

Post-approval Monitoring of Approved Animal Research Protocols

One of the tasks that AAALAC International expects to be performed by the IACUC (or comparable oversight body - OB) is the oversight of approved research protocols involving animal care and use at the institution, once they have started. This post-approval monitoring (PAM) procedure is considered important to help ensure that animal study procedures are conducted in accordance with the approved protocol, to identify and review potential unexpected outcomes or adverse events and their management, and ensure the principles of the 3R's are applied. AAALAC acknowledges that in some countries and institutions there may be other institutional bodies or named individuals (e.g., animal welfare officers, compliance staff, quality assurance units) participating in this process. In all cases, AAALAC applies a performance-based approach based on the efficacy of the system in place, while acknowledging that the final authority over the process relies on the IACUC/OB.

One component of a PAM program is the periodic program review and facility inspection by the IACUC/OB. The collaboration of research personnel in the self-evaluation or and in proactively reporting protocol changes, and involvement of animal care and veterinary staff are very important for the success of the PAM process. As indicated in the *Guide*, PAM methods may include continuing protocol review; laboratory inspections, conducted either during regular facilities inspections (link to Guidance Statement) or separately; veterinary or IACUC/OB observation of selected procedures and evaluation of personnel competency; and observation of animals by animal care, veterinary, and IACUC/OB staff and members.

Factors that may be considered when deciding on the frequency of PAM and on the attention to be paid to specific protocols include history of (non)compliance; potential risks to animals or staff; severity of experimental procedures; and legal requirements (e.g., triennial review required by PHS in the US). Although AAALAC agrees that ensuring compliance with approved protocols is critical, AAALAC International interprets the *Guide* recommendation for a PAM program in the broadest sense for the international community, namely that there will be a system for ensuring animal procedures conform with the approved protocol or study plan (including amendments), and that unexpected outcomes or adverse events are appropriately managed.