

Meeting Date: September 20, 2007

Members Present:	J. Angelosante	D. Fitts	I. Washington
	S. Cunningham	T. Brabb	R. Murnane
	S. Skerrett	D. Lee	V. Batterson
	M. Slosberg	S. Kelley	C. Baker
	P. Fink		

Members Absent:	G. McLean	L. Hajar	N. Phillips
	W. Dickhoff	J. Kauffman	

Opening Business:

Dr. Cunningham called the meeting to order at 2:34pm.

Dr. Cunningham called for the approval of the August 16, 2007 IACUC meeting minutes. Dr. Batterson moved to approve the minutes and Dr. Brabb seconded the motion. The minutes were approved with 11 members voting in favor. Dr. Washington was not present for the vote.

Attending Veterinarian's Report

- ❖ As part of the July 19, 2007 IACUC meeting the Committee voted to require that Dr. D'Ambrosio meet with the Attending Veterinarian to discuss the need for veterinary consultation prior to implementing changes for animal welfare, and to review the role of the veterinarians and how he should be utilizing that resource. Since that meeting Dr. Brabb spoke with Dr. D'Ambrosio on the phone and discussed consultation with her or veterinary services prior to changing procedures that are likely to affect the animals. Since this discussion, he has consulted with Dr. Brabb on several issues.

- ❖ IACUC #4065-01, "MMPs in Lung Injury"- Dr. Parks:

Dr. Brabb explained that this group studies atopic dermatitis in mice. As part of their research, they apply bandages to hold antigen-impregnated gauze on the backs mice. In this case, they put the bandages on too tight and the majority (17/20) of the mice did not recover from anesthesia. Veterinary services met with the group and discussed the procedures and simpler ways to hold the gauze in place. They started a new cohort on Monday and everything went well. Dr. Brabb reported this incident to OLAW.

Veterinary Monitoring:

- ❖ IACUC #4156-01, "Mitogen Activated Protein Kinases: Role of Signal Transduction in Wound Healing and Infection" - Arbabi:

This project is the only active protocol on monitoring during the last two months. The veterinarian is still working with the group on anesthetic and analgesic administration. The last cohort of six mice had no anesthetic-related issues and made it to their end point.

Executive Secretary's Report - No report

Protocol Review:

❖ IACUC #2896-01, "1) Neural Coding Vision 2) Neural Mechanism of Visual Perception 3) Howard Hughes Medical Institute" Dr. Shadlen

Dr. Brabb presented the following Significant Change Requests for two animals on this protocol.

1) Animal #A03074

Dr. Brabb explained that the purpose of this research is to understand the function of neural circuits in the cerebral cortex focused on visual pathways. Each animal is highly trained and the information gained is cumulative such that the scientific importance of each animal is great.

This animal has received two experimental surgeries (eye coil, head post, chamber). It had one clinical surgery to repair a dehiscence associated with the first surgery, and one repair surgery to replace an eye coil.

Motion: Dr. Brabb moved to approve this animal for one repair or clinical surgery as indicated. Dr. Murnane seconded the motion.

Discussion Regarding the Motion: None

Vote on the Motion: This motion was approved with 11 members voting in favor. Dr. Washington was not present for the vote.

2) Animal #A07004

Dr. Brabb explained that the purpose of this research is to understand the function of neural circuits in the cerebral cortex focused on visual pathways. Each animal is highly trained and the information gained is cumulative such that the scientific importance of each animal is great.

This animal has received one experimental surgery for implantation of an eye coil. The investigator is planning to do second experimental surgery to place a recording chamber (chamber implant approved as part of the original PRF). The existing eye coil is currently working, however, the investigator is asking for permission to replace that eye coil if it is not working at the time of the surgery for placement of the recording chamber. The PI already has approval to repair the eye coil. The purpose of this request is to repair the eye coil if necessary, during the chamber implant surgery. Additionally, the investigator is asking for a second as yet undefined clinical or repair surgery.

Motion: Dr. Brabb moved to approve an eye coil replacement surgery for this animal at the time of the chamber implantation and one surgery clinically indicated in the future. Dr. Batterson seconded the motion.

Discussion Regarding the Motion: Dr. Cunningham commented that the Committee usually only approves one surgical request at a time. Dr. Murnane commented that he thought the request to replace the eye coil if necessary during the planned chamber implant surgery made sense in that they could perform two procedures during one surgery rather than in two separate surgeries. Dr. Cunningham replied that she thought that the rationale made sense, but had an issue with approving two surgery requests at one time when the Committee normally only approves one request at a time. General discussion followed regarding the approval process for surgical requests in accordance with current practices.

Vote on the Motion: This motion was approved with 8 members voting in favor and 4 members opposed.

❖ IACUC #2326-08, "Spinal Interneurons Controlling Voluntary Limb Movements" - Dr. Fetz

Dr. Brabb presented the Significant Change request for animal #M02375.

Dr. Brabb explained that this animal is part of a research protocol which is designed to develop treatments for spinal cord injury and stroke. The group is testing a method whereby signals from the brain are re-connected to peripheral nerves and muscles through artificial circuits. In order to study the monkey's ability to use brain activity to overcome paralysis, they induce temporary paralysis of the hand and arm by injecting a local anesthetic into implanted nerves cuffs or catheters.

The purpose of the significant change request is to perform a surgery to repair nerve cuffs placed around the radial, ulnar and median nerves.

The investigator would like to continue with this animal because it has been successfully using brain activity to control muscle stimulation during the nerve block for several months. Additionally, the animal has been recently implanted with chronic electrodes in the motor cortex.

This animal has had five previous experimental surgeries. On August 20, 2007, the PI submitted a request to remove and/or repair currently implanted nerve cuffs. On September 13, 2007, prior to IACUC approval of the PI's request, an emergency clinical surgery was performed to remove the nerve cuffs because they had developed tissue reaction. As a result, the August 20, 2007 significant change request was withdrawn and replaced with the revised significant change submitted September 14, 2007, which is under review today. The investigator felt that based on the amount of connective tissue observed on the nerves, they may need to use their IACUC approved alternate method of inducing nerve blocks in the next surgery. This alternate procedure involves placing small catheters in the epineurium of the radial, ulnar and/or median nerves at the next level of the brachial plexus. Dr. Brabb spoke with the clinical veterinarians taking care of this animal, and they told her that they would not allow another surgery until the current surgical site is completely healed.

Motion: Dr. Brabb moved to approve animal #M02375 for a nerve catheter repair when the veterinary staff at the primate center feels it is appropriate for the animal. Additionally, because the surgery is scheduled to occur within 2-4 weeks, Dr. Brabb also moved to approve this animal for one future clinical or repair surgery as required. Dr. Batterson seconded the motion.

Discussion Regarding the Motion: Dr. Washington commented that she does not have a problem with the request itself, but did not feel that it is consistent with current IACUC procedures. Dr. Brabb replied that she felt that this situation was a little different in that the Committee is approving a specific surgical procedure and also approving a non-specific general surgical repair or clinical surgery. Dr. Brabb confirmed that if the Committee only approved the nerve cuff surgery, then the investigator will need to ask to have the 2nd repair approved in the next meeting. Dr. Brabb further commented that the IACUC usually requests that the PIs have one repair in the bank. Dr. Murnane said that the purpose of the policy is that we evaluate each case individually. Dr. Brabb read the policy and explained that it does not specifically state that they can only ask for 1 surgery. Dr. Brabb further commented that the policy needs to be refined to address the issues associated with clinical surgeries. She is going to revise the policy for IACUC consideration.

Vote on the Motion: This motion was approved with 9 members voting in favor and 3 members opposed.

❖ **IACUC #3252-01 "Strategies to Improve Hematopoietic Stem Cell Transduction" - Dr. Kiem**

Dr. Batterson presented a summary of the protocol highlighting areas that required additional information or clarification.

Motion: Dr. Batterson moved that she be assigned as the designated reviewer under the Designated Reviewer Method. Dr. Fitts seconded the motion.

Discussion Regarding the Motion: The Committee discussed the following issues regarding the protocol:

1) Justification of animal number – The PI requested additional animals in the event of animal mortality. Dr. Brabb explained that she did not think that mortality was expected. Dr. Fitts commented that the PI needs to only ask for the number of animals that they require for their study, excluding the animals requested for replacement in the event of mortality.

2) Disposition of animals upon completion of their study procedures. The protocol indicated that the animals would be returned to stock after conclusion of study procedures. Dr. Kelley explained that the animals are not returned to stock. He thought that the group meant that the animals go into a "holding" status in the colony while they are determining the long term effects of their research.

3) Better description of study procedures for different groups of animals. Dr. Brabb explained that the protocol is very complex, and it is difficult to determine what happens to each group of animals from the start of the study to completion.

Mortality

1) Dr. Batterson explained that the protocol does not indicate that there has been any past mortality however, Dr. Murnane said that animals had been euthanized as part of this project and this information should be included in the 3 year renewal.

Dr. Fitts suggested that a Subcommittee be appointed to review the protocol.

Modified Motion: – Dr. Batterson moved that she be assigned as designated reviewer to approve the protocol under the Designated Reviewer Method and that a subcommittee of Dr. Kelley, Dr. Murnane and Mr. Slosburg be appointed in an advisory role to Dr. Batterson to review the revised protocol.

❖ **IACUC #2195-09 "Sexually Transmitted Disease Prevention – Primate Unit" - Dr. Patton**

Virginia summarized the significant change request. The purpose of the study is to study the effects of candidate microbicides on vaginal tissues and against Chlamydia and trichomoniasis infections using non-human primates. The purpose of the Significant Change is to include mating as part of their protocol. The investigator feels that this is important aspect of the protocol as they are studying the spread of sexually transmitted diseases.

Motion: Dr. Batterson moved to approve the significant change request. Dr. Kelley seconded the motion.

Discussion Regarding the Motion: Dr. Batterson commented that the justification of animal number is problematic. The investigator has asked for one amount of animals and the Study Section has requested for additional animals to be added to the grant. Dr. Kelley commented that the animals may exhibit mating behavior but they may not actually mate, so it is difficult to determine how many animals they will actually require. Dr. Batterson confirmed that this is an issue the group is facing. They are able to determine how many animals are required to test their agents, but don't know how many animals they will need to pair before mating is achieved. The actual number of animals required for the study needs to be determined. Dr. Brabb commented that it's okay if they don't know how many animals they will require for mating purposes, but they do need to determine how many animals they need to evaluate following a successful mating. Dr. Washington asked about the disposition of offspring resulting from the mating. Dr. Kelley replied that they are going to return any offspring to the colony. The Committee agreed that this should be added to the protocol.

Modified Motion: Dr. Batterson moved that she be assigned as designated reviewer and that Dr. Fitts be assigned as the back up reviewer to approve the protocol under the Designated Reviewer Method once adequate clarification regarding the noted issues has been received. Dr. Fitts seconded the motion.

Vote on the Motion: This motion was approved unanimously with 12 members voting in favor.

The meeting was brought to a close at 3:39pm.

The floor was opened to public comment.