

Date: 5-13-03
To: Dr. Ei Terasawa
Wisconsin Primate Research Center
From: Dr. Eric P. Sandgren, Graduate School ACUC
Re: Protocol G00146

Dear Dr. Terasawa,

Thank you for your letter of May 7 describing the monitoring issue regarding rh2116 on protocol G00146. Based on this and other issues (outlined below), the Graduate School ACUC has voted to suspend this protocol until we have been able to gather certain information. I first present our response to your letter, and then outline additional issues that the committee needs to have addressed.

Your protocol states that animals will be "continuously attended" during the course of the push-pull experiment. We do consider this to mean that an individual will be present at all times with the animal, and that this person will be able to see the animal. Therefore, the documented departure of your technician for up to 25 minutes does constitute a protocol violation. The committee accepts your proposal to have substitute personnel attend the animal when the primary experimenter must leave the room, and expects that this individual will have visual access to the animal during this time.

During the course of our discussion it became clear that members of the committee have incomplete and sometimes conflicting understanding of the nature of the push-pull experiments and associated manipulations, including the procedures employed and the associated monitoring. It also seems that in some cases we and you have different interpretations of the protocol. In view of the invasive nature of the experiments, it is particularly critical that we understand all that happens to each animal, and that you understand the committee expectations regarding these experiments.

To correct this problem, we request that you meet with members of the committee to provide a detailed step-by-step description of the experiments outlined in this protocol. This will provide us with an opportunity to ask you questions and for you to ask us questions. We would like the discussion to include the following points.

1. As noted above, a thorough description of the experimental process, monitoring, and documentation from the time of cannula implantation to the time the cannula is removed.
2. A thorough description of monitoring and documentation once the cannula is removed until monitoring can be taken over by primate animal services.
3. Description of a mechanism to immediately report any deviations from the intended experimental design or any complications to a research animal veterinarian.
4. Description of the maximum number of cannula implantation procedures per animal and the maximum time between cannula implantation procedures.

5. Description of the aseptic techniques employed during the cannula insertion and the push-pull experiments.
6. Description of monitoring and documentation of instrument performance.
7. Description of any written documentation indicating that all personnel have read the animal care and use protocol.
8. Provision of examples of animal records pertinent to this protocol that you maintain.

We believe that a meeting to discuss these and related issues is essential to our adequate understanding of the experiments described in G00146. Our hope is that, once this has been accomplished, we can reinstate the protocol. This action by the Graduate School ACUC also will be reviewed by the All Campus ACUC, which must approve any final resolution. Finally, as required by federal regulations, Dr. Christine Parks will provide the appropriate staff at OLAW and USDA with a report of this incident. Regulatory bodies take seriously noncompliance incidents. A persistent pattern of such incidents or apparent disregard of the requirements for responsible animal care and use could result in the withholding of federal and nonfederal funds supporting research not only for the investigator involved, but also for the University of Wisconsin.

The committee's objective is to identify all issues that contributed to non-compliance in this case, and to work with you to establish a plan to prevent their reoccurrence. We look forward to your continued assistance in assuring animal care and biomedical research of the highest quality at the University of Wisconsin.

For the committee,

Eric P. Sandgren, VMD, PhD
Associate Professor
Chair, Graduate School Animal Care and Use Committee