

In response to NOT-OD-14-063 regarding how changes to ongoing animal activities should be handled, I submit the following information.

First, I urge OLAW, NIH, and relevant HHS staff to make a significant effort to reduce the ever-expanding regulatory burden on investigators who use animals in their NIH sponsored research programs. The last 10 years has seen an explosion of new regulations and ever more stringent conditions on the use of animals. These changes have had a significant impact on the ability to carry out critical biomedical research that is needed to reduce harm in individuals suffering from chronic diseases. The relentless lobbying of Congress by well-organized and well-funded animal rights groups has tipped the balance of the responsible and justified use of animals in research and unnecessary and costly changes to animal use policy made in response to these demands have advanced their goal of eliminating all use of animals in research. These changes significantly threaten the future of NIH disease-based research and will have irreparable harm to these efforts if left unchecked.

With regard to the specific issue of what constitutes a significant change to an ongoing animal activity that requires IACUC review, I offer the following comments.

1. Items listed under Section A that do not increase the level of pain or distress of the animal should be classified as non-significant and handled by administrative review. This should include any change in an approved anesthetic, analgesic, sedative agent or euthanasia method to another IACUC/NIH approved agent or method. As these agents/methods are already approved and in use, changing from one to another can not result in increased harm to the animal.
2. Items listed in Section B regarding animal numbers, approved housing, scope of approved animal activity should be down-graded to non-significant and handled by administrative review. These activities have no bearing on animal welfare and place a needless administrative burden on investigators and their laboratory staff.
3. Items listed in Section C should be revised to make them less restrictive. This would include dropping the 10% limit on the increase in number of animals to be used under an approved protocol and eliminating review of changes that would result in less discomfort or invasiveness to the animal regardless of changes in items listed under Section A. As these changes would result in less harm, they do not need IACUC review.

As an example of the ever-increasing burden on investigators regarding IACUC protocols, a recent submission of a 3 yr continuation of a colleague's protocol ran in excess of 80 pages. The time and effort required to generate this document is further compounded by the needless and wasteful requirement to report minor changes to the protocol that have no bearing on animal health and welfare. I again urge OLAW and NIH to streamline reporting requirements for use of animals in research and make common sense changes to the currently existing policies and procedures in order to enhance our ability to carry out our NIH funded mission.