

Informational IACUC Brief for the Hegde Complaint

Dr. David Stepp and Dr. Michael Brands, as past and current chair, respectively, of the Institutional Animal Care and Use Committee (IACUC), provide the following information for clarification of issues related to the complaint filed by Dr. Jay Hegde.

Reason for not being present at the hearing

The IACUC is a federally constituted body charged with the protection of research animals from inappropriate pain and distress. The Animal Welfare Act (AWA) insulates the IACUC from reprisal by institutions or individuals seeking to coerce the use of animals in violation of standards of good conscience and veterinary care. Accordingly, the use of institutional oversight, including university grievance mechanisms, to alter the decisions or challenge the conclusions of the IACUC, is in violation of the AWA. Because our participation in this process inappropriately empowers this committee to question the decisions of the IACUC, Drs. Stepp and Brands respectfully decline to appear today. For the committee's information, we have provided a statement documenting decisions made and actions taken to date for your consideration.

Role of the IACUC on campus

The Animal Welfare Act requires registered research institutions to appoint an IACUC which "serves as the agent of the research facility that ensures that the facility is in full compliance with the Act." All PHS-funded research also requires IACUC approval of the research. Federal law, regulation, and policy place the IACUC in a pivotal position as the institutional regulatory body that ensures animal welfare

Specific Issues Relative to Dr. Hegde's Complaint

1) The loss of the non-human primate Ovetchkin in January 2014

Dr. Hegde requested the surgery January 2014 and received veterinary approval to proceed. Dr. Hegde contracted the services of Dr. Charles Gray of Montana State University to assist him in the surgery. Dr. Gray failed to obtain the required TB screening in advance. The IACUC coordinated a last minute TB screening at 9 AM the day of the procedure to avoid having to cancel the surgery.

Communication failure between Dr. Hegde and LAS resulted in Ovetchkin being sedated and prepped for surgery at 6 AM. Upon realizing that Dr. Gray's TB status had yet to be determined, the staff stopped the procedure and allowed Ovetchkin to recover. When Dr. Gray was cleared at 9 AM, Dr. Hegde requested the animal be re-anesthetized and to resume surgery. The vet staff supported Dr. Hegde's request and they proceeded with surgery. Dr. Hegde's team were the primary surgeons and LAS

staff provided surgical support. As the surgery concluded, the animal's condition deteriorated and he was lost during, or shortly after, recovery.

Dr. Hegde expressed concerns about whether the LAS staff had contributed to Ovetchkin's death and Dr. Stepp, as the IACUC Chair, assembled a subcommittee to review the case. Three IACUC members reviewed the surgical record, the necropsy report and the relevant portions of the protocol. Dr. Stepp also sent these documents to an external reviewer, and he interviewed the vet staff as well. No individual was considered responsible and the incident was considered an accident.

The external reviewer recommended that, while he did not consider this an event warranting a formal report to OLAW, in the interest of being overly sensitive to compliance concerns that we self-report verbally in a phone call to their office. Dr. Stepp called OLAW and offered a formal report if they thought it was needed. They concurred with the conclusions of the subcommittee and commended the actions taken. The affected parties and the IACUC were notified by email on February 27th, 2014).

The IACUC then considered this regrettable matter closed. At that point, neither Dr. Hegde nor anyone else had offered tangible evidence of wrong-doing by any party involved (the Hegde team or the LAS Team). Indeed, Dr. Hegde had offered no correspondence to the IACUC or the chair of any sort.

2) Allegation that the Non-Human Primate, Crosby, was removed in retaliation for the loss of Ovetchkin

Dr. Hegde's experiments use a well-established practice of restricting food intake to motivate his experimental animals to perform assigned tasks in his experiments. The Attending Veterinarian has clinical authority to determine whether animals' health is at risk and can stop the food restriction and/or make recommendations to the IACUC regarding use of the animals in the experiment. Because the IACUC's primary purpose is to protect animal research subjects, it has no authority to override clinical decisions of the veterinarian, especially in emergency situations.

Crosby was pulled from study by Dr. Monterosso, who cited concerns for the animal's health due to emaciation. At the next convened meeting, the IACUC asked Dr. Monterosso for an update on Crosby's condition. Dr. Monterosso outlined a clinical plan for the animal, including reaching what his staff considered a normative body weight and condition. He invited the IACUC to observe Crosby's next physical and the chair agreed to be the representative. During that physical, Dr. Stepp concurred that the animal was indeed extremely thin and that, using a standard veterinary reference, there was no basis to challenge the vet's interpretation. This outcome was reported to the IO immediately and the IACUC at the next meeting.

The following were reported to Dr. Hegde about this event:

1 – That the IACUC found no basis to challenge Dr. Monterosso’s clinical judgement in this case. Such a challenge would have to clear a very high bar in any case, but there was certainly no basis in Crosby’s case.

2 – Dr. Hegde had requested an independent veterinary consult but was informed there was no basis for such action. Dr. Monterosso was GRU’s veterinarian of record at the time and with no basis for action by the IACUC, an external consultant would have no legal weight against the opinions of GRU veterinarians.

3 – Dr. Hegde was reminded that he still had an active protocol and was encouraged to purchase a replacement for Ovetchkin and continue work.

3) Allegation that the food restriction policy was in retaliation for Crosby.

The IACUC is charged with setting policy on all aspects of animal research. In light of Dr. Monterosso’s concerns about Crosby, the IACUC recognized it had formulated no formal guidance on the issue of food restriction. This concern became more acute in May 2014 when Dr. Monterosso also expressed concern that Dr. Blake’s animals did not meet his expectations for health. The IACUC began to work in earnest on a policy that would define more effectively the conditions under which food restriction should occur so that the PIs and the vets could find some common ground.

Over the next several months, the IACUC deliberated extensively on the issue. A number of sources of information were pooled including an email chain with input from Drs. Blake, Hui, and Hegde. The IACUC chair at Penn State was contacted at the recommendation of Dr. Blake. When Dr. Blake’s animals were pulled off study, OLAW recommended an external consult, and Dr. Stepp invited Dr. Fawn Stroud-O’Connor from the Yerkes Primate Facility at Emory to review the policy and records for comparability to the Yerkes protocols. A difference between Dr. Blake’s and Dr. Hegde’s protocols is that Dr. Blake had juvenile monkeys that were still growing, so the IACUC asked Dr. Blake to come to an IACUC meeting to answer questions as we tried to address how our new food restriction policy would be applied to growing monkeys.

The IACUC’s new policy defined the minimum calories per day for animals on food restriction studies, but it specifically allowed the PI to request an exemption from the policy if animals on a given protocol did not perform at all. Dr. Blake requested immediate exemption, before he tried to implement the new feeding guidelines, and was declined. He applied the policy, documented evidence to provide scientific justification to the IACUC, and the IACUC approved an exemption under veterinary guidance. **Dr. Hegde refused to abide by the policy and his protocol remained inactive until it expired due to failure to renew.**

4) Dr. Hegde has been denied the opportunity to address the IACUC about his concerns or his allegations of misconduct on the part of LAS Veterinarians.

Dr. Hegde has made a series of assertions that “illegalities”, “cover-ups”, and/or “falsifications” have occurred. However, it should be noted that he has:

1 – Met with Drs. Stepp, Hamrick, and Monterosso and provided no physical evidence of illegal or inappropriate behavior.

2 – Been instructed by Dr. Stepp to prepare his concerns in writing to IACUC@gru.edu for the IACUC to investigate. No report was submitted. He attempted to interrupt meetings of the IACUC without having offered anything for the agenda and was asked to leave until he had done so.

3 – Met with Dr. Diamond when he was appointed as new IO. Nothing from those meetings was ever forward to the IACUC.

4 – Met with James Rush, head of GRU Compliance Office to address these allegations. No information was forwarded to the IACUC from that investigation.

5 – Filed allegations with OLAW alleging lack of due process and falsification of records. OLAW found no basis for misconduct and closed the case.

Rather than being denied access, Dr. Hegde has in fact exhausted almost every possible avenue of consideration for his concerns but has failed or refused to meet the standard of evidence of any avenue tried to date. In the current complaint, an updated necropsy report is offered as evidence of “falsification” but 1) Dr. Hegde never submitted this to the IACUC for consideration, and 2) it remains to be determined if this is an error, a legitimate update by the veterinarian, or falsification.

5) Dr. Hegde’s protocol was terminated and his animal threatened in retaliation for actions related to Crosby and Ovetchkin

Once the food restriction policy was passed, all PIs had to incorporate that into existing protocols. A protocol has a lifespan of 3 years at which point federal regulations mandate a full review to continue. Dr. Hegde’s protocol was up for standard renewal in 2014. Because he would not comply with the feeding protocol, his protocol could not be approved as it would be illegal to approve a protocol that would not comply with standing policy. Dr. Hedge’s protocol lapsed, despite continued notifications that termination of the protocol was approaching, and he did not seek to renew it.

Scientific justification is the only justification for having research animals on this campus and instrumented for experiments. The IACUC approves that justification through the Animal Use Protocol submitted by the PI. Once the protocol lapsed, Crosby could either be euthanized or adopted out. Because of uncertainty whether Dr. Hegde would resubmit an AUP, the IACUC erred on the side of caution and transferred Crosby to the LAS Holding Protocol. After 6 months of non-renewal, the decision was made to remove the surgical instrumentation, again because such instrumentation is not allowed unless scientifically justified, and there was not an active AUP to justify it. If an adequate home cannot be found, or it cannot be transferred to another PI at AU, the institution will be required to euthanize the animal.