



Graduate School Animal Care Committee
May 12, 2003

Present: Bolton, Evans, Fechner, McEntee (n.v.), Sandgren, Schultz-Darken, Welter and Zhang

Absent: Abbott

Guests: Dr. Kemnitz, Amanda Crumbaugh, Dr. Parks

Approval of April 14, 2003 Minutes

Sandgren/Schultz-Darken moved for approval pending minor corrections. Vote was unanimous.

Compliance Issues

Recently, two USDA investigators visited RARC and the Primate Center.

During this investigation the investigators learned that monitoring was not provided continuously for chaired animals as described in protocol [REDACTED]. During a 25-minute absence by a technician, an animal in the chair died. The fact that the animal died during the experimenter's absence was not provided to the Graduate ACUC at the time of the animal's death. It is clear to the committee that the lack of continuous monitoring constitutes a protocol violation.

[REDACTED] noted that the USDA investigators also raised a concern about the length of time needed between chairing episodes. The PI verbally reported to the investigators that she waits four weeks between chairing sessions, but the investigators found records from summer 2002 where only three weeks of rest was given between sessions. The length of rest time between sessions was not explicitly stated in the protocol. [REDACTED] will investigate this inconsistency.

Dr. Nancy Schultz-Darken noted that many of the concerns of the USDA investigators regarding this protocol highlight the necessity that the descriptions of the procedures be very clear, especially given the nature of the experiments. The AAALAC site visitors voiced many of the same concerns in March 2003.

In light of new information related to this protocol, it seems that the committee is not confident that the procedures are being followed as detailed in the approved protocol. Additionally, it seems that there are inadequacies in the protocol as it currently stands that could impact the animals' health.

Research Animal Resources Center

Dr. Sandgren identified two issues for the ACUC to address:

- 1- The lack of continuous monitoring (the protocol violation); and
- 2- Increase the familiarity of the committee with the exact nature of [REDACTED] experiments.

It seems that critical information regarding this experiment was never made known to the committee. The committee discussed a response letter from [REDACTED] regarding the break from continuous monitoring. (See attached letter dated 05/07/03.) [REDACTED] letter states that she will revise the protocol to re-emphasize that substitute lab staff will cover for any time when researchers take breaks so that continuous attendance is ensured. The committee accepted this proposal provided that the substitute must have visual contact with the restrained animals.

Welter/Schultz-Darken moved to suspend [REDACTED] and have the ACUC send a letter to [REDACTED] to include the committee's acceptance of her plan to include substitute monitors and contingencies under which protocol reinstatement could occur. (See attached letter dated May 13, 2003.) Vote was unanimous with Su-Chun Zhang abstaining.

In the course of studying documentation regarding the incident with protocol [REDACTED], the USDA investigators also inquired about [REDACTED] surgeries and asked to see the intraoperative records. It appeared that these records were not immediately accessible to the investigators. This was of high concern by the investigators.

Documentation of Monitoring During Surgeries

A concern was raised by the USDA investigators regarding the lack of consistent documentation of monitoring during surgeries. Dr. Sandgren distributed a draft policy for surgical monitoring and record keeping. The committee read the draft and made suggestions for clarifications and additions.

There do not seem to be specific requirements described in AWAR of the type of intra-surgical monitoring documentation. Dr. Parks is consulting with USDA and other agencies to get more information. "Standards of Veterinary Care" have been cited as the best guideline for surgical monitoring documentation, which is what Dr. Sandgren's proposed policy is loosely modeled upon.

Dr. Kemnitz left the meeting at this time.

Dr. Parks reminded the committee that the committee could adopt a minimum policy and then require more stringent monitoring documentation for invasive procedures described in particular protocols. Attending vets and PIs can also choose to upgrade the monitoring documentation.