

May 24, 2011

Dr. Patricia Brown, Director
Office of Laboratory Animal Welfare
Office of Extramural Research
National Institutes of Health
Suite 360 – RKL 1
6705 Rockledge Drive
Bethesda MD 20892-7982

SUBJECT: Proposed Adoption and Implementation of the Guide for the Care and Use of Laboratory Animals: Eighth Edition (NOT-OD-11-042, 056, 066)

Dear Dr. Brown:

The Massachusetts Institute of Technology (MIT) appreciates the efforts to produce the proposed Guide for the Care and Use of Laboratory Animals: Eighth Edition. MIT also appreciates the time to comment on these new guidelines since there are several remaining issues that still require attention. These include the impact of regulatory-sounding language within a guidance document, significant requirements regarding adjustments to cage size for laboratory animals, and the need to reevaluate the implementation date to allow universities and related laboratories to comply with the new guide.

On these issues, MIT supports comprehensive and detailed commentary from such organizations as the National Association for Biomedical Research (NABR), the American Physiological Society (APS), and the coalition letter sent by the Council On Governmental Relations (COGR)/ Association of American Universities (AAU)/ Association of American Medical Colleges (AAMC). MIT will refer to the comments submitted by these organizations regarding the Proposed Adoption and Implementation of the Guide for the Care and Use of Laboratory Animals: Eighth Edition throughout the commentary below.

Of specific concern for MIT is the impact of much of the language used throughout the proposed Guide. For instance, the new Guide contains more than 40 statements about what institutions “must” do. In addition, there are now approximately 660 recommendations incorporated in the Guide stating what PHS award seekers “should” do.

The 2011 Guide defines “must” statements as “actions that are imperative and mandatory duty requirements.” “Should” is said to mean “a strong recommendation for achieving a goal” noting “individual circumstances might justify an alternative strategy.” We support reexamination of this language and we refer you to the further commentary from the American Physiological Society (APS) (attached) on this issue.

In addition, the significant adjustment of cage size will impact our campus and will have a negative effect on our ability to conduct important research. These adjustments include the 2-inch increase in the height of rabbit cages and several changes in non-human primate caging. These adjustments also include the revision of minimum space for laboratory rodents, specifically for “Female + litter” for both mice and rats, which specifies a floor area of 51 in² (330 cm²) for the former housing group and 124 in² (800 cm²) for the latter. This will require replacement of existing cages for breeding pairs and trios with larger cages. Further complicating the issue, according to these guidelines, “Floor space taken up by food bowls, water containers, litter boxes and enrichment devices (e.g. novel objects, toys, foraging devices) should not be considered part of the floor space.” There are significant issues associated with these recommendations and we request a full review of these guidelines. We refer you to the comprehensive commentary provided by the National Association for Biomedical Research (NABR) (attached) for more in-depth comment on these issues.

In an effort to continue to address these issues, as well as ease the transition to the new Guide with any required administrative changes in each of our affected laboratories, we request an extended implementation date. On this issue, MIT agrees with the commentary submitted by the American Physiological Society (APS). NIH’s proposal to require completion of a semi-annual inspection and devise a plan for correcting deficiencies by March 31, 2012 is insufficient given the significant changes discussed above. MIT requests that NIH delay the effective implementation date of the new Guide until March 21, 2013 and refers the reader to the commentary from APS (attached) for a more in-depth treatment of this subject.

We request a review of these new guidelines, as well as a review of the implementation plan to enable our university to fully comply with the new Guide. We refer you to additional commentary provided by COGR/AAU/AAMC on development and implementation of the proposed Guide for the Care and Use of Laboratory Animals: Eighth Edition. Again, we appreciate your efforts in updating the Guide and we are available for further comment as requested.

Sincerely yours,



Claude R. Canizares

Attachments:

1. Related commentary from the National Association for Biomedical Research (NABR).
2. Related commentary from the American Physiological Society (APS)
3. Related commentary from the coalition comments of the Council On Governmental Relations (COGR)/ Association of American Universities (AAU)/ Association of American Medical Colleges (AAMC).

cc: Dr. Francis S. Collins, MD, PhD
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