

School of Veterinary Medicine Animal Care and Use Committee Open Session – June 9, 2020

Present (voting):	(for),
Present (nonvoting):	
Guests:	
Absent:	

Dr. called the meeting to order at 10:00 a.m. and thanked everyone for their willingness to meet remotely in order to promote social distancing.

Approval of May Open Session Minutes and Semi-Annual Program Review Reports

reports with minor editorial modifications. The vote was unanimous.

joined the meeting. assumed non-voting status.]

Annual Reapprovals

moved to approve the annual updates. The vote was unanimous.

Senior Program Veterinarians Reports

Dr. had no report for Open Session.

Dr. had no report for Open Session.

Dr. provided an update on the dual-school protocol involving submarine rescue. She said that the protocol is still under development and that additional veterinary consultations are being provided to the PI.

Report from the Animal Program Assessment Specialists (APAS)

Mr. had no report for Open Session.

Report from ARC

Mr. had no report for Open Session, noting that all is well except for a developing situation involving a broken water pipe.

Logs: Designated Review/other

The committee reviewed and discussed the designated review and VVC logs. Dr. thanked members for their continuing efforts on protocol review.

Committee Training/ Policy Review

Dr. reminded members that all of the campus ACUCs review and reapprove the Designated Review of Protocols and Adverse Events Reporting Policies annually. Members noted that there is some overlap between changes that may be approved by vet-chair review and veterinary verification and consultation (VVC). After brief discussion, members agreed that having flexibility in how these changes may be approved is appropriate.

Other Business

Dr. called for other business. Hearing none, **busy** / **busy** moved to adjourn into Closed Session for discussion of research protocols or other documents containing confidential proprietary information and personnel matters relating to such research protocols, pursuant to Wisconsin Statutes Section 19.85(1)(c), (d), (e), (f), and (g). The vote was unanimous by polling. Dr. **busy** invited **busy** Morris to stay for closed session.

The meeting was adjourned from Closed Session without reconvening into Open Session.





School of Veterinary Medicine Animal Care and Use Committee Closed Session – June 9, 2020

Present (voting):
Present (nonvoting):
Guests:
Absent:
<u>Approval of Closed Session Minutes May 12, 2020</u>
moved to approve the minutes. The vote was unanimous.
Senior Program Veterinarians Reports
Neither Drs. nor had reports for Closed Session.
Report from the Animal Program Assessment Specialists (APAS)
Mr. had no report for Closed Session.
Report from ARC
Mr. had no report for Closed Session.
Other Business
Dr. called for other business for closed session. Hearing none,

Dr. **Dr. c**alled for other business for closed session. Hearing none, adjourned the meeting directly from closed session at 10:20 a.m.

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LOGS for SVM ACUC – June 2020

PI	Prot #	Date Rec'd	Title	Species	N/R
	V5016- R02	5/11	Cartilage implants in a pig model	Pig	Renew
	V5017- R02	5/12	Tumor vaccines for the treatment of melanoma: in vivo cytokins therapy for the treatment of neoplasia	Dog	Renew
	V5932- R01	5/22	COTC026: Evaluation of a recombinant, attenuated Listeriain the adjuvant setting	Dog	Renew
	V6353	5/27	Investigating the acute anti-parasitic mechanisms of therapies for intestinal schistosomiasis	Mouse	New

Designated Review New/Renewal

PI	Prot #	Date Rec'd	Title	Species	Sum of change
	V5375- R01-A04	5/6	Mechanotransduction and the Regulation of Skeletal Muscle Mass	Mouse	Modified weight pulling model
	V806	5/13	Molecular Pathogenesis of Viral Disease	Mice, ducks, chickens, hamsters, ferrets, guinea pigs, quails	Updated age groups of hamsters, +addl timepoints to challenge study, +addl compounds
	V5209- R01-A03	5/15	Genetics of Body Size Evolution in Island Mice	Mouse	+addl information regarding metabolic cages
	V6223- A04	5/20	Molecular Pathogenesis of Emerging and Re-emerging viruses	Mouse, hamster	+new vaccine work for SARS
	V5847- R01-A01	5/31	In Utero Programming of Adult Diseases	Rat	+addl behavioral tests, +tMCAO

Designated Review Amendment

Veterinary Verification and Consultation (VVC) Res	member to notify safety	
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PI	Prot #	Date	Title	Species	Sum of change
		Rec'd			
	V806	5/13	Molecular Pathogenesis of Viral Disease	Duck,	+chg in hamster blood draw
				mice,	
				chickens,	
				hamster,	
				ferrets,	

			guinea pig, quail	
V5851- V05	5/4	Understanding synapse formation/maturation in models of schizophrenia and autism	Mouse, rat	Proc/room association corrected.
V5794- R01-V01	5/20	Mouse model for respiratory tuberculosis	Mouse	+addl delivery route
V6143- V02	5/22	Molecular Pathogenesis of type 0 Virus (Large Animals)	Cat, dog, pig	Endpoint extended

Dual School Review

PI	Prot #	Date Rec'd	Title	Species	Addl ACUC

University of Wisconsin-Madison, Research Animal Resources and Compliance Policy Number: 2002-020-c

Policy Title: Designated Review of Protocols

Purpose: Both the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Act regulations regarding review and approval of animal activities, described in animal protocols, allow for the use of Designated Review of those activities. This policy details the circumstances under which the Designated Review process is practiced by the UW-Madison Animal Care and Use Committees (ACUCs), and how the Designated Review process is implemented.

Policy: The Designated Review method of protocol review and approval is practiced in three circumstances, described below. On an annual basis each ACUC shall review and ratify this policy at a convened meeting.

Protocol amendments to identify procedures in a grant proposal to be performed in years beyond those of a current ACUC-approved protocol must be handled via method 1 of this policy. Such amendments must be clear that such procedures will not be performed without ACUC approval.

- 1. Designated Review can be used as an alternative to review of a protocol at a legally convened **meeting.** The process described below will be used to facilitate Designated Review.
 - a. All voting committee members will be provided with a full copy (electronic or hard-copy) of each protocol for which Designated Review is requested. Specific eligibility is left to the discretion of the individual school/college-level ACUC.
 - b. Any voting committee member may request that a protocol undergo review at a legally convened meeting ("full-committee review"). If such a request is made, then the protocol will be reviewed by way of the normal full-committee review/approval process. Such full-committee review/approval will be conducted at a convened meeting with a constituted quorum of members present and eligible to vote.
 - c. While a request for full-committee review of a protocol can be made anytime, for the purpose of keeping the review/approval timely, if the response deadline for voting committee members as designated by the chair has passed without a request for full-committee review, the chair will initiate the Designated Review process.
 - d. To proceed with the Designated Review process, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review the protocol, and have the authority to approve, require modifications in (to secure approval), or request full-committee review of the protocol. If the chair assigns multiple designated reviewers, there must be unanimous approval by all designated reviewers. If there is not unanimous agreement, the protocol will automatically go to the full committee for review. Disapproval of a protocol requires full-committee action.
 - e. Animal use protocols that are submitted for the purpose of serving as umbrella grants (e.g., base training grants) will be reviewed via Designated Review by the appropriate ACUC Chair and Senior Program Veterinarian. Either may call for full-committee review of such protocols, in which case the protocol will be scheduled for the next legally convened ACUC meeting.
 - f. Subsequent submissions (rewrites) of protocols that are deferred at a convened ACUC meeting cannot be approved for Designated Review at that meeting unless all voting members are present and unanimously vote to approve the rewrite for Designated Review and select those Reviewers at the time of the vote.

At least quarterly, the full ACUC shall be provided for review a copy of the log of amendments reviewed and approved by the Designated Review described above. Any ACUC member may request a full-committee review of any previously approved amendment noted on the log.

- Designated Review by the ACUC Chair (or vice-chair if a conflict of interest exists) and Senior Program Veterinarian (or veterinary designee) can be used when an amendment to an ACUCapproved protocol is limited to one or more of the criteria below.
 - Addition of locations where procedures are conducted on animals, or where other animal activities of a duration less than 12 hours occur
 - Addition of an ACUC-approved housing location within the reviewing ACUC's oversight

- Qualifications and training of instructors invited by the university to teach specific procedures, generally for continuing education courses, in lieu of completing on-line animal user orientation for UW-Madison
- The addition of adopting out animals at the end of a study following established school/college procedures and RARC veterinary approval
- The addition of language to allow the transfer of animals between ACUC-approved protocols with RARC veterinary approval
- Changing from one approved commercial source of animals to another
- Changing brand names of materials or substances (e.g., "Kleenex" instead of "Puffs")
- Changing from a specific brand name to a generic term (e.g., from "Kleenex" to "tissue")
- Decreasing the frequency or volume of previously approved blood draws
- Removal of procedures and/or procedure locations

At their discretion, either the ACUC Chair or Senior Program Veterinarian may refer any amendment to fullcommittee review. Any amendment not falling within the guidelines will automatically require Designated Review via method 1 of this policy or at a convened meeting.

At least quarterly the full ACUC shall be provided for review a copy of the log of amendments reviewed and approved by the ACUC Chair and Senior Program Veterinarian. Any ACUC member may request a full-committee review of any previously approved amendment noted on the log.

3. Designated Review can be used following an ACUC approval of a motion at a convened meeting to require modifications to secure approval

All voting committee members will be provided with a full copy (electronic or hard-copy) of each protocol scheduled for review at convened meetings. The Designated Reviewer in this circumstances shall be the Senior Program Veterinarian or other voting committee member(s) as determined by the ACUC Chair. Any ACUC member may request a full-committee review of any previously reviewed protocol at any time.

See also ACAPAC Policy 2016-058, "Veterinary Verification and Consultation (VVC)".

Author:

ePublication Date: 12/14/1999

History: amended 1/2010, 2/2010, 12/2012, 4/2013, 8/2014, 4/2016, 2/2019 and 3/2019 (all ACUCs)

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University of Wisconsin-Madison, Research Animal Resources and Compliance

Policy Number: 2012-050-c

Policy Title: Adverse Event Reporting

Purpose: This policy provides a campus-wide definition of "Adverse Events" and identifies reporting and review requirements for both protocol-related and non-protocol-related adverse events. The purpose of adverse event reporting is to improve monitoring, focus resources on problem areas, ensure appropriate follow-up when problem areas are identified, and clarify expectations between the IACUCs, the PIs, and the veterinary and animal care staff. The ultimate goal of this policy is to improve animal welfare.

- Definition:
 - An adverse event is defined as any event that caused harm to a vertebrate animal and that meets either of the following conditions:
 - 1. The event is research*-related but is not identified in the approved protocol or occurring at a rate or severity higher than is indicated in the approved protocol; or
 - 2. The event is not research-related, but is unanticipated or due to a facility, physical plant, or equipment failure or malfunction, or personnel mistake.

Policy: Adverse events must be promptly reported to the appropriate Animal Care and Use Committee (ACUC). Any member of the research community (PI, lab staff, veterinary staff, animal care staff) with knowledge of an adverse event may submit a report. Please consult with a research animal veterinarian for assistance with adverse event reporting.

The ACUC will review adverse event reports and may approve proposed corrective plans or require additional actions to ensure animal welfare. The responsible parties will be notified by the ACUC of any actions taken or requirements made regarding an adverse event.

See also Policy 1999-008-io, Policy on Protocol Non-Compliance.

*for purposes of this policy, "research" also includes teaching and outreach.

Author: ePublication Date: 9/19/2012 (orig.) History: amended 2/2017; 4/2017; 8/2019

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