentations:

[Agreement], NIH Acting Chief of Staff and Associate Director of the Office of Science Policy addressed 'Perspectives of Animal Research at NIH' focusing on NIH support to NHP research and NIH's commitment to developing and using the right animal model for the disease or therapeutic product being studied. She described how Congressional, US taxpayer, and science opinions influence NIH's policies regarding NHP and other animal use. She noted how a recent Advisory Committee to the Director subcommittee looking at how animal research interplays with research rigor and reproducibility was an example of [Agreement] support and commitment to animal research. She provided suggestions on how NIH staff members could describe their work activities to more positively inform nonscientists of their and NIH's contributions to therapeutic discoveries. A short discussion regarding the SD's NHP Use Review Board followed [Agreement] remarks. The ARAC gave consensus approval to add a line in the current ASP form recording the ACUC's receipt of a letter from the SD's NHP Review Board documenting the Board's approval of the use of NHPs for that specific IC ASP.

[Agreement] addressed 'The Impact of Implementing the Sex as a Biological Variable Policy on Enhancing Research Reproducibility through Increased Rigor and Transparency' at NIH. She presented several recent examples of studies demonstrating significant and effective therapeutic responses which were only expressed in either males or female animal models, and presented report data showing an increase in studies designed to detect sex as a biological variable at NIH. She concluded her presentation with a summarization of her Office's funding support to researchers and an Emory University program focused on sex studies and announced the future release of a primer on incorporating sex as a variable. She closed with a discussion of her 4 C's - consider sex as a variable during experimental design, collect data in manner which will allow separation of results into sex groups, characterize the influence of sex in your discussion of the results, and communicate that sex was considered in your study during presentations and manuscripts. She closed by announcing that her office would soon be issuing a primer on sex as a biological variable in cooperation with NIGMS.

New Business:

Animal Awareness Poster [Agreement] presented and explained the poster proposed for display in the next quarter titled '*Diseases are Not Conquered by People Alone*'. The committee approved the poster as presented.

Animal Incident Summaries [Agreement] led a short review of the NIH animal incidents reported to OLAW and closed by OLAW over the past three months. The committee accepted the report.

Old Business:

Animal Tribute. [Agreement] announced the 2019 NIH Animal Tribute Ceremony would be held on September 12 at 2:45 p.m.

Adjournment: The meeting adjourned at 11:59 a.m. The next meeting is scheduled for September 25, 2019 in Building 1.

Agenda

Animal Research Advisory Committee Meeting

Building 1, 3rd Floor, Wilson Hall

Wednesday, September 25, 2019

11:00 am - 12:00pm

Teleconference #: (b) (5), (b) (6) Participant Code: (b) (5), (b) (6)

* Contact OACU @ (301) 496-5424 if you have a connection problem

	Item	Presenter	Meeting Packet Page #
1.	Call to order	Agreement	
2.	Review: APD Meeting Minutes from the July 24, 2019 Meeting		
3.	Presentation: NHP Program Changes following Bite Incidents in May 2019	Agreement	
4.	Old business: ARAC Guideline Reviews <ul style="list-style-type: none"> - Personal Protective Equipment - Co-Housing Multiple Species of Laboratory Animals - Survival Bleeding of Mice and Rats - Diet Control in Laboratory Animals - ACUC Oversight of Animal Protocol Activities in Shared and Central Facilities - Euthanasia of Rodents Using Carbon Dioxide - Prevention & Control of Tuberculosis in Nonhuman Primates 	Agreement Agreement Agreement Agreement Agreement Agreement Agreement	
5.	New business: FOIA Requests	Agreement	
6.	Training Opportunities: →September 26, 2019: OLAW webinar, "Application of the AVMA Guidelines for the Depopulation of Animals to Biomedical Research, Individual enrollment details here: https://olaw.nih.gov/education/online-seminars.htm →September 27, 2019: SCAW IACUC Training Workshops, New York City, NY, https://scaw.com/iacuc-training-workshops/ →October 2-3, 2019, Beltsville, MD, USDA Animal Welfare Information Center, Meeting the Information Requirements of the Animal Welfare Act: A Workshop, - https://www.nal.usda.gov/awic/awic-workshop →October 13-17, 2019: AALAS National Meeting, Denver, CO, https://www.aalas.org/national-meeting →November 19, 2019: AALAS webinar with free CE, "Fish Welfare and Analgesia," 1-2:30 EST, location-tbd →November 22, 2019, Chicago, IL, SCAW IACUC Training Workshops, https://scaw.com/iacuc-training-workshops/ →December 9-10, 2019, San Antonio, TX Scientists Center for Animal Welfare Winter Conference →November 6-7, 2019, Knoxville, TN, IACUC Administrators Association (IAA) Best Practices Meeting →December 11, 2019: AALAS webinar with free CE, "Resistance is Not Futile! Judicious Antimicrobial Use in Laboratory Animal Medicine," 1-2:30pm EST, location tbd	Agreement	
7.	Adjournment:	Agreement	
8.	Next Meeting: Monday, October 23, Building 1, 1st Floor, Room 151 ***		

***Room Change

Minutes of the September 25, 2019 ARAC Meeting

Call to Order: Agreement, ARAC Chair, called the meeting to order at 11:00 a.m.

Meeting Minutes Approval: The July 24, 2019 ARAC meeting minutes were reviewed and approved.

Presentation: Agreement presented the 5 Changes to the Animal Bite, Scratch, and Splash Exposure (BSSE) Prevention and Response Plan. He outlined the processes undertaken to identify and select these changes, and described the groups involved in making these selections. The five changes presented were:

- 1) **Procedures:** change BSSE guidance to direct staff or patients to: immediately flush BSSE wounds caused by any animal; call OMS ASAP after every animal BSSE incident; expect to talk to an OMS Medical Provider within one minute of reporting the incident to OMS; and if warranted, expect to receive clinical treatment within 15 minutes of arrival at the OMS clinic.
- 2) **Supplies:** increase the Valacyclovir stockage in the Monkey Bite Response Kits and update the Monkey Bite Response SOPs and Monkey Bite Kit Use Instruction sheets to reflect the changes listed in subparagraph (1) and this subparagraph (2).
- 3) **Equipment:** update the nonhuman primate (NHP) BSSE Response posters to reflect the increased emphasis on flushing the wound or exposure site and place them near all NHP housing and use areas; install improved wound flushing equipment in the animal facility; identify items for immediate staff member access and use during an NHP BSSE event and pre-place them in NHP housing rooms.
- 4) **Policy:** ensure NHP rack/cage change-out personnel are familiar with the facility's current NHP Rack/Cage Change-out SOPs; establish and use two-person NHP rack/cage change-out teams; and establish a policy requiring two people be in the NHP housing room during NHP rack/cage change-outs.
- 5) **Training:** provide annual training to all NHP handlers and caretaker personnel on: treating a NHP BSSE wound; procedures for reporting an NHP BSSE to OMS; responding to an uncaged monkey; regaining control of a monkey on a pole and collar restraint device; and methods to repel an NHP during a BSSE incident.

The discussion following the presentation focused on clarifying the rationale for implementing these changes, reviewing one program's experience implementing these changes, the expected timelines for instituting these changes, and clarifying the applicability of these changes to all animal bites. Agreement stated the changes are effective today. He said he would follow up with the ICs over the next month to track their progress in implementing the changes, especially those programs using or holding old world primates to survey their experiences procuring the additional Valacyclovir and the wound flushing equipment.

New Business: Agreement presented the APD subcommittee's proposed revision to the ARAC Guidelines for Personnel Protection in the Animal Facilities. Following a short discussion, the committee approved the revision unanimously with minor changes.

Old Business: None.

Announcements: Agreement announced the OACU received the 2019 USDA Annual Report Data Call yesterday. He said the data call announcement and form completion instructions would be issued by OACU soon.

Adjournment: The meeting adjourned at 11:59 a.m. The next meeting is scheduled for October 23, 2019 in Building 1, Room 151.