

A. Significant changes are those changes that have or may have a direct impact on animal welfare including but not limited to changes:

No issue with the items listed.

B. Some activities that may not have a direct impact on animal welfare are also significant. These include but are not limited to changes:

No issue with the items listed.

C. 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:

- change in stock, strain, or genetic modification, unless the new stock, strain, or modification results in abnormalities that require special support;

What is the benefit gained from IACUC review of this item? The added value compared to the associated administrative burden would be infinitely small.

- 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;

There currently exists no requirement for the IACUC to review the details of changes in housing location that are part of the centralized animal housing program. Transfers of animals from approved centralized managed housing location A to approved centralized managed housing location B are not required to be submitted to, or reviewed by, the IACUC. These are insignificant changes that not only do not need to be reported to the IACUC when handled as minor changes by IACUC staff, but are not even required to be reported to the IACUC by the principal investigator or the animal facility manager in the first place.

What is the benefit gained from IACUC review of this item? The added value compared to the associated administrative burden would be infinitely small.

- change in personnel other than the Principal Investigator (An appropriate administrative review must be 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. The IACUC should have a procedure in place to ensure that this review is conducted.);

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." However, as long as that process is in place, there is no value in requiring the reporting of all such administratively approved personnel changes to the IACUC. The added value compared to the associated administrative burden would be infinitely small.

- correction of typographical errors;

What is the benefit gained from IACUC review of this item? The added value compared to the associated administrative burden would be infinitely small.

- correction of grammar;

What is the benefit gained from IACUC review of this item? The added value compared to the associated administrative burden would be infinitely small.

- contact information updates.

What is the benefit gained from IACUC review of this item? The added value compared to the associated administrative burden would be infinitely small.

Additional comments: Administrative personnel within the IACUC office are capable of reviewing the above types of items. A cost-benefit analysis of the proposal would probably suggest that the IACUC would have more information than necessary as IACUC members are already bombarded with information that is too vast to digest and act on. Is it not more important to have IACUC members concentrate on issues within the protocol that affect animal welfare rather than diluting the important issues with these non-animal welfare related details? Does this proposed guidance address some larger mandate or law? Is there any evidence to suggest that this would improve the care and well-being of the animals?

The potential benefits of requiring IACUC review of the above items are small or insignificant, whereas the extra burden on administrative staff and the IACUC are extremely high. If NIH proposes such a change, it should provide an analysis as to how the animal care program benefits from such a change and does this benefit outweigh the burden it would place on administration and the IACUC.