NIMH ACUC Meeting Virtual Meeting May 12th, 2020 2:00 P.M.

Members Attending:		T. Usdir	ı, J. Rabe		dacted by agreement				
		Redacted by a	greement						
		Redacted by							
Ab	sent:	agreement							
Vis	sitors:	Redacted by a	greement						
Ex	ecutive Secretary:	Redacted by ag	greement						
1.		nutes, F	Review	of	Designated	Items	&	Commi	ttee
	Correspondences								
	Minutes of the Marc	h Meeting	– Approv	ed					
	Minor Amendments	Approved	in March	and	April – Review	ed			
	Items Approved via	Designate	d Review	duri	ng March and	April – Re	eview	ved	
	Annual Review and	Renewal N	Memos S	ent [During March a	nd April–	Revi	ewed	
2.	<u>Reports</u>								
	A. ACRF Tower:								
	Redacted by agreemer	nt				L al bas			
	•		•		t helicobacter ad not been de				
	not a pathoge	en that the	facility ex	xcluc	les.				
	B. Primate Report:								
	Redacted by agreemen	re	eported th	ne cu	rrent pair hous	ina perce	ntag	es. Curre	ently
		3 macaque	es in the	colo	ny; 34 animals	are per	mane	ently exe	empt
		-			ons (11%), 11 5 animals exen				
	We have 70 a	animals cu	rrently pa	aired	(representing 3	30% of th	e en	tire color	ny; if
	-				ave 38% of av oward pairing.	aliable m	acac	ques paii	ea).
			. •		. 3				

Currently there are about 175 animals in the colony, 70 percent of which are socially housed in either pair or group settings. We are working with investigators to pair or group house the remaining animals. Currently no marmosets are exempt from social housing for research reasons.

3. Old Business

- Suspension of Animal Activities At the March ACUC meeting the Committee reviewed the memo from the PI discussing the recent suspension of animal activities related to an incident of work outside of a protocol. At that time, the Committee requested additional information regarding training, supervision, and the arrangement of scheduled and unscheduled visits by the VMRB staff to assure that procedures are being carried out as described in the contacted the PI and conveyed the Committee's requirements for the reinstatement of the protocol. Another memo was generated by the PI providing greater details addressing the Committee's concerns. This memo was circulated to the Committee who by consensus agreed that it met the requested criteria for reinstatement. The PI was sent a notice on March 23, 2020 that her protocol was reinstated. The laboratory will contact the VMRB staff to alert them at the start of any research related procedures. After further discussion, the Committee voted to close this incident. Dr. Usdin and Dr. Raber will write a memo to be sent to Redacted by agreement and OLAW for the official close out of the matter.
- **Tail Biopsy Policy** One member asked about the status of the proposed policy. Redacted by agreement stated that the subcommittee met and discussed the differences in ages for rats between the proposed NIMH policy and the ARAC guideline. They also discussed the potential impact on a behavioral study if some rats had experienced anesthesia for a tail biopsy and others had not. The sub-committee felt that this issue could be addressed by working to streamline the procedure by requesting tail biopsies through VMRB staff and litter weaning from Redacted by agreement so that pups would have their tail biopsy collected as soon after weaning as possible such that general anesthesia would not be needed. If that change can be made, then the sub-committee recommended no changes to the NIMH Tail Biopsy Policy as currently written. The sub-committee also recommended performing a study to verify that the L.E.T. ointment is efficacious but did not require that the policy wait until this study could be done. The final draft of the policy will be forwarded to Redacted by agreement for distribution and consideration at the next the next meeting.

4. New Business

- OLAW Audit Follow-Up Communication

 — Dr. Raber informed the Committee about the follow-up communication from the Office of Laboratory Animal Welfare (OLAW) regarding their findings from their recent site visit. In the letter provided by OLAW NIMH received several commendations. The letter also included several issues to be addressed, without attributing them to specific sites. Dr. Raber stated that the items relevant to NIMH are as follows:
 - Inconsistent justification for certain potentially painful procedures OLAW observed that scientific justifications provided by investigators and the subsequent ACUC review were inconsistent.

The discussion at our March meeting, that our Committee will strive to provide a through and consistent review and approval of the justification for all potentially painful and/or distressful procedures, was reviewed.

OLAW stated that some protocols lack strong justification for the conduct of behavioral tests, (e.g., forced swim test, prolonged restraint, and tail suspension protocols).

The discussion at our March meeting, that our Committee will ensure that strong justifications are present for all studies proposing to use column E behavioral tests was reviewed. The justification will not only include the test endpoint, but also a discussion of why that specific test is required to achieve the scientific goal.

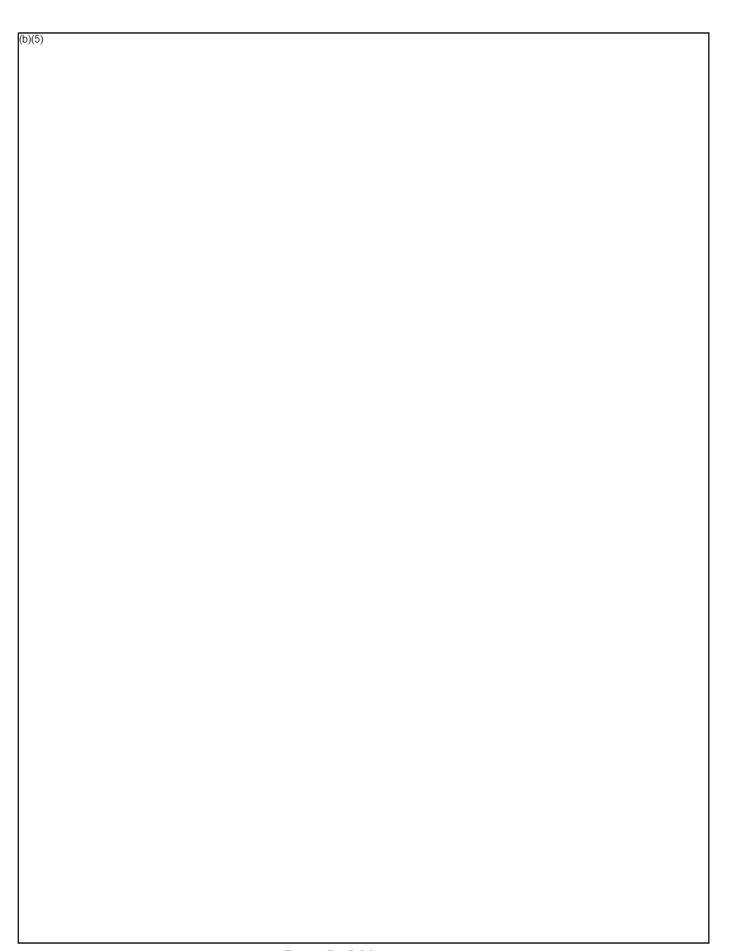
- 3. OLAW reported that they found potential fire egress issues in some NIMH NHP laboratories ir Redacted by agreement. Dr. Raber stated that the NIH Fire Marshal was asked to evaluate all laboratories in this building and no code violations were identified. This will be reported to OLAW.
- 4. OLAW stated that "in numerous areas throughout the campus behavioral equipment and caging in PI laboratories and procedure rooms (both within central facilities and in laboratories), were hand disinfected. However, there was no system for routine monitoring of sanitation efficacy.". OLAW recommended implementation of a process for the routine monitoring of the efficacy of sanitation.

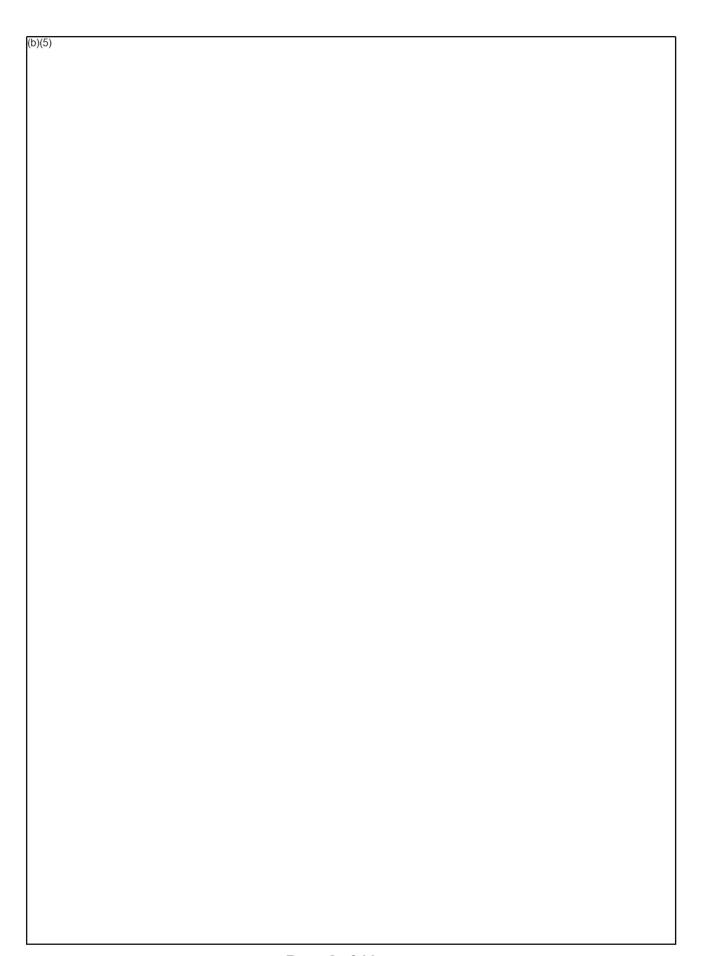
The ACUC discussed that while this verification has not been routinely done, there is substantial evidence that our policy is effective in prevention of disease transmission between groups of animals. The Committee discussed several potential methods of verification that could be put in place to address this issue. It was stated that since this appears to be an NIH global husbandry issue, the item will be addressed by OACU following input from individual institutes and will likely be brought before the Animal Research Advisory Committee for discussion. One member asked when our responses were due back to OLAW. It was stated that institute responses were due to OACU by June 1st and that the NIH full response was due to OLAW by July 31st. The Committee will be updated on the NIH response.

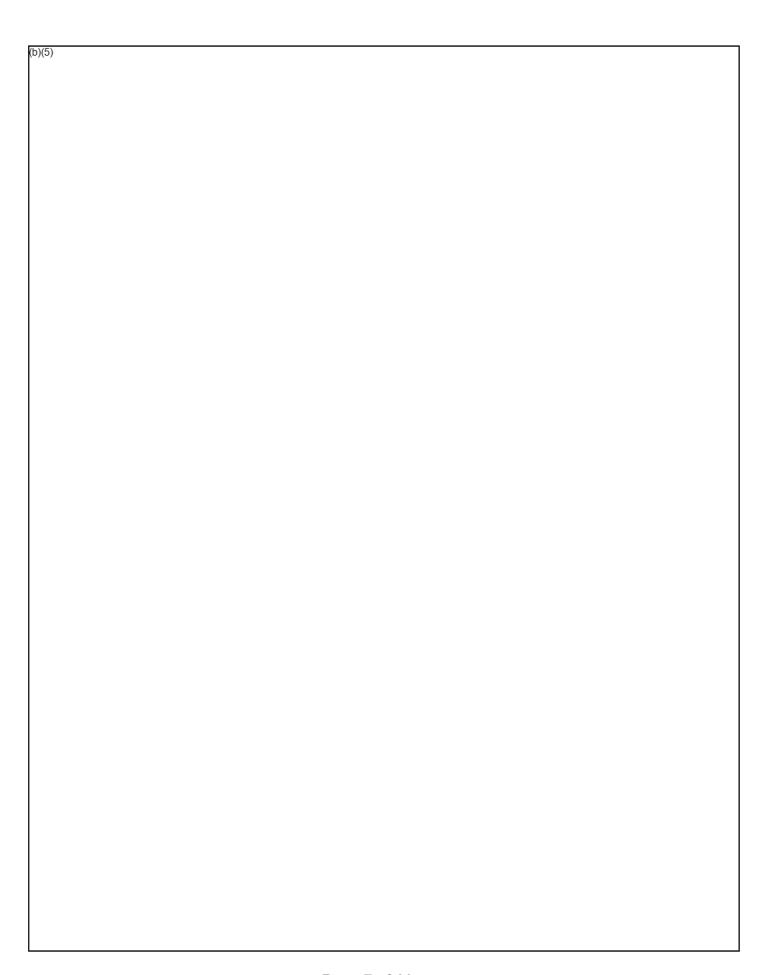
5. Animal Protocol and Amendment Review

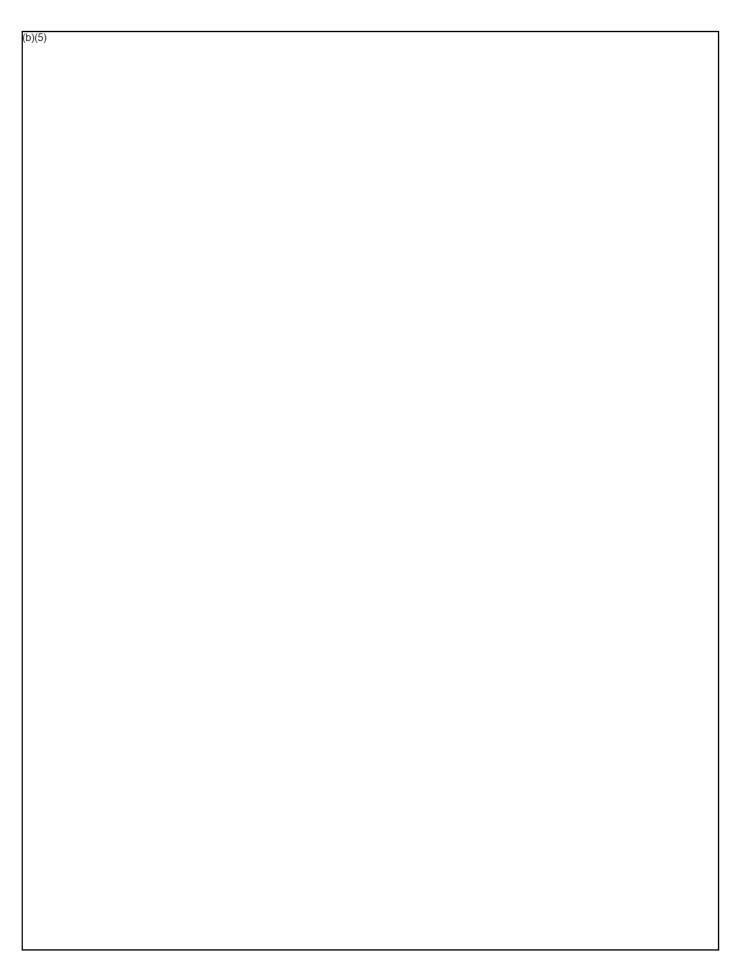
* Recommendations have been broken down into two categories, "Administrative Recommendations" and "Clarification Items". The identified items in each category are provided below. The "Administrative Recommendations" are highlighted in yellow and the "Clarification Items" are not highlighted. The "Administrative Recommendations" will be made to the original version of the item by the ACUC Executive Secretary using the "Track Changes" feature in Microsoft Word® and forwarded to the PI for their review.

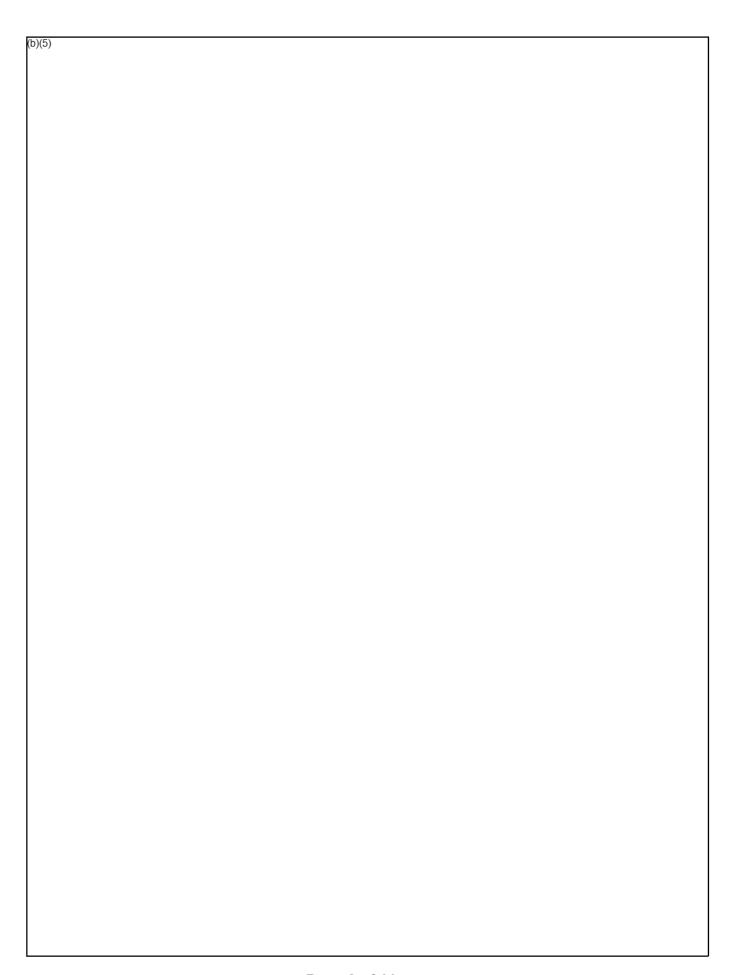
Animal Study Protocol: Tabled to Designated Review (b)(5)











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Meeting was adjourned at 4:41 PM.	

The next meeting is scheduled for June 9th, 2020 at 2 pm.

NIMH ACUC Virtual Meeting June 9th, 2020 2:00 P.M.

Members Attending:	T. Usdin, J. Raber,	
	Redacted by agreement	
Visitors:	Redacted by agreement	
Executive Secretary:	Redacted by agreement	

1. <u>Approval of Minutes, Review of Designated Items & Committee</u> <u>Correspondences</u>

Minutes of the May Meeting - Approved

Minor Amendments Approved in May – Reviewed

Items Approved via Designated Review during May – Reviewed

Items Approved Via Veterinary Verification and Consultation - Reviewed

Annual Review and Renewal Memos Sent During May– Reviewed

2. Reports

A. Redacted by agreement

Dr. Raber reported no change to the status of the animal facility.

B. Primate Report:

Dr. Raber reported no significant changes to the pairing numbers.

3. Old Business

group had discussed and revised. One member suggested accepting this draft until such time as a more comprehensive one that covered more biopsy procedures (i.e. – ear samples, buccal swabs, etc.) could be created. Concerns over this protocol included the routine use of a non-pharmaceutical grade reagent and use of an analgesic agent for a purpose for which its efficacy is not documented. A concern that the compounded analgesic L.E.T was a non-pharmaceutical grade product was brought up. Subsequent to the meeting it was determined be currently listed as available at pharmaceutical grade. A second concern was that use of L.E.T as not been established as efficacious for rodent tail biopsies. The rationale for its use includes that it has been used

in both human and veterinary clinical situations for pain relief involving injuries more extensive than a tail biopsy. The Committee will re-evaluate the use of L.E.T. as more information becomes available. One member stated that the working group also wanted some follow-up review done to see if the policy is working as intended. It was suggested that follow up could be conducted during post-approval monitoring of laboratories and during the semi-annual walk-throughs. The Committee voted to approve the guideline as presented and Ms. Drake will forward a copy of the approved document to all rodent investigators.

• AAALAC Site Visit — Redacted by agreement informed the Committee that, after a recent conversation with AAALAC International, he was planning on having a discussion with Redacted by agreement about moving the accreditation site visit to June of 2021. Further information will be as it becomes available.

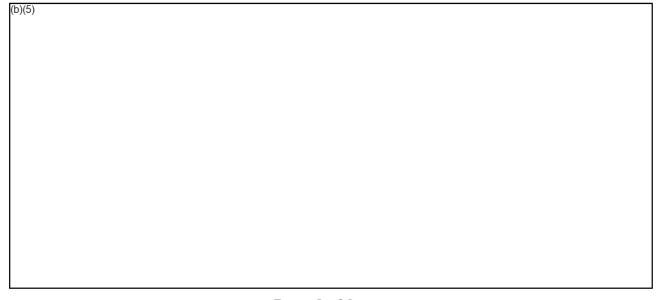
4. New Business

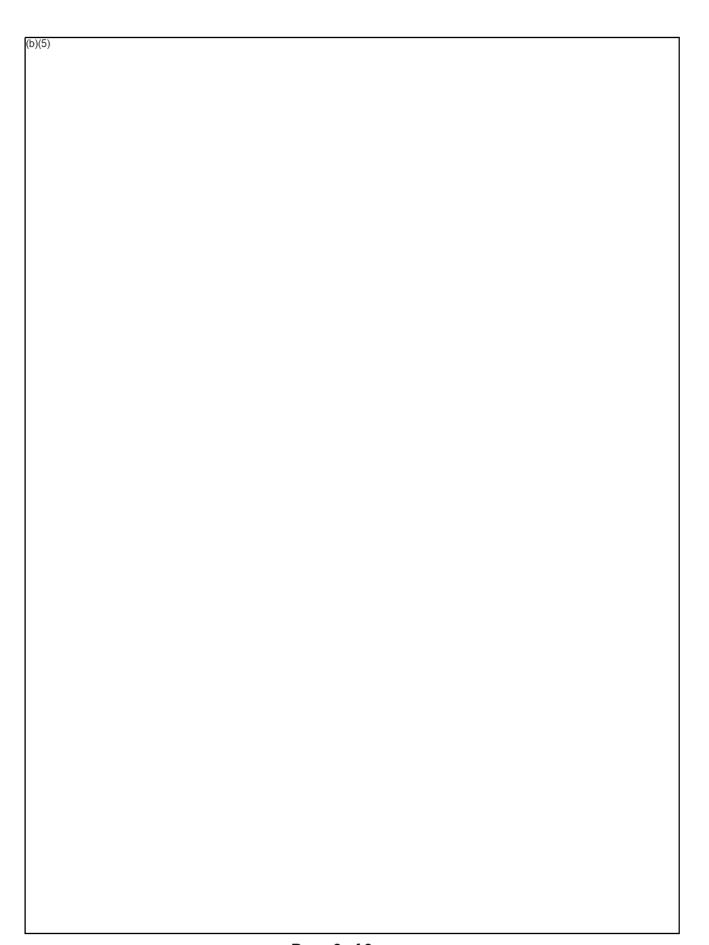
Microsoft Teams – Dr. Usdin stated that he was working on establishing a
ACUC group on Microsoft Teams that would allow members of the ACUC to
review and comment on documents and view the comments made by other
members. It is hoped that this would make meetings more efficient and assist
in providing feedback to the submitting investigator.

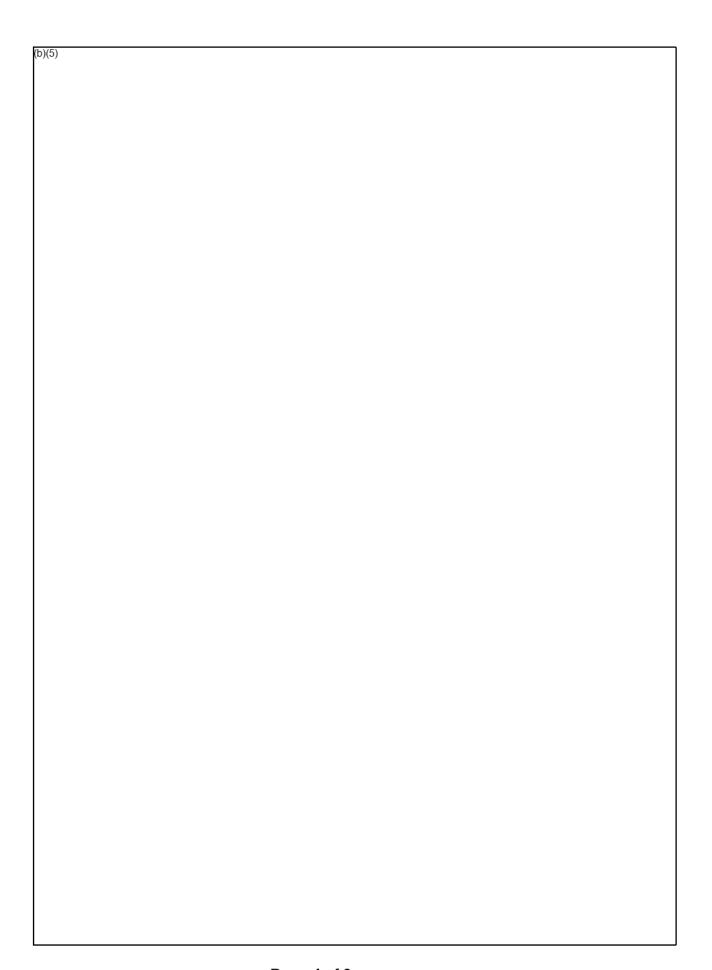
5. Animal Protocol and Amendment Review

* Recommendations have been broken down into two categories, "Administrative Recommendations" and "Clarification Items". The identified items in each category are provided below. The "Administrative Recommendations" are highlighted in yellow and the "Clarification Items" are not highlighted. The "Administrative Recommendations" will be made to the original version of the item by the ACUC Executive Secretary using the "Track Changes" feature in Microsoft Word® and forwarded to the PI for their review.

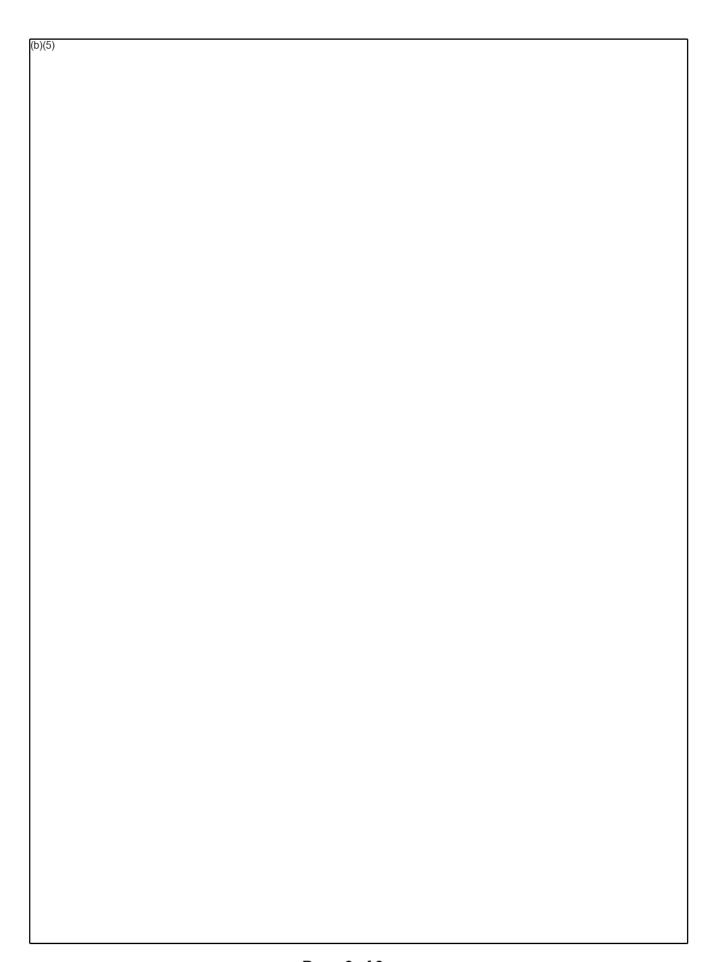
Animal Study Protocol: Tabled to Designated Review







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	Animal Study Protocol Amendments: Tabled to Designated Review
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Meeting was adjourned at 4:15pm

The next meeting is scheduled for July 7th, 2020 at 2 pm.

NIMH ACUC Virtual Meeting July 14, 2020 2:00 P.M.

Μe	embers Attending: T. Usdin, J. Raber, Redacted by agreement
	Redacted by agreement
Vis	Redacted by agreement sitors:
	Redacted by agreement
Ex	ecutive Secretary:
1.	Approval of Minutes, Review of Designated Items & Committee Correspondences
	 Minutes of the June Meeting – Approved The Committee further discussed the previous Tail Biopsy Policy deliberations as reflected in the minutes and required the following modification: "A concern that the compounded analgesic L.E.T was a non-pharmaceutical grade product was brought up. Subsequent to the meeting it was determined be currently listed as available at pharmaceutical grade. A second concern was that use of L.E.T as not been established as efficacious for rodent tail biopsies. The rationale for its use includes that it has been used in both human and veterinary clinical situations for pain relief involving injuries more extensive than a tail biopsy. The Committee will re-evaluate the use of L.E.T. as more information becomes available." The Committee voted to approve the minutes with the above modification.
	Minor Amendments Approved in June – Reviewed
	Items Approved via Designated Review during June – Reviewed
	Items Approved Via Veterinary Verification and Consultation - Reviewed
	Annual Review and Renewal Memos Sent During June– Reviewed
2.	Reports
	A. Redacted by agreement Pedacted by agreement reported no change to the status of the animal facility.
	B. Primate Report:
	reported that VMRB continues their work on establishing success pairings of animals in both the rhesus and marmoset colonies but that the pairing numbers have not changed significantly.

3. Old Business

 Microsoft Teams – Dr. Usdin stated that several members participated in the review of the July agenda items on the Team site and that it appeared to work fairly well. He is continuing to work with the IT department to allow our outside members to utilize this format as well.

4. New Business

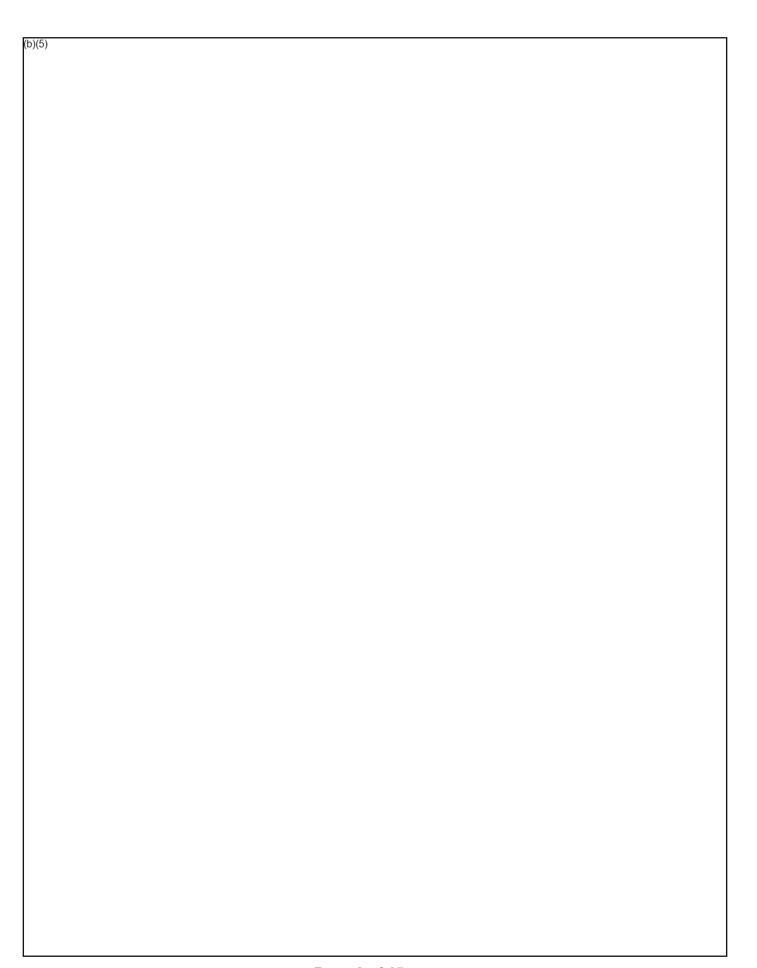
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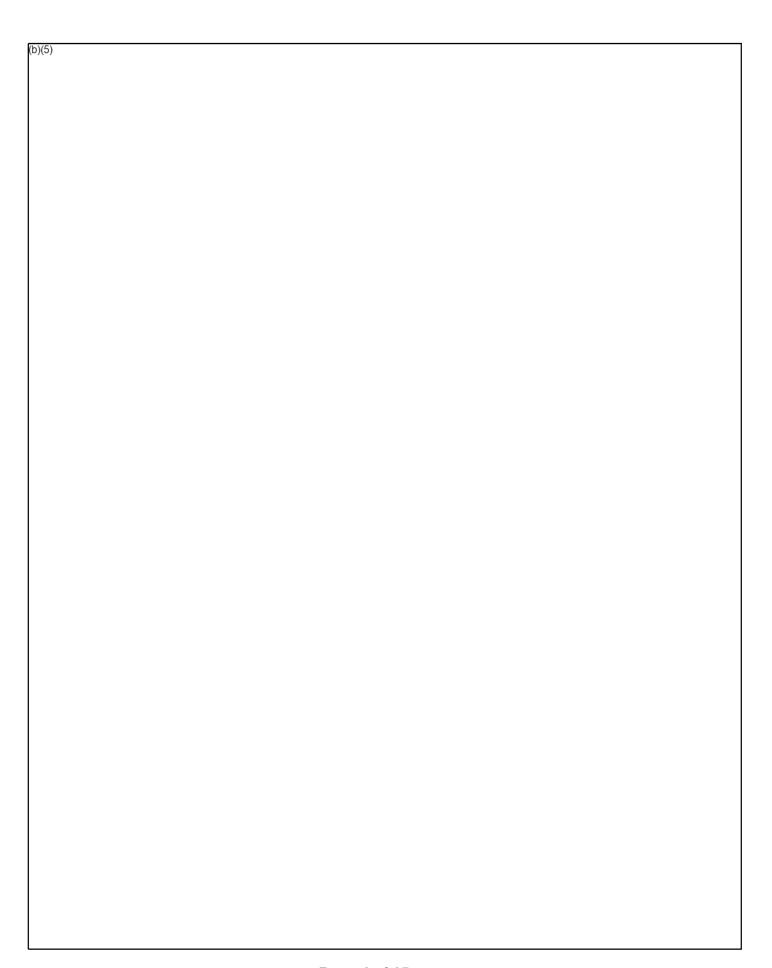
5. Animal Protocol and Amendment Review

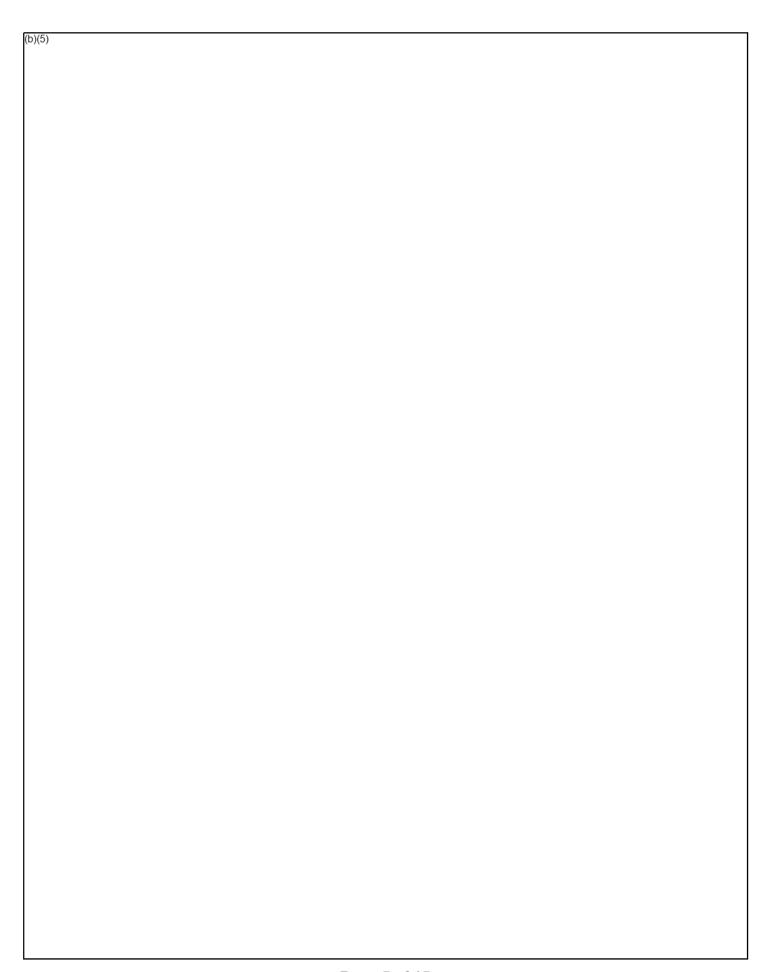
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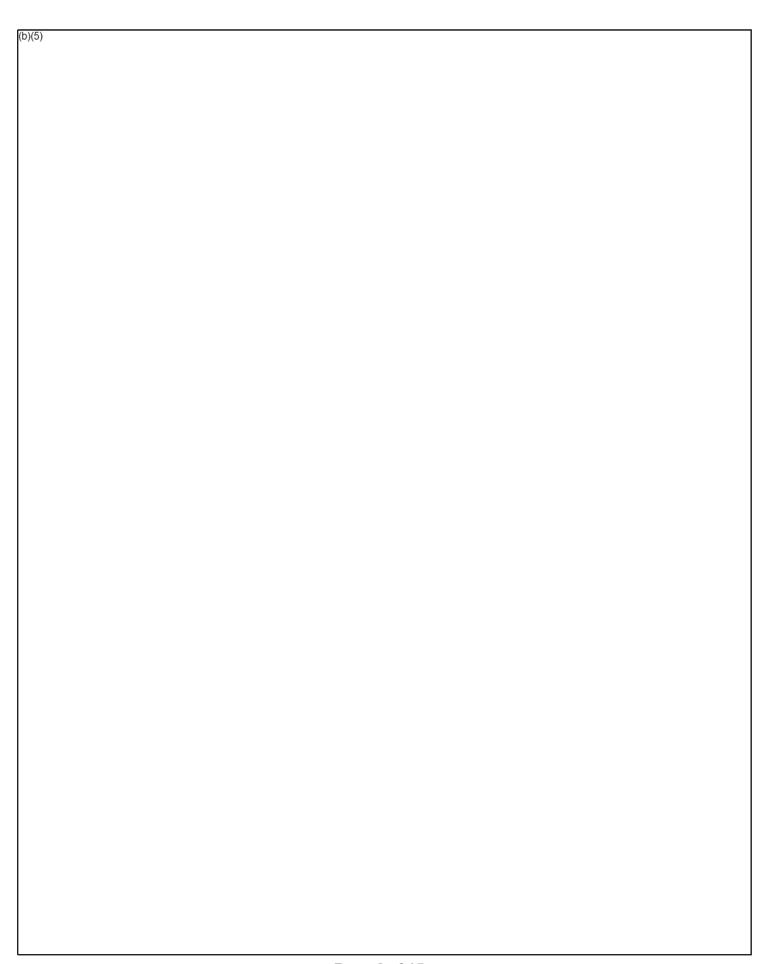
Animal Study Protocol: Tabled to Designated Review

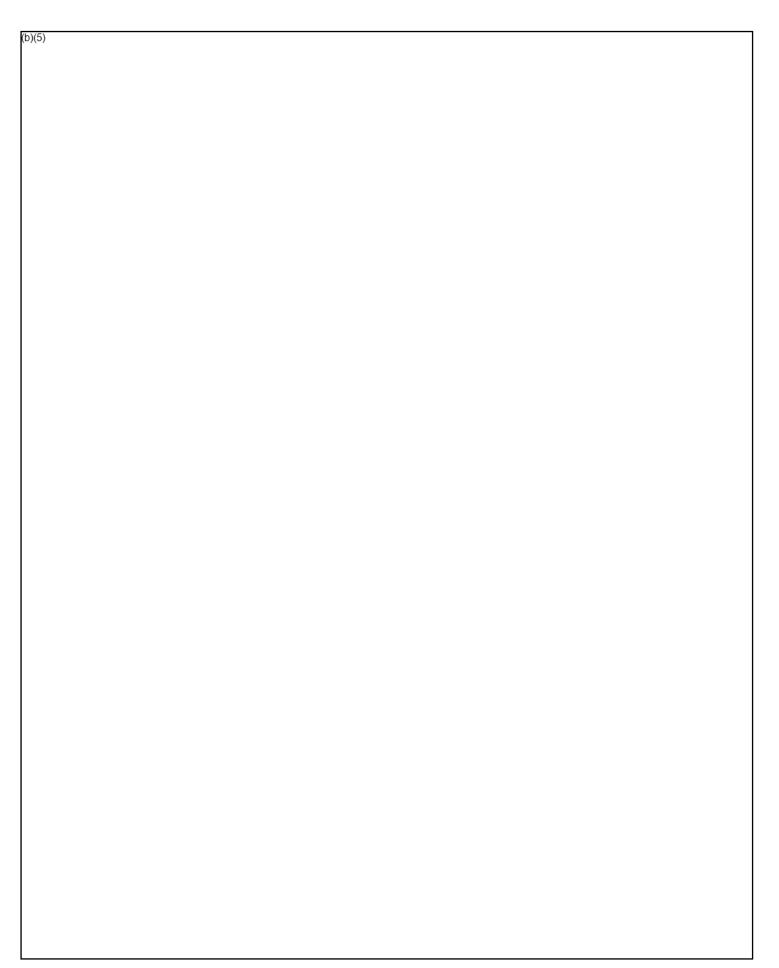
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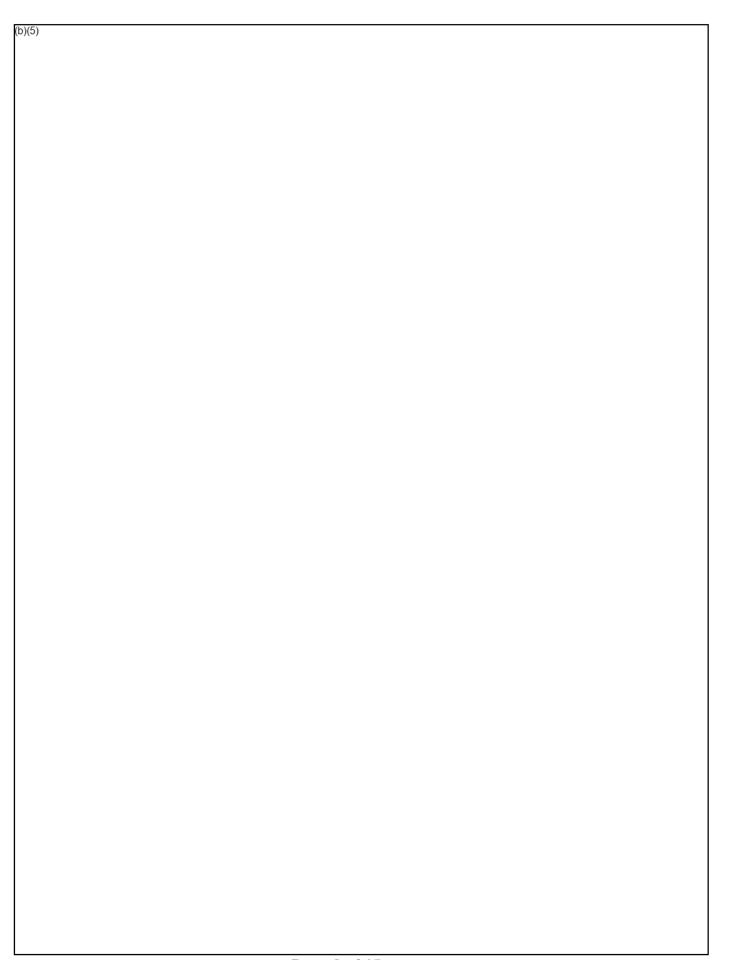


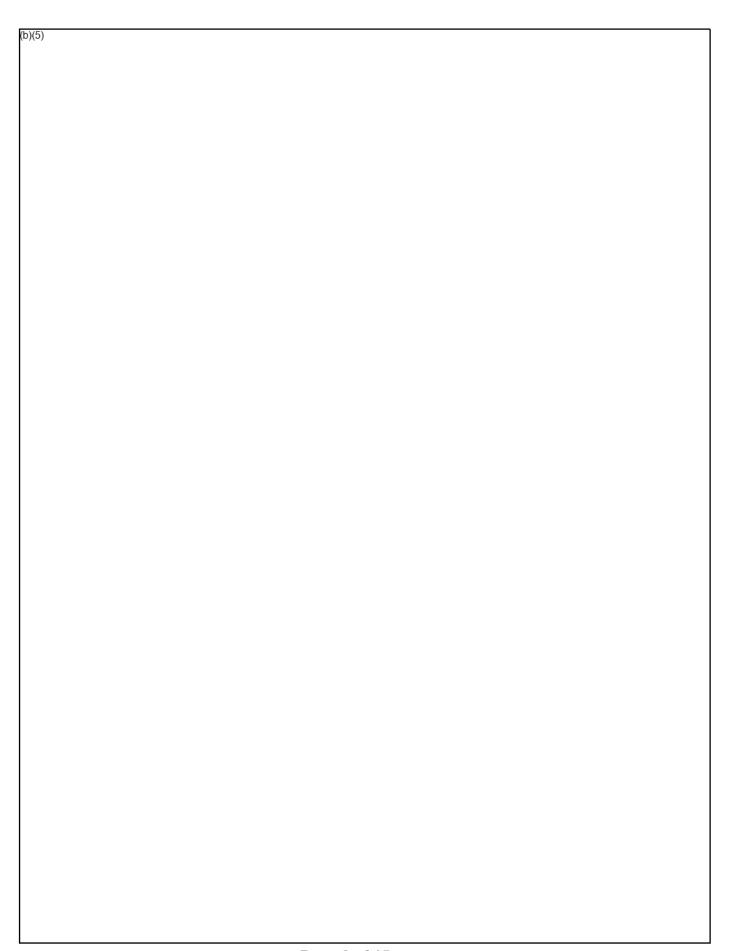


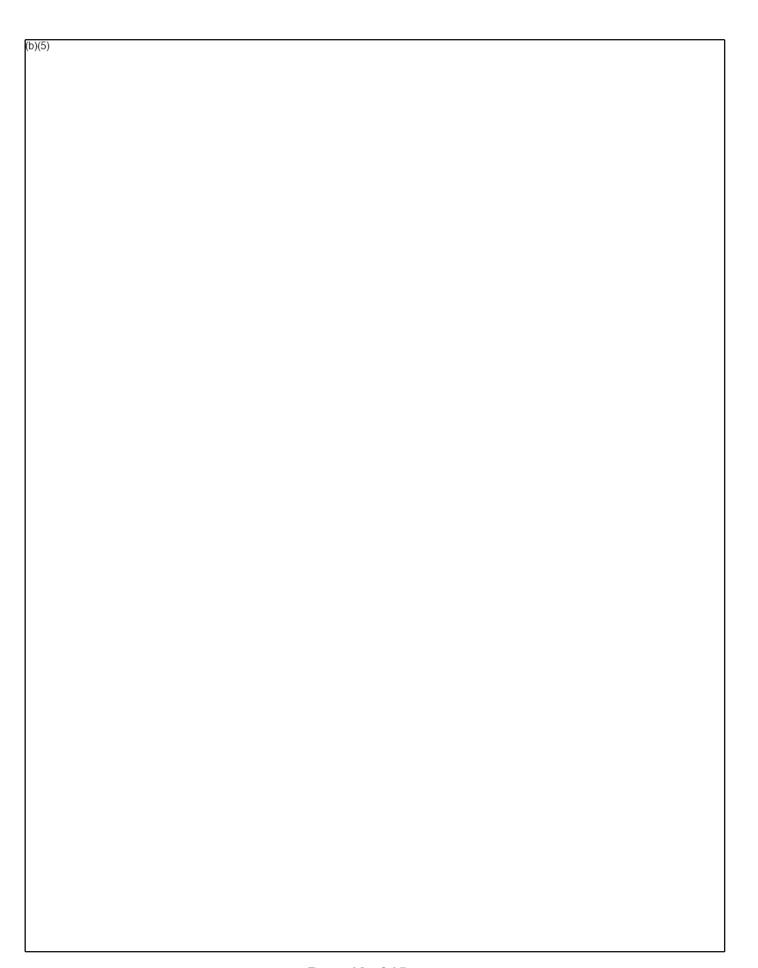


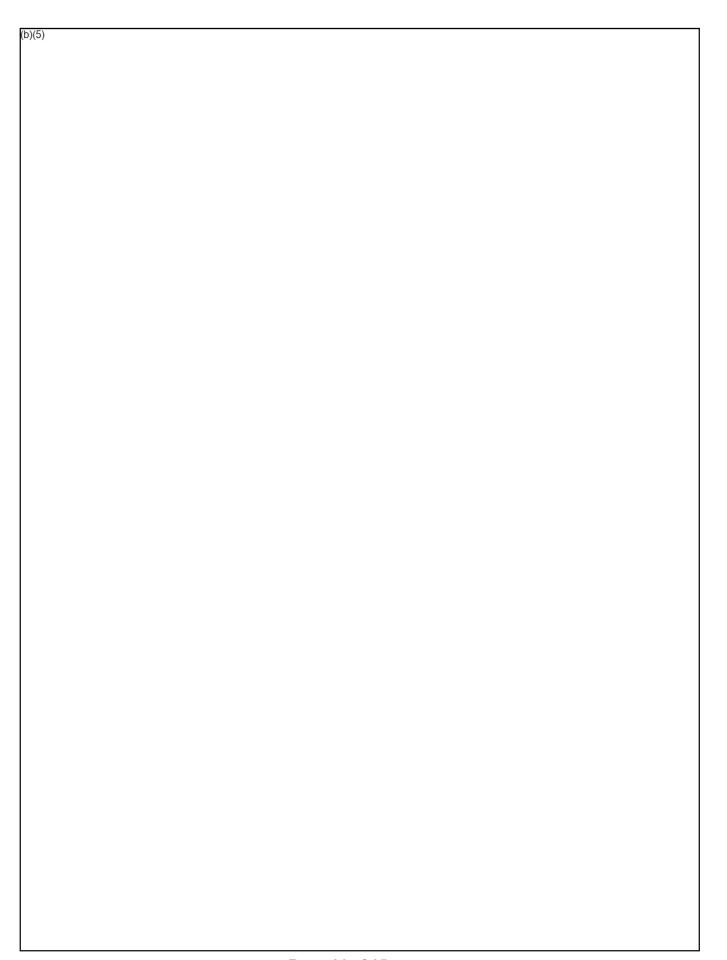


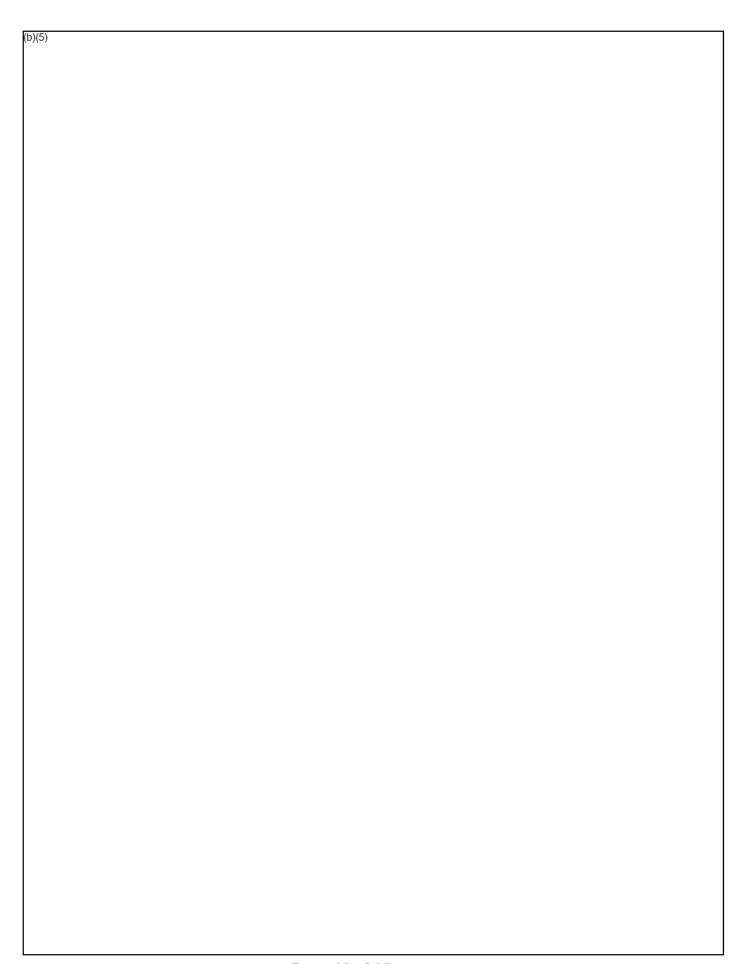


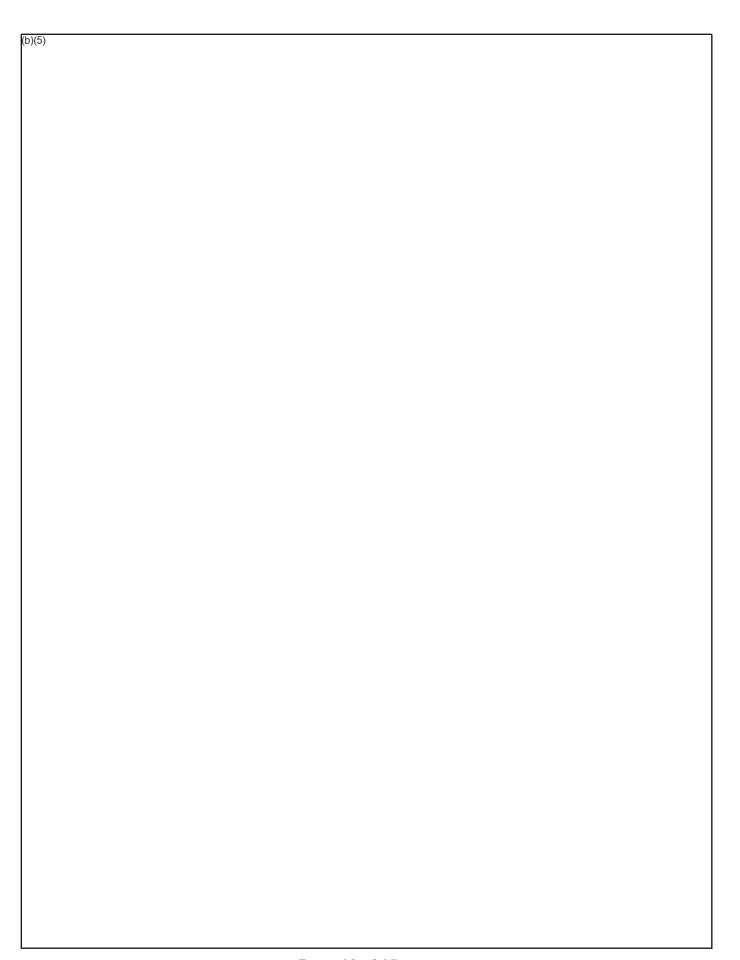


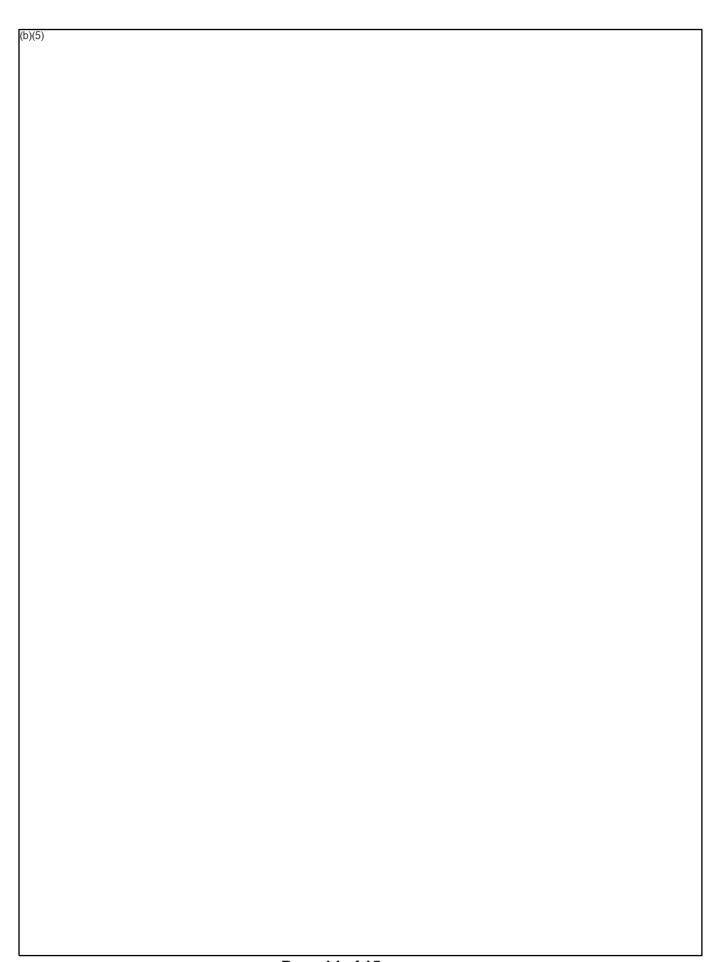












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Animal Study Protocol Amendments: Approved

Neural Coding of Visual Stimuli and Their Relation to Reward

Contingency in the Awake Monkey Redacted by agreement PI)

Meeting was adjourned at 4:06pm

The next meeting is scheduled for August 11, 2020 at 2 pm.

NIMH ACUC Virtual Meeting August 11th, 2020 2:00 P.M.

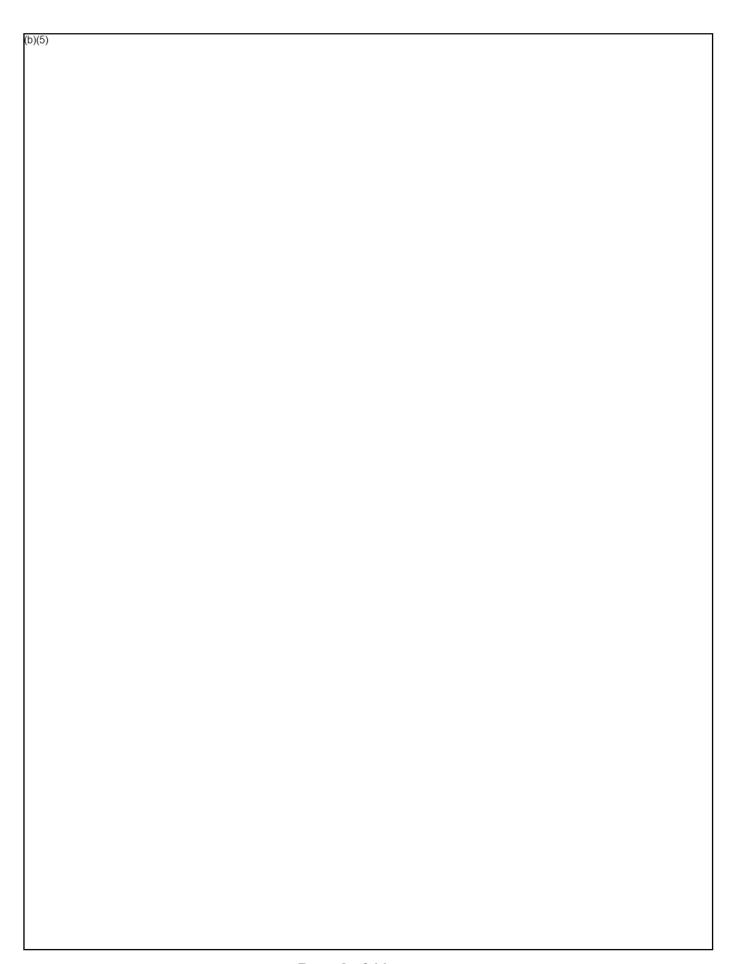
Me	embers Attending: T. Usdin, J. Raber, Redacted by agreement
	Redacted by agreement
N	Redacted by agreement
IVIE	embers Absent:
Vis	Redacted by agreement
Ex	ecutive Secretary:
1.	Approval of Minutes, Review of Designated Items & Committee Correspondences
	Minutes of the July Meeting – Approved
	Minor Amendments Approved in July – Reviewed
	Items Approved via Designated Review during July – Reviewed
	Annual Review and Renewal Memos Sent During July – Reviewed
2.	Reports Redacted by agreement
	Redacted by agreement reported no change to the status of the animal facility.
	B. Primate Report:
	reported that VMRB continues their work on establishing success pairings or animals in both the rhesus and marmoset colonies but that the pairing numbers have not changed significantly.
3.	Old Business
	 Microsoft Teams – Dr. Usdin stated that both of our outside members now have access and we will continue to work on navigating the system as we work to review and edit agenda items on the system so that we do not have multiple revised versions on the site.
4	New Rusiness

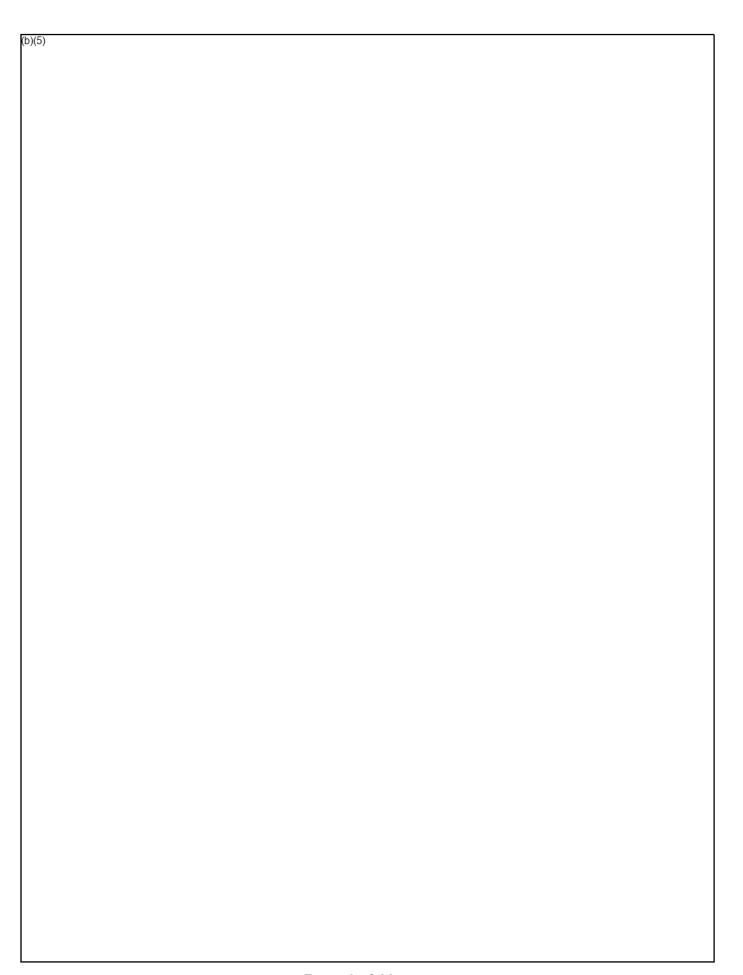
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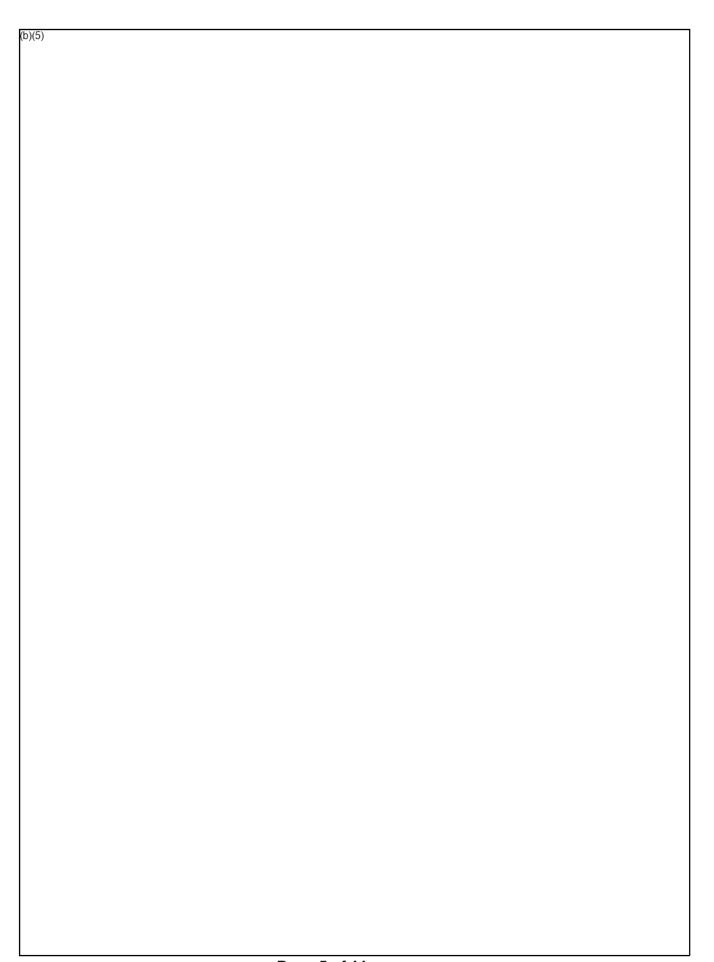
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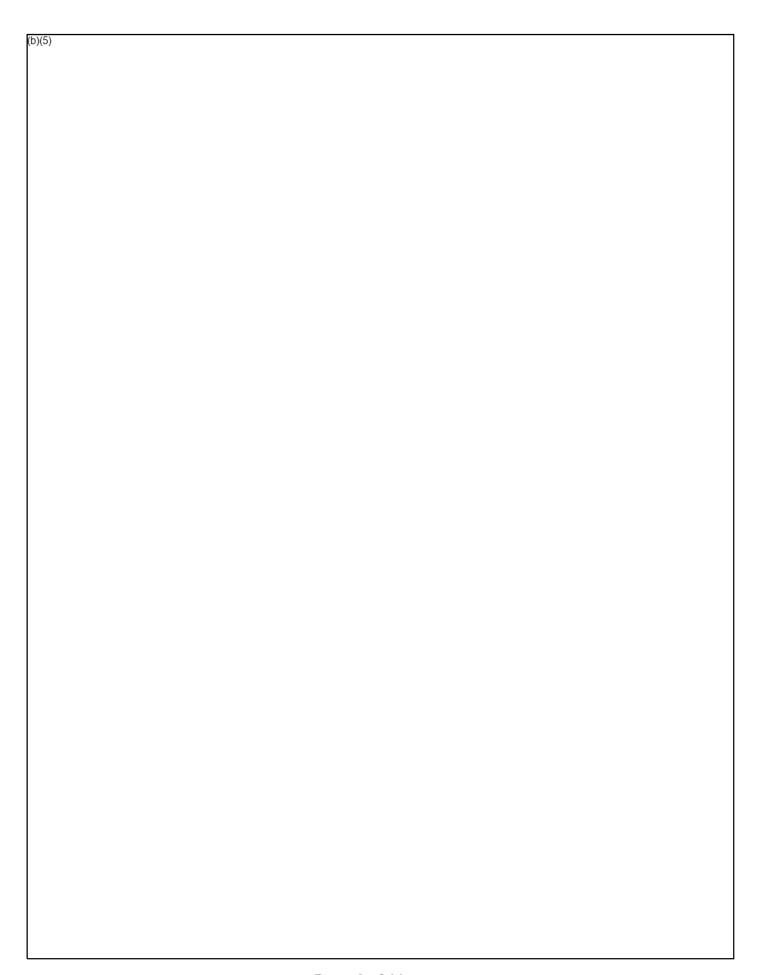
 Targeted Attack and FOIA Requests – Dr. Usdin initiated a discussion of an email that was sent to many NIH employees by (b)(5)

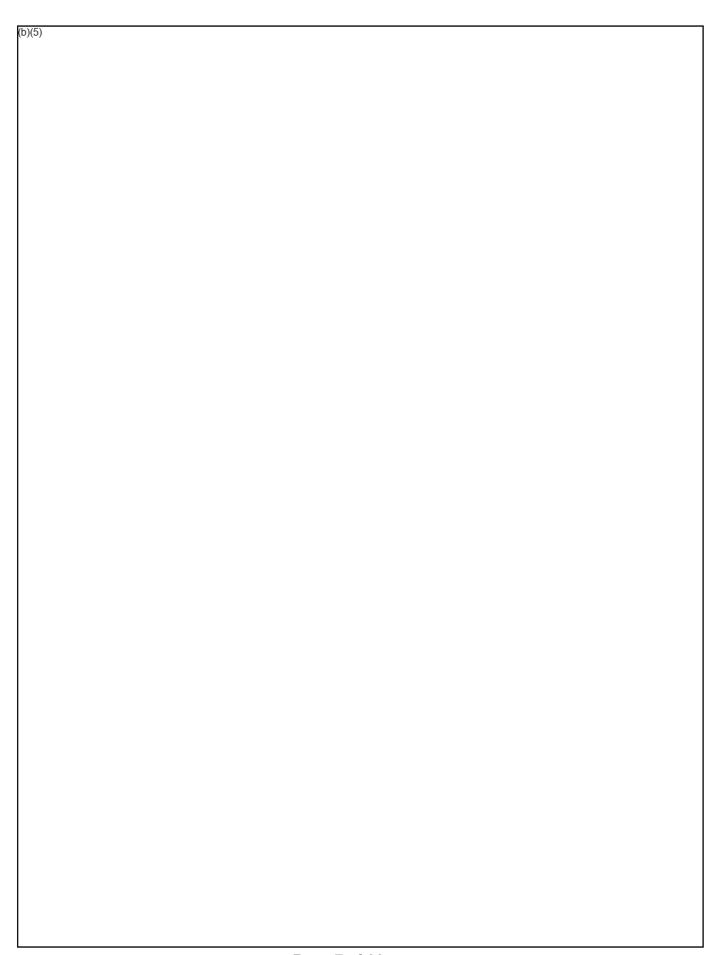
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Dr. Raber stated the New England Anti-Vivisection Society (NEAVS) has sent a FOIA request to several other institutions requesting their most recent AAALAC Program Description. This document provides a very detailed description of an entire program including floor plans, species, types of research, animal numbers, and laboratory locations. NIH has not yet received such a request, (b)(5)
(b)(5)
Animal Protocol and Amendment Review
* Recommendations have been broken down into two categories, "Administrative Recommendations" and "Clarification Items". The identified items in each category are provided below. The "Administrative Recommendations" are highlighted in yellow and the "Clarification Items" are not highlighted. The "Administrative Recommendations" will be made to the original version of the item by the ACUC Executive Secretary using the "Track Changes" feature in Microsoft Word® and forwarded to the PI for their review.
forwarded to the PT for their review.
Animal Study Protocol: Tabled to Designated Review or Full Committee Review Pending Pl Action
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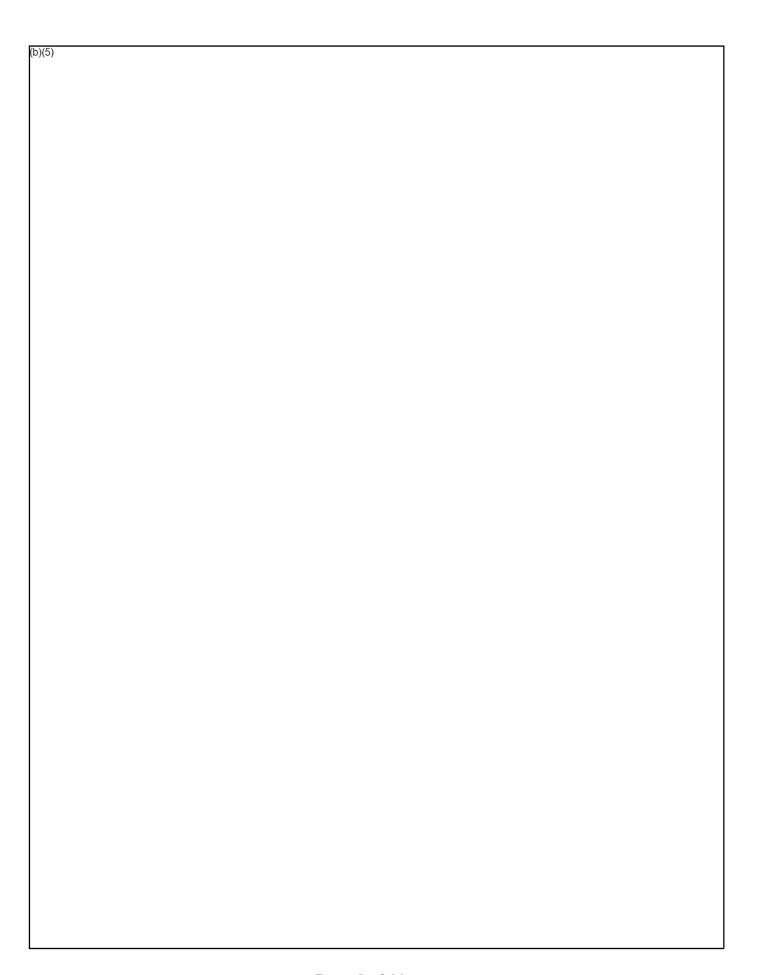


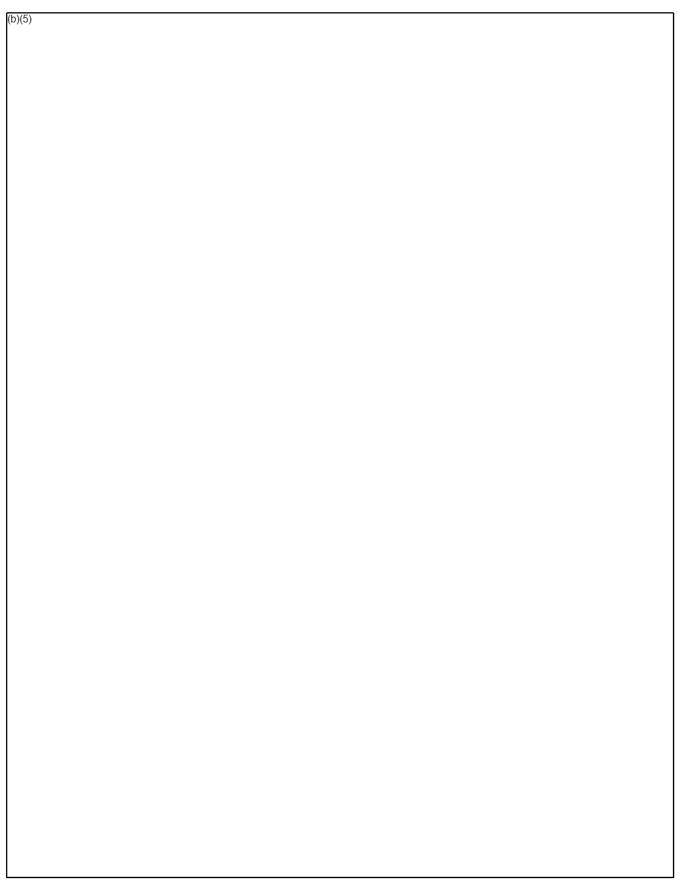






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Meeting was adjourned at 3:37pm.

The next meeting is scheduled for September 8th, 2020 at 2 pm.		

NIMH ACUC Virtual Meeting September 8th, 2020 2:00 P.M.

Me	embers Attending:	T. Usdin, J. Raber		
		Redacted by agreement		
Me	mbers Absent:	Redacted by agreement		
Vis	sitors:	Redacted by agreement		
		<u> </u>		
Ex	ecutive Secretary:	Redacted by agreement		
1.	Approval of Minute	es, Review of Designated Items & Committee Correspondences		
	Minutes of the Augu	st Meeting – Approved		
	Minor Amendments	Approved in August – Reviewed		
	Items Approved via	Designated Review during August – Reviewed		
	Annual Review and Renewal Memos Sent During August – Reviewed			
	Annual Reviews Submitted for Review During August – Reviewed and Approved			
2.	<u>Reports</u>			
	A. Redacted by agreement			
	Redacted by agreement	reported no change to the status of the animal facility.		
	B. Primate Report:			
	Redacted by agreemer	reported that several primates have been move <u>d to the NIH</u>		
	Animal Cente	er to make room for construction that is about to begin in Redacted by agreement		
	move well, bu	s have been moved within Redacted by and appear to be tolerating the at the NIMH Technicians have increased their monitoring of the animals there are no adverse behavioral effects.		
	C. Incident Report (a None	adverse events, reportable incidents, animal welfare concerns):		
3.	Old Business			
	 Smith Review protocol, arra certain protocol 	w of Procedures – As a condition of the reinstatement of Redacted by agreement of Redacted by agreement to observe when col related procedures were conducted. Redacted by agreement asked if the vets		

had been contacted. It was stated that they had not. It was decided that Redacted by would send a reminder to Redacted by agreement egarding this requirement.

4. New Business

•	Fall Semi-Annual Walk Inroughs – Dr. Raber asked the Committee to consider for		
	this Fall's semi-annual review the use of ad hoc reviews for the Redacted by agreement		
	Redacted by agreement animal facilities. The ad hoc		
	reviewers would be members of other ACUC's that would act as our agents and		
	forward their walk thru findings relating to our animals to us. This would help reduce		
	the number of areas our reviewers would have to enter and limit the number of		
	potential COVID related exposures. Our reviewers would still need to inspect our		
	facility as well as all primate laboratories and laboratories where		
	surgery is performed outside of an animal facility. Dr. Raber went on to stated that		
	we would receive the names of the reviewers used by the other institutes and appoin		
	them as ad hoc consultants to our Committee. Any items needing correction would		
	be listed in our semi-annual report and would be our responsibility. The Committee		
	voted to approve the use of ad hoc reviewers for the Fall semi-annual review.		

stated that she would be sending out an email to the Committee to determine possible dates and times when members would be available. One member asked if we could establish narrow windows for the times for the walk thru to allow the laboratories to be empty during the review. Another member stated that we like to have lab member(s) present to answer questions and that both the reviewers and lab members could wear a face shield in addition to a face mask, in addition to being conscious of social distancing requirements.

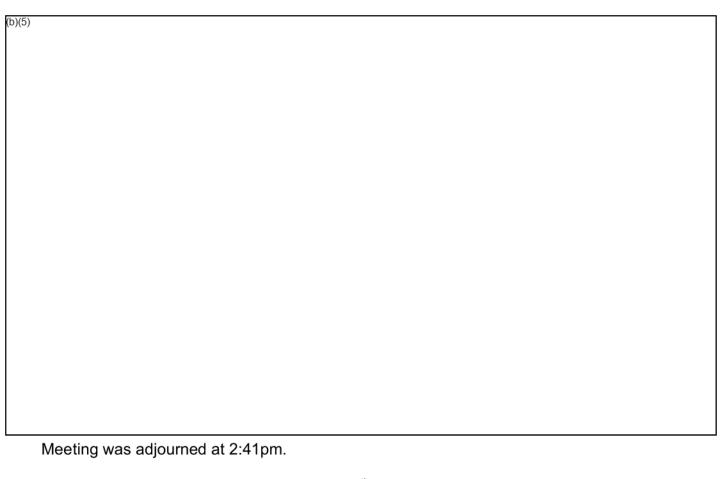
The Committee also discussed the OLAW recommendation regarding the participation of outside members participating on semi-annual reviews. While OLAW did not state that the participation of the outside members was a requirement for all semi-annual reviews, they did stress that they should participate. While our outside members did not participate in the Spring 2020 review due to the OLAW site visit and the reduction of on-campus activities due to COVID-19, our outside members have always been encouraged to participate and have been extremely generous with their time. One or both of them have participated in each of the Spring and Fall reviews since the Fall of 2016.

•	Announcemen	nt - At the end of the	meeting, Dr. Raber ar	nnounced that this will be
	Redacted by agreement	last 4000 i	meeting for a while as	she will be (b)(6)
	(b)(6)	next week. We wish	Redacted by agreement	well and congratulate her
	(b)(6)	ι	1	l

5. Animal Protocol and Amendment Review

* Recommendations have been broken down into two categories, "Administrative Recommendations" and "Clarification Items". The identified items in each category are provided below. The "Administrative Recommendations" are highlighted in yellow and the "Clarification Items" are not highlighted. The "Administrative Recommendations" will be made to the original version of the item by the ACUC Executive Secretary using the "Track Changes" feature in Microsoft Word® and forwarded to the PI for their review.

Animal Study Protocol: Tabled to Designated Review (b)(5)

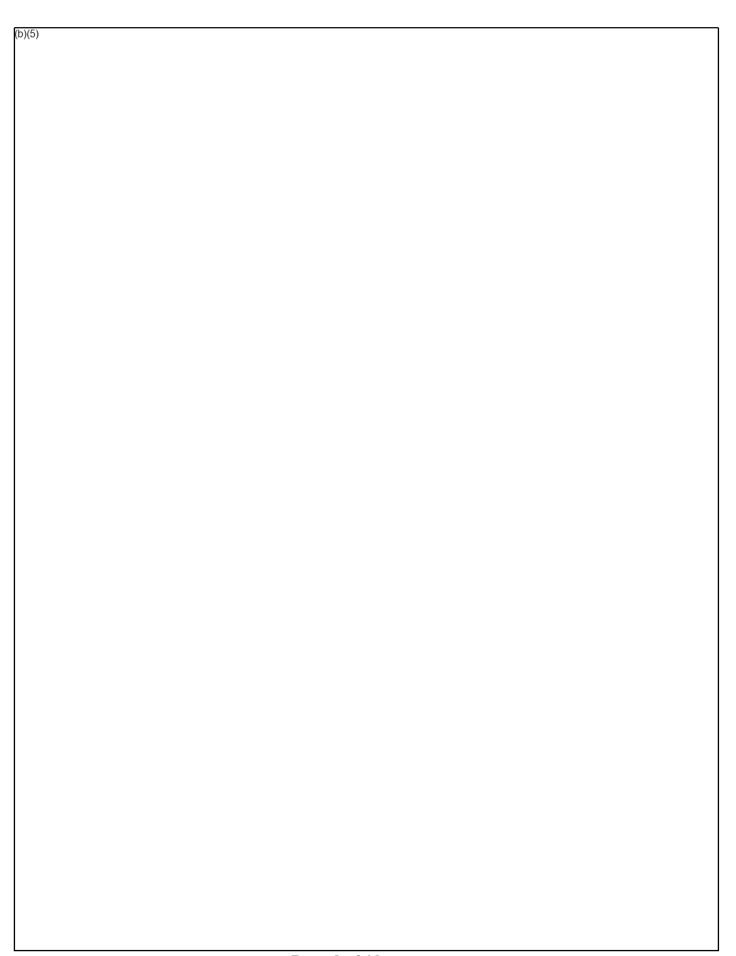


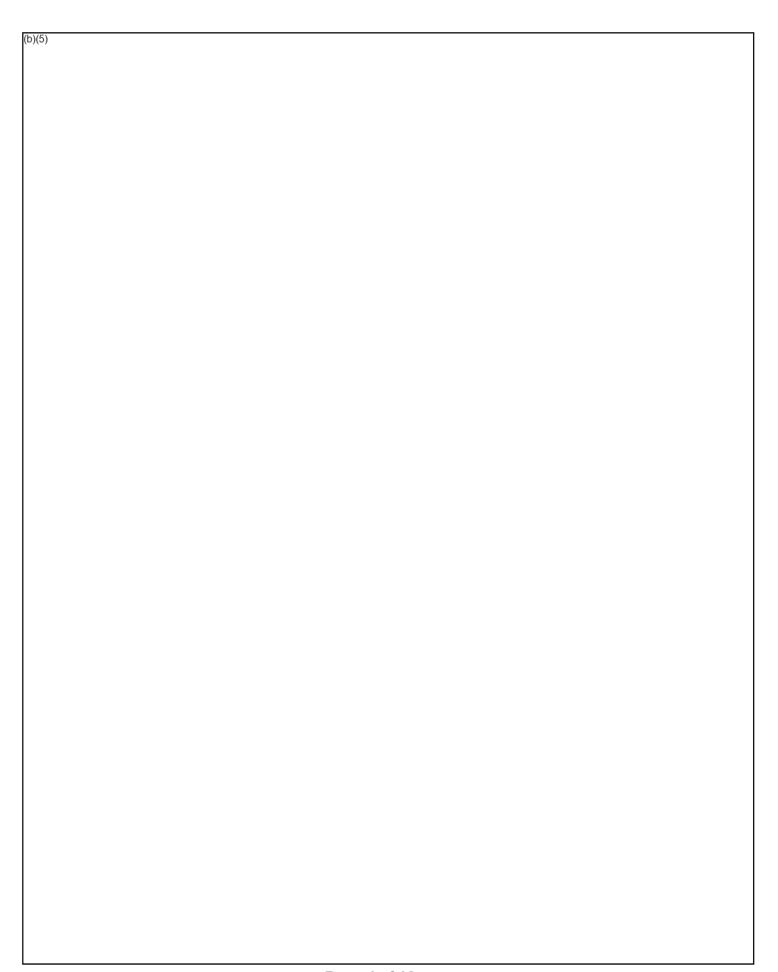
The next meeting is scheduled for October 13th, 2020 at 2 pm.

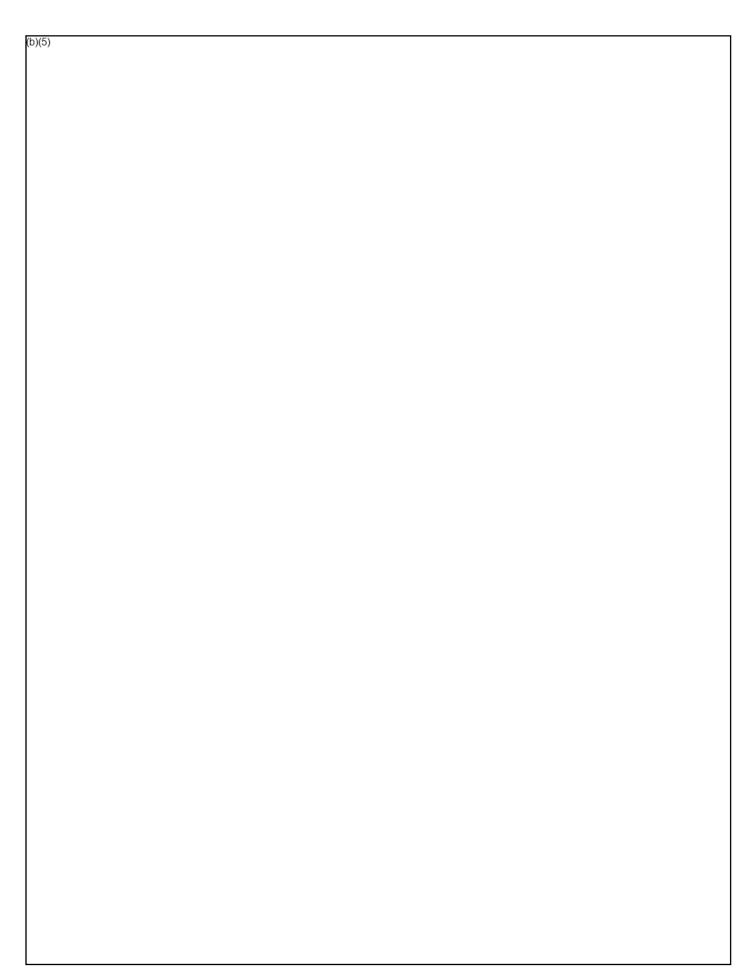
NIMH ACUC Virtual Meeting October 13th, 2020 2:00 P.M.

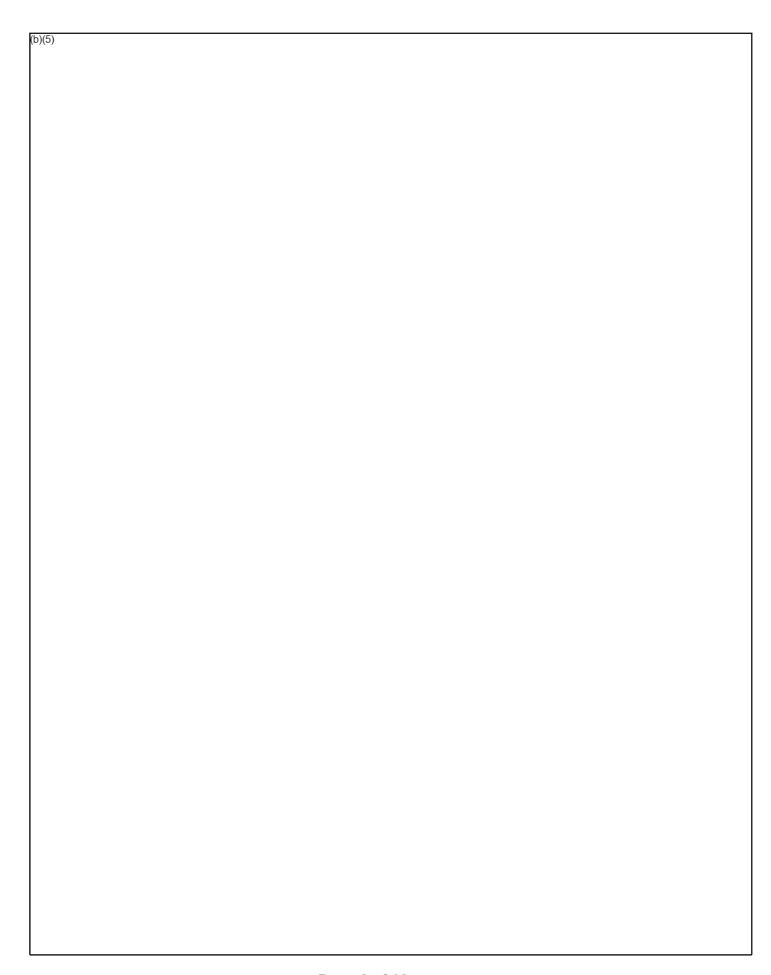
Me	mbers Attending:	T. Usdin, J. Raber, B. Redacted by agreement
		Redacted by agreement
Me	mbers Absent:	Redacted by agreement
Vis	sitors:	Redacted by agreement
Ex	ecutive Secretary:	Redacted by agreement
1.	Approval of Minute	es, Review of Designated Items & Committee Correspondences
••		-
	Minutes of the Sept	ember Meeting – Approved
	Minor Amendments	Approved in September – Reviewed
	Items Approved via	Designated Review during September – Reviewed
	Items Approved via	VVC during September - Reviewed
	Annual Review and	Renewal Memos Sent During September – Reviewed
	Annual Reviews Su	bmitted for Review During September – Reviewed and Approved
2.	Reports A.	
	Redacted by agreement	reported no change to the status of the animal facility.
	B. Primate Report:	
	Redacted by agreement	reported that several primates have been moved to the agreement agreement reported to the green
		The pair housed rhesus monkeys remains at approximately 30% and
		ir or group housed animals is about 70%.
	C. Incident Report (None	adverse events, reportable incidents, animal welfare concerns):
3.	Old Business	
	protocol, arra	w of Procedures – As a condition of the reinstatement of agreement angements were to be made for a NIMH veterinarian to observe when col related procedures were conducted. It was decided at the last ACUC would send a reminder to Redacted by agreement agreement regarding this Page 1 of 16

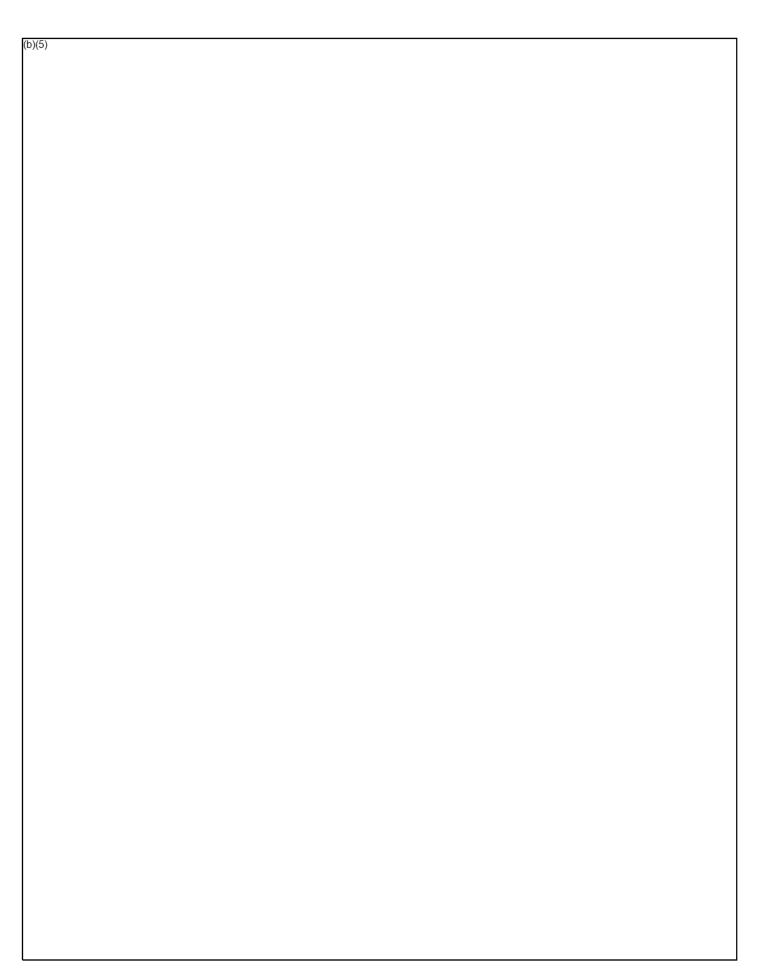
	requirement asked if the vets had been contacted. It was stated that they had not. As of the time of this meeting, no communication has been received from reducted by agreement are being carried out.
	• Fall Semi-Annual Walk Throughs – Dr. Usdin asked for a brief report concerning how the semi-annual walk-throughs had gone. Redacted by agreement agreement had been able to complete the inspection of all laboratory areas and our Redacted by agreement facility. The site visit team was able to review all areas while maintaining social distancing and felt comfortable with their safety and ability to carry out the inspections. In addition to the standard face mask, the group also wore disposable face shields or all-enclosed safety glasses Redacted by stated that the areas for the most part seemed uncluttered and in a good state Redacted by stated that she had received reports from most of the other ACUC's ad hoc appointed teams concerning the other areas reviewed and would send out our report to the Committee for review once all of the ad hoc reports had been received.
4.	New Business
	• Report about the accidental loss of an head implanted mouse – Dr. Raber informed the Committee that he and Redacted by a veterinarian in the Redacted by agreement Facility concerning a mouse that had gotten its head implant snagged in the filter top of a ventilated mouse cage. Animals with head implants are routinely housed in cages without a wire bar feeder to prevent the implant from being damaged. This animal chewed through the filter in the cage lid and get its head caught in the outer mesh work. After some discussion with the veterinarians and the investigator, a stainless-steel plate was designed to be fitted into the lid that will prevent contact with the filter but not impede air flow. After discussion, the Committee determined that the measures being taken are an appropriate step to prevent further occurrences and that no action by the ACUC is necessary at this time.
5.	Animal Protocol and Amendment Review
	* Recommendations have been broken down into two categories, "Administrative Recommendations" and "Clarification Items". The identified items in each category are provided below. The "Administrative Recommendations" are highlighted in yellow and the "Clarification Items" are not highlighted. The "Administrative Recommendations" will be made to the original version of the item by the ACUC Executive Secretary using the "Track Changes" feature in Microsoft Word® and forwarded to the PI for their review.
	Animal Study Protocol: Tabled to Designated Review
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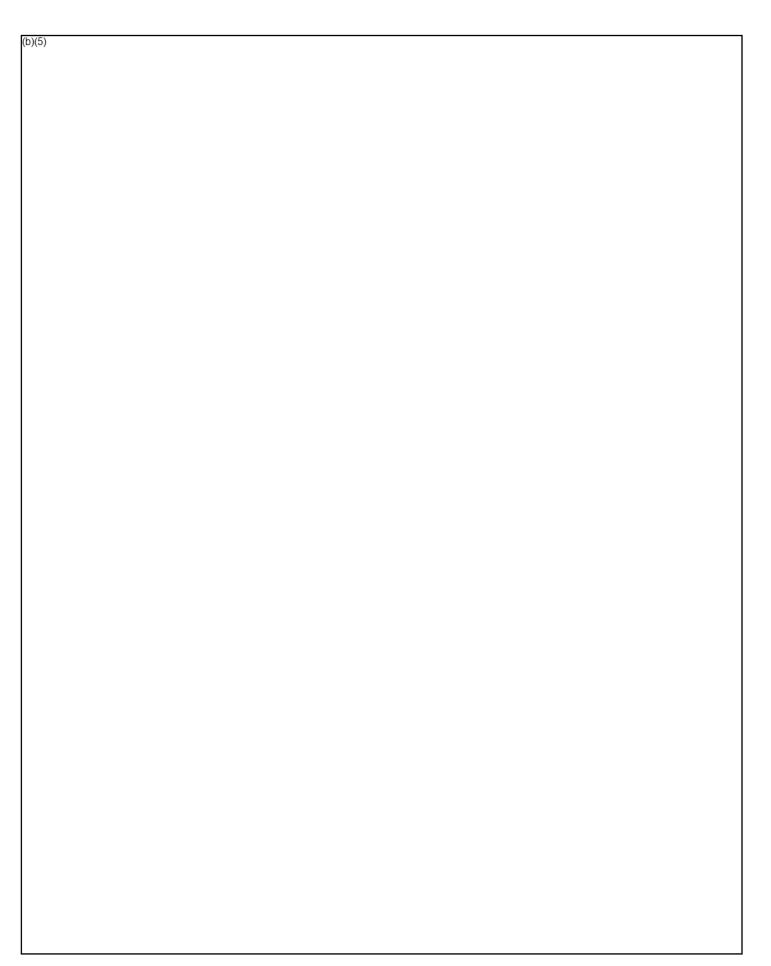


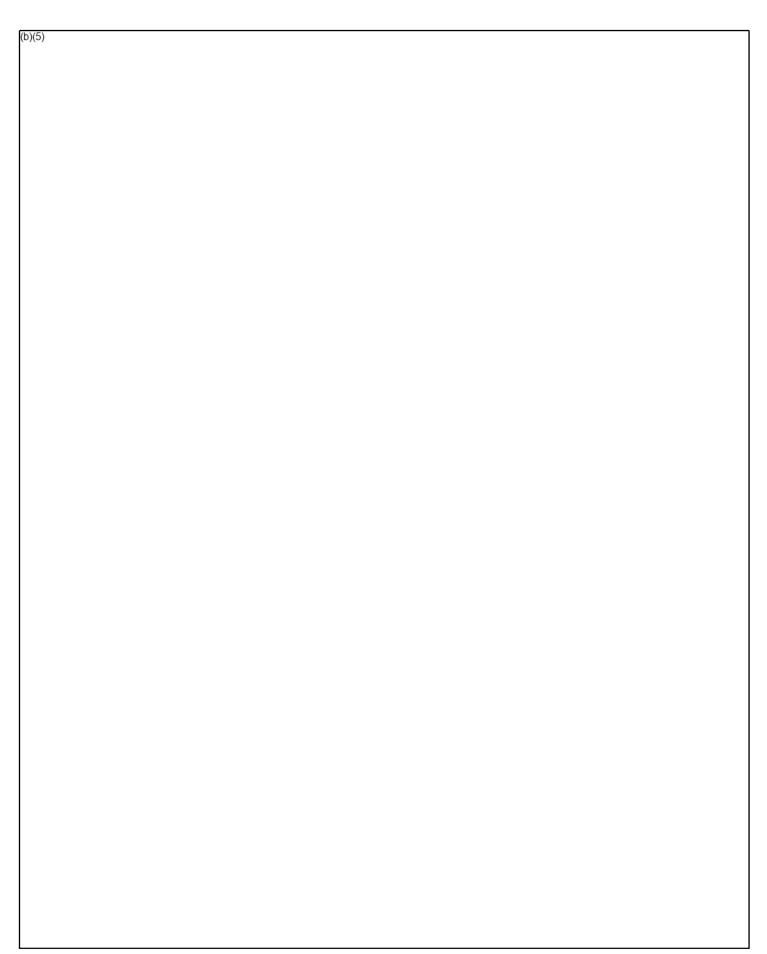


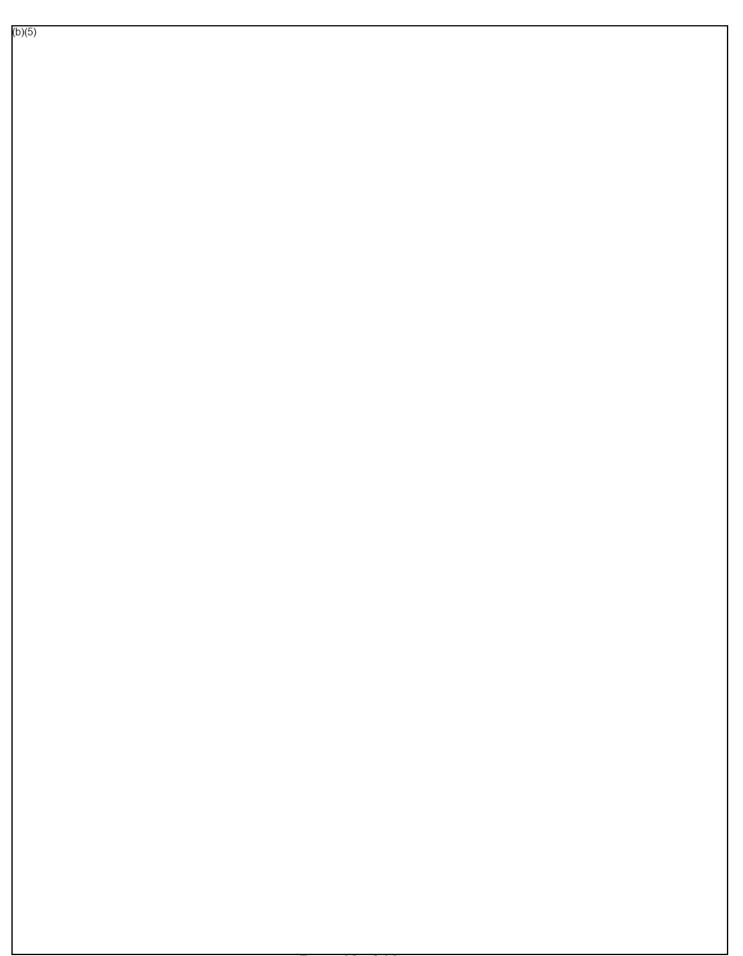


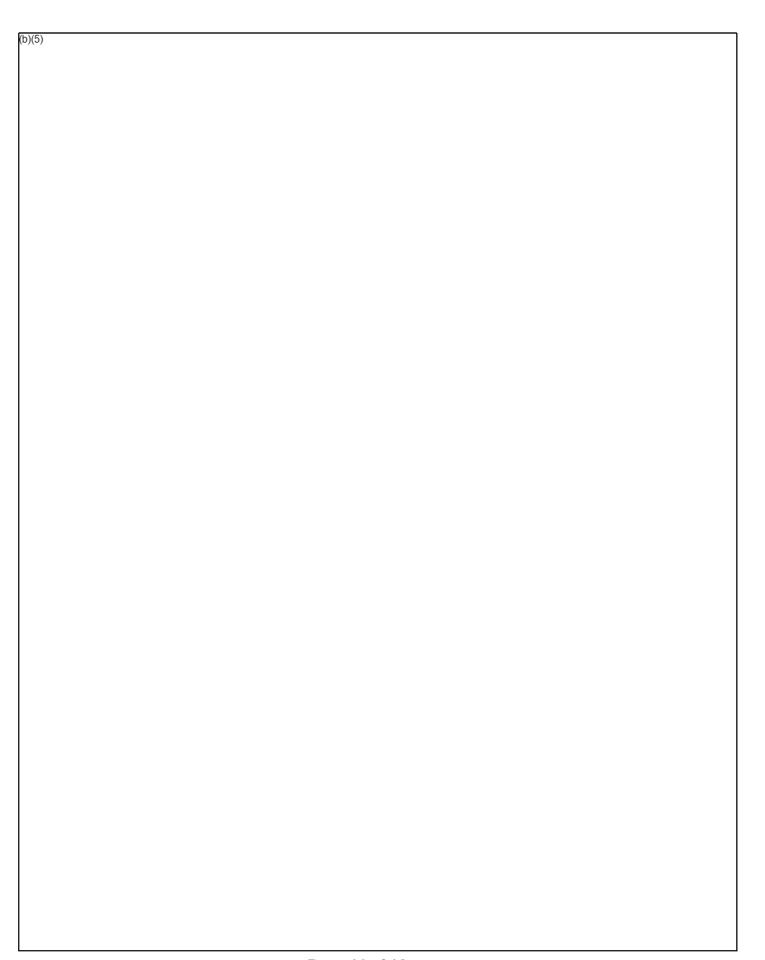


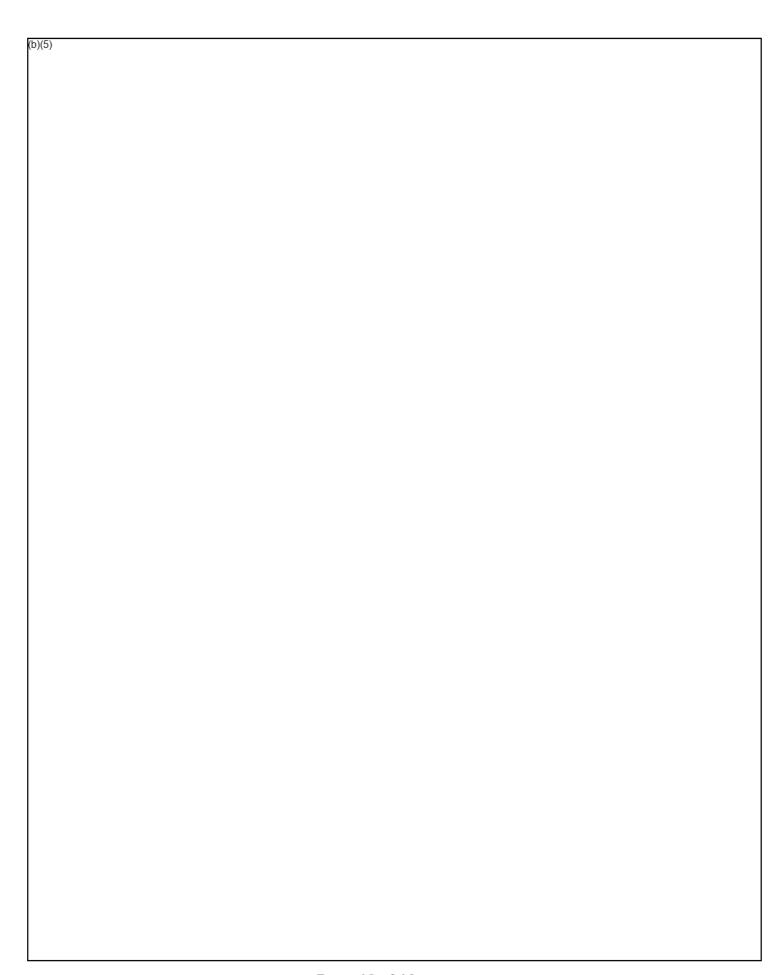




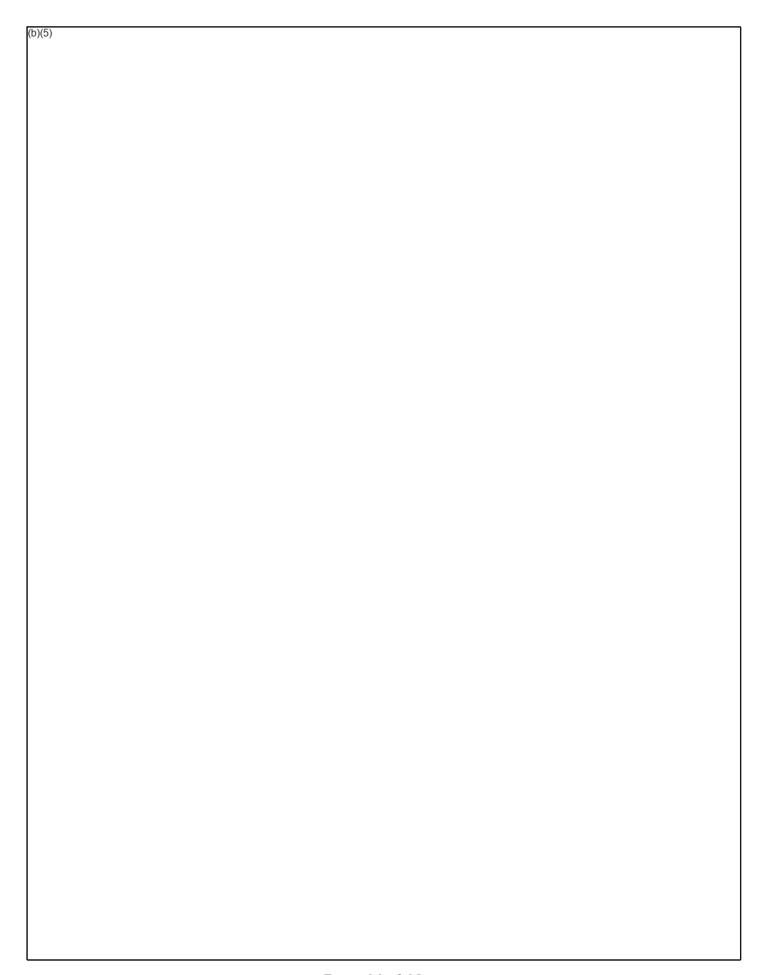




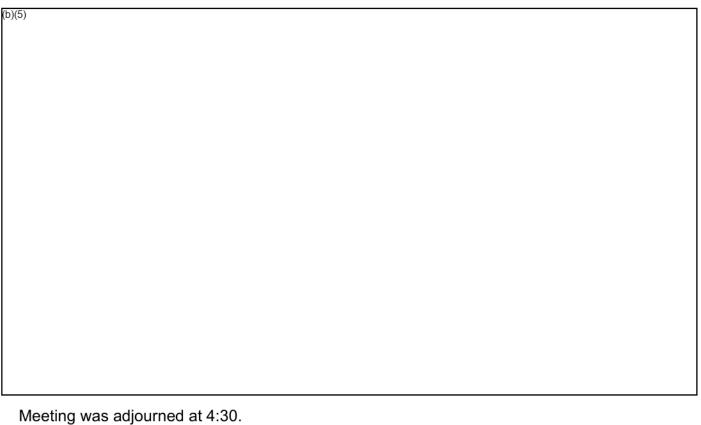




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Animal Study Protocol Amendments:	Tabled to Designated Review
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The next meeting is scheduled for November 10^{th} , 2020 at 2 pm.