The Incorporation of a Research Study Plan to Enhance Support of Research Oversight Activities.

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Abstract
The IACUC has a responsibility for oversight of new and ongoing animal activities within the institution. Often times the IACUC reviews and approves activities under a single animal use protocol which includes multiple studies set to occur over a three to five year period. Details for specific study activities are typically outlined in the animal use protocol, however the actual timing or schedules for these studies is not usually provided. A simple and transparent method (A Research Study Plan) to provide the IACUC, post approval monitors, veterinary staff, or other support entities key information regarding the actual studies ongoing at any given time will increase the ability for the IACUC to provide effective continuing oversight of animal activities. These study plans would be used by the IACUC for timely post approval monitoring, as well as by research management to help with strategic planning, resource management, and progress evaluation. Another benefit is that completion of study plans with the knowledge that the IACUC will be reviewing them, encourages research staff to frequently review and reference their approved IACUC animal use protocols.

Rationale
In order to improve the transparency and oversight of in vivo research activities, our organization has put a new program in place requiring that an individual study plan entitled “Research Study Plan”) be submitted to the Animal Welfare and Governance team for each individual animal use study to be conducted. Development and use of these study plans will be used to facilitate the requirement for post approval monitoring (PAM) of approved animal use activities. The study plan will be used for management review of study activities and objectives such as veterinary support, facility use, and research Team activities.

Methods
A standardized template (a simple one page form) was developed by a team consisting of research personnel and IACUC members. The form was piloted for several months and subsequently modified using input from the user groups. Methods for distribution, collection and review of the study plans were implemented. All research personnel received training consisting of why the program was implemented, how it will benefit our program, and instructions for its use. Figure 1.

Results
After compiling feedback from the user groups in the pilot program, we finalized the Research Study Plan (RSP) as shown below in Figure 2. Basic study information such as start and end dates, protocol number, PI, species, etc., are outlined in the first seven rows of the form. Experience has shown that requiring the user to add a brief description of the procedures to be performed, as well as defining the experimental groups, encourages them to reference the approved protocol more frequently, thus aiding in compliance. The sections for anesthesia and animal reuse also allow for easy compliance checks against the approved protocol and anesthesia records. Errors have markedly decreased as a direct result of the investigators finding it necessary to consult their IACUC protocol when filling out their RSP. For example, at our institution we have seen the incidence of inaccurate anesthesia records filed drop from 31% to 8% after the implementation of the RSP. The RSP has also played an instrumental part in planning for veterinary services. Knowing in advance which studies are coming up allows us to better preplan for post-procedural observations and treatment.

Moreover, we have found that choosing protocols for post approval monitoring is facilitated due to the ability to easily determine which protocols are the most active and which present the greater risk for welfare issues by monitoring the RSPs.

Discussion
By increasing the transparency of the ongoing animal use activities within the vivarium our support teams are better able to provide continuing oversight of animal activities. We have been able to improve animal welfare by reviewing potential protocol deviations before they occur, by better risk-based targeting post approval monitoring observation, and by preplanning veterinary observations of animals post procedure. The schematic in Figure 3 represents the relationships the Research Study Plan has with other aspects of our animal welfare program. PAM review of study plans has allowed the IACUC to assure that conduct of studies is consistent with those procedures that were reviewed and approved by the IACUC and that research staff are in compliance with animal use requirements.

Abstract
In Vivo Research Study Plan

<table>
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<tr>
<th>Start Date(s):</th>
<th>End Date:</th>
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Protocol #/PI: Study ID:

Person(s) performing procedure(s):

Objective for this specific experiment:

Study Type: (per or both may apply) ☐ Development ☐ Research

Species:

Number of animals: Animal ID:

Non-naïve animals used? ☐ NO ☐ YES

Brief description of procedure(s) performed and time points:

(Examples: IOP measured at baseline, then 2, 4, and 6 hours post dose in 10 DB rabbits.
ERG’s done in 20 BALBC mice.)

Experimental Groups (include n/group):

Anesthesia/Analgesics Used? ☐ NO ☐ YES

If any, what agent(s), dose and route of administration:
Also use appropriate IVS anesthesia form. Completed form is sent to IVS Veterinary staff.

Disposition: ✘ Returned to colony for future studies on same protocol ☐ Transferred to different protocol ☐ Returned to colony for future studies on different protocol ☐ Euthanized ☐ Other:

Figure 1. Timeline Research Study Plan development

Figure 2. Research Study Plan - Final

Figure 3. Research Study Plan Relationships

Improved Data Collection
Integration of the “Research Study Plan” program has proved a useful resource for reporting to the IACUC regarding compliance of ongoing activities within the vivarium. Furthermore, the Research Study Plan has facilitated post approval monitoring in a positive, direct way. The increased transparency of ongoing daily activities has improved our animal welfare program.