Poster Abstracts from the 
2005 IACUC Conference: Communication, 
Cooperation, Collaboration...The Cornerstones 
of an Effective Animal Care and Use Program

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Developing an Integrated Post-Approval Auditing Program for IACUCs Focusing on Assessment, Trending, Education, Auditing, and Adjustments
Authors: Ron Banks, DVM; Michelle Keys, RLATG; Sonia Doss, RLATG; Julie Sharp, D.V.M.; Lee Tyrey, PhD

Background
A long recognized requirement, but rarely engaged activity, is post-approval assurance mechanisms of animal care and use. There has not been an effective manner to tie the requirements of the various references to responsibilities of the institution, to the skills of the individuals, the plethora of either not or under reported deficiencies, and the ability of the program to effect any change. To this end, the animal program at Duke has partnered with the Duke endowment to perform an 'experiment' using integration of education into a strong compliance liaison program.

Hypothesis
A focused education program decreases compliance deficiencies and strengthens the overall integrity of the animal research program. The success of such a program is highly dependent upon developing a culture of `partnership for good practice' (rather than constabulary interference) between the research community and the oversight agencies - the research community must view compliance as a tool to facilitate their research objectives, assure their privilege for continued animal use, and a defense against allegations of misconduct.

Methods
The strategic plan for this partnership consists of 5 parts:
1. Develop an auditing process to capture program deficiencies.
2. Develop a methodology of capture and trending of deficiencies.
3. Partner with the IACUC to assess concerns and resolutions.
4. Use the trended deficiencies to develop the focused training program.
5. Audit the process and progress, adjusting as necessary as new threats arise and old problems are resolved.

Results
We have begun to see trends within our program that is providing clear direction on the specifics of training required in our community. Charts and data will be available at the presentation.

Conclusions
When we began looking at our program, we discovered non-compliances and protocol deviations that we had never realized before. We also projected that with similar institution elsewhere performing similar works there were likely similar sorts of concerns where were not being realized. The IACUC and researchers have embraced the auditing process as a tool for improving overall program integrity while have a direct impact upon the quality of the work within their laboratory. Our efforts of seeking out and resolving concerns will engender an enhanced trust from the regulatory agencies on our ability to properly oversee animal care and use, as we are able to objectively show the evidence of our efforts and track the resolution of our identified concerns.
NOTE: This is a novel program being conducted at Duke, which involves the use of compliance auditing, IACUC Guidance, investigator partnerships, and focused education.
Fear, Anxiety, and Stress in the Laboratory: Why Nonhuman Primates Make Poor Research Subjects

Author: Mary Beth Sweetland

Overview
This paper appraises more than 200 published studies on nonhuman primates, conducted primarily between 2000 and 2005, on the consequences of stressors in laboratory conditions. The literature reviews the comprehensive range of effects of fear, anxiety, and stress in the laboratory in nonhuman primates, from profound biochemical and physiological changes to disturbing cognitive, psychological, behavioral, and social pathologies. These effects compromise any research findings and cannot be mitigated, as they result from even the most routine and conscientious protocols. Neither can the effects of stress be controlled or generalized, as primates experience stress in complex and individualized ways. The utility of using nonhuman primates for laboratory research must be reexamined from both scientific and ethical perspectives.

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Novel IACUC Outreach Effort to Facilitate Animal Protocol Submissions
Authors: Gina Schmitt and Kim Ingham

Abstract
The Institutional Animal Care and Use Committee (IACUC) has oversight responsibility of its institution's animal program, facilities, and procedures. One of its primary responsibilities is to review and approve animal use protocols submitted by investigators. To facilitate protocol submission and review, many Committees offer training to their investigators to explain the process. The training does not generally cover every aspect of the institution's animal protocol as it relates to the various forms of research that may be performed at the facility. As such, it is not uncommon for an investigator to receive requests for modifications from the administrator or Committee after a protocol has been submitted for review. To help minimize the number of modifications requested, our IACUC assessed the questions raised during the routine review of protocols and communicated this information to investigators. Initial assessment of IACUC questions was done on protocols submitted within a three month period of time. Modifications requested from the Committee during this period were clustered into broad categories (e.g., consistency, alternatives, and personnel), and into subcategories where applicable (e.g., for "alternatives", omission of years covered in the literature search or search dates). The top five categories of comments and corresponding subcategories returned to investigators were posted to the IACUC's website as well as suggestions for limiting the number of comments returned for these reasons. New investigators were encouraged to visit the website prior to submitting a protocol. Since posting this information to the website, quarterly assessments of IACUC comments were conducted for one year for trend evaluation. For three of the five broad categories and eleven out of seventeen of the subcategories, we observed a decreasing trend in the number of comments returned. We continue to assess the comments that are returned to investigators and update the website as needed.

Introduction
In order to facilitate protocol review, our IACUC assessed the questions raised during the routine review of protocols and explored outreach efforts to communicate results to investigators. The IACUC reviews over five hundred research protocols annually at our facility. Typically, protocols are approved with modifications. In order to determine whether requested modifications were common between various protocols, an assessment of requested modifications was conducted. Protocols submitted within a three month period were grouped and requested modifications categorized. Categories that contained the largest quantity of requested modifications were communicated to the investigators to facilitate protocol approval. In 2003, requested modifications were assessed in this manner for all four quarters.

Procedure
Requests for modifications from the IACUC administrator or IACUC committee are recorded in the activity log of the animal protocol. The requests are numbered, and each request was individually reviewed and assigned into a category. Categories were developed based on recurring requests for modifications, or comments. An example of a comment category is "alternatives". This category encompasses requests for modifications which involve providing assurance that there are no alternatives to proposed procedures. A total of 28 such categories were identified for comparison. Two of the 28 categories, "consistency" and "procedural issues", were identified that could be further segmented into subcategories. The protocol system at our facility includes a Study Abstract section and additional sections for elaboration on study procedures. Additional sections, depending on the type of study performed, may include Survival Non-Surgical Procedures, Survival Surgical Procedures, Blood Collection, and Test Article Administration. Within the category of "consistency", it was possible to further compartmentalize comments returned based on the sections of the protocol form (e.g., Blood Collection or Test Article Administration) that were found to be inconsistent with the Study Abstract. Likewise, the "procedural issues" category was amenable to subdivision according to the type of procedural comment returned (e.g., elaboration on surgical descriptions may be requested by the IACUC, or additional
clarification on terminology such as "behavioral studies").

Totals within the categories were used to determine the top five categories of comments returned per quarter. Quarterly top comments were posted to the IACUC website as "APS Tips" in order to communicate findings to investigators. The website provided examples of comments in each category, as well as suggestions on how to reduce the number of comments returned and sample acceptable responses where applicable. Investigators may consult the website for information and guidance prior to submitting a new protocol or amending an existing protocol.

Results
During the first quarter, 463 comments were returned, 591 were returned in the second quarter, 693 in the third quarter, and 576 in the fourth quarter. To facilitate trend assessment between quarters, comments were normalized by dividing the comments returned in each category or subcategory by the total number of comments returned in that quarter. A total of 126 protocols received IACUC approval in the first quarter, 110 in the second, 141 in the third and 144 in the fourth. For three of the five broad categories, Figure 4 illustrates a decreasing trend in requests for modification observed through the fourth quarter. Decreasing trends are exhibited in eleven out of seventeen of the procedural issues and consistency subcategories. Figure 5 demonstrates that a decreasing trend was observed in three out of four procedural issues subcategories, and Figure 6 shows a decreasing trend in eight of thirteen consistency subcategories.

Discussion
Several methods of outreach contributed to the decreasing trends in comments returned. The APS Tips website is publicized in several ways. Upon receiving initial IACUC training, an investigator requesting access to the protocol system is prompted to visit the APS Tips website prior to submitting protocols. The link to the APS Tips website is also provided within the electronic APS form. Collaborative discussions between IACUC administrators and investigators prior to protocol submission may also contribute to the decreasing trend in comments returned as well as notification reminders incorporated into the electronic protocol form where possible. As an investigator begins to type in the Study Abstract, for example, a pop-up message box appears with a reminder that proprietary information should not be included in the protocol. A pop-up message box also appears in the section for alternatives, offering suggestions of acceptable methods and sources to assure no alternatives are available to potentially painful procedures. Lastly, an investigator may submit several protocols throughout the course of the year and review previous requests for modifications in order to streamline the approval process for the next submission.

Conclusions
An assessment of requested modifications on IACUC protocols was performed and results communicated to investigators. Multiple methods were used to reach out to the investigators and communicate results. Examples include posting top comments to a website and utilization of message boxes in key areas of the protocol form. Decreasing trends in comments returned were observed in the majority of broad and subcategories assessed. Communication of comment assessments to the investigative staff helped to facilitate the protocol review and approval process. Thus, investigators and IACUC committees may both benefit from periodic analysis of requests for modifications. Methods employed to convey this information, such as communication prior to protocol submission, can be used to facilitate a cooperative relationship between Principal Investigators and the IACUC.