



Cornell University

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Dr. Francis S. Collins, M.D., Ph.D.  
Director  
National Institutes of Health

Dear Dr. Collins:

This letter is in response to the National Institutes of Health's (NIH's) solicitation of comments concerning the Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities published in the NIH Guide for Grants and Contracts on March 11, 2014, NOT-OD-14-063. Cornell University's Ithaca Campus has a very large, diverse animal care and use program and we are committed to regulatory compliance and upholding the highest standards in the humane care and use of animals utilized in our research and teaching programs. We commend NIH for seeking to provide more clarity and better definition of the Institutional Animal Care and Use Committee's (IACUC's) role in maintaining oversight for changes to approved animal use protocols.

We agree with the clarification of significant changes outlined in sections A and B of the proposed guidance document, as we believe that these clarifications are consistent with the intent of the regulations and they are material to assuring the humane use of animals.

We do not, however, agree that the types of changes outlined in Section C require IACUC review or approval or that the IACUC needs to be kept informed of all such changes when they are handled by the IACUC staff. We fail to see how such changes have any material impact on animal welfare. Instituting new requirements for such changes will add to the already heavy burden on administrative staff, IACUCs and investigators, without having any positive impact to either animal welfare or to the institutions' ability to run an effective and efficient animal compliance program. We believe that time spent on these activities will be a waste of scarce institutional resources and will distract the staff and the IACUC from performing other duties that do in fact have an impact on animal welfare. We note that a very recent [report from the National Science Board](#) has pointed out specifically the heavy and seemingly constantly growing burden imposed on researchers, IACUC committees, and administrators by regulations that do not provide any material enhancement to the humane care and use of animals in research. These changes in Section C will, in our assessment, definitely add to that burden.

Our specific comments are inserted following the relevant language in the notice. In writing these comments, we have built upon similar comments posted by our colleagues at other research institutions.

Section C of the guidance includes *"Changes that are not significant may be handled by the IACUC staff without IACUC review and approval. However, the IACUC is to be informed of changes handled by the IACUC staff. This information may be provided after the change has been reviewed and initiated. Such minor changes include but are not limited to-*"

1) "change in stock, strain, or genetic modification": we disagree that these changes require IACUC approval, or notification to the IACUC, unless they necessitate special care or handling of the animals. Since there is no current requirement for the investigator to report these types of changes to the IACUC, this clarification in fact introduces a new requirement for the Principal Investigators (PIs), IACUC staff and the IACUC, with no influence on animal care. Examples of such insignificant changes include change from Duroc to Landrace swine, Balb/C to FVB mice, domestic short hair to long hair cat.

2) "change to house or use animals in a location that is currently used for the same purpose and is part of the animal program overseen by the IACUC": Transfers of animals from one approved housing location to another approved housing location are not required to be submitted to, or reviewed by, the IACUC. Instituting this new requirement will be a serious impediment to the ability of animal facility managers and PIs to manage on a day to day basis, the utilization of the animal spaces that have already been inspected and approved by the IACUC. It is inconceivable that facility managers or PIs would report every such change to the IACUC and wait for notification of approval before moving animals, for example when mouse cages are moved from one room in a managed facility to another. We fail to understand the value of this new requirement.

3) "change in personnel other than the Principal Investigator" - As indicated in the guidance, changes in personnel must have an appropriate administrative review "conducted to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC." We fail to see the value in having IACUC staff report all such changes to the IACUC.

4) "correction of typographical errors", "correction of grammar", "contact information updates" : we do not see any reason why the IACUC must be made aware of such changes when they have no impact on animal care or use. The only impact of this change will be to add unnecessary administrative burden to IACUC staff in keeping track of such changes and determining a mechanism for reporting them to the IACUC. In that regard, it can serve as a regrettable disincentive to make these changes that could improve the overall readability of animal protocols.

We are concerned that the changes included in this list are "not limited to" the items on the list. Thus other such changes that are purely clerical or administrative in nature could be perceived to require IACUC notification/approval. In an effort to be compliant with regulations, institutions may scramble to find other such examples and further compound the problem of unnecessary administrative burdens. A possible example of this type of change is the change in the brand of a drug or an administered substance, or gloves used to handle animals. We fail to see the motivation for such changes in the Guidance, other than an assumption, without evidence, that PIs and IACUC staff require more oversight from the IACUC in order to run an animal care and use program. We strongly contest any such assumption.

We urge the NIH to be especially watchful for, and strenuously refrain from, instituting new requirements without a clear demonstrated value in improving the humane care and use of animals. Seemingly innocuous regulatory clarifications or changes cause tremendous administrative burden for researchers and administrators. We strongly believe that the proposed changes in Section C of the guidance do not meet the standard of improving the humane care and use of animals and therefore should be removed from the guidance. In fact we urge the NIH to explicitly state that changes such as the ones outlined in Section C do not require IACUC notification.

We appreciate the opportunity to provide these comments and look forward to working with the regulatory agencies to conduct animal work with the highest standards for the humane care and use of animals while managing the administrative burden on our researchers and administrators and the overall costs of conducting research with animals.

Sincerely,

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