

In response to the invitation to comment on the guidance proposed in NOT-OD-14-063, I offer the following comments.

With regards to Section C, the statement “Changes that are not significant may be handled by the IACUC staff without IACUC review and approval” may be too specific due to the wide range of organizational structures used by institutions. Perhaps the sentence could be adjusted to read “Changes that are not significant may be handled “administratively” without IACUC review and approval.”

**Change that would result in less discomfort or invasiveness to the animal, except the changes described in Section A:** Such changes are not always readily apparent, and their identification may require specific expertise in the particular field of study. Therefore, this bullet point should include some qualification of the individual tasked with making that judgment, or should not be included in Section C.

**Change in stock, strain, or genetic modification, unless the new stock, strain, or modification results in abnormalities that require special support:** There is currently no regulatory requirement for a Principal Investigator to inform the IACUC of specific stocks or strains, only species. If genetic modifications are such that they require special support, such a change should require IACUC review and approval and should not be processed administratively in the first place. Therefore, this bullet point should not be included in Section C.

**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:** The IACUC is currently required to inspect all (centralized) animal facilities, but there is no requirement for a PI to notify the IACUC every time an animal is transferred between rooms within that centralized animal facility. In reality, IACUCs trust animal facility managers track the housing locations for all animals within the centralized animal facility. Therefore, it would add unnecessary administrative burden to require PIs, or the animal facility, to inform the IACUC every time a location transfer occurs.

**Change in personnel other than the Principal Investigator:** As indicated in NOT-OD-03-046, “IACUCs may, by institutional policy, classify certain proposed additions and changes in personnel, other than the Principal Investigator, as “minor” provided that an appropriate administrative review mechanism is in place 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.” Assuming such an appropriate administrative mechanism is in place, and based on the reality that the IACUC is automatically informed every time it reviews a “significant” amendment (see Part A and B above), as well as at the time of the 3 Year *de novo* Renewal, informing them every time there is a personnel change creates unnecessary administrative burden with little additional benefit to the overall animal program.

**Correction of typographical errors and grammar:** Assuming that the typos and grammar did not interfere with the understanding of the content of the protocol such that it could not be approved in the first place, correcting them after the fact provides little value to the IACUC’s understanding of the content of the protocol. Therefore, the administrative burden created by this proposed requirement outweighs the potential benefit to the overall animal program and contributes nothing to animal welfare.

Thank you for your consideration.