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RE: Invitation to Comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities

The University of Texas System is pleased to have the opportunity to respond to the March 11th NIH Office of Laboratory Animal Welfare (OLAW) invitation to comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities. The University of Texas System is the second largest public university system in the United States, with nine academic universities, six health institutions and \$2.4 billion in total research expenditures funded by federal, state, local and private sources. The researchers at the University of Texas System understand that regulatory oversight is a necessary component of federally supported research. They are committed to the humane, ethical and regulatory compliant conduct of their research. While acknowledging the importance of regulatory oversight, additional guidance can have the unintended consequence of diverting faculty time and resources from active research and increasing workload on administrative units such as the Institutional Animal Care and Use Committee (IACUC). It is imperative that guidelines that are a part of the oversight of research that involves animals advance the goal of animal welfare and not simply increase regulatory burden. It is in this spirit that the University of Texas System provides the following comments on the proposed guidance.

The IACUC has discretion to add to the following sections A. and B. or to establish a mechanism for determining significance on a case-by-case basis while remaining consistent with A. and B. It is the responsibility of the IACUC to clearly define and communicate to investigators its policy for determining significance.

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

- that have the potential to increase the level of pain or distress of the animal and includes all changes that involve anesthesia, analgesia, sedation, or euthanasia;

University of Texas System Comment:

Euthanasia, under the current regulations, is not considered a painful or distressful procedure. While euthanasia, when performed improperly, may have the potential to cause pain or distress, the way the proposed guidance is worded it indicates that euthanasia could be classified as painful and/or distressful. The guidance can be reworded to indicate that euthanasia, when performed properly, is not considered a painful or distressful procedure. Alternatively, euthanasia changes could be stated separately so as not to infer that euthanasia is a painful and/or distressful procedure.

- in frequency, interval, type, number, or anatomical location of:
 - procedures; and
 - substances delivered to the animal.

University of Texas System Comment:

Many studies involve only procedures that are not considered to induce more than a momentary or slight pain or distress. The proposed guidance would seem to require procedures originally identified as not causing more than a momentary or slight pain or distress that are changed to procedures which still do not cause pain or distress be considered as a significant amendment. It is unclear how this would significantly improve animal welfare. This is not currently a regulatory requirement and this requirement would result in a significant increase in regulatory burden. Additional clarification is required.

It is unclear what the proposed guidance means by “substances”. For example would changes in frequency, interval or type of food or treats need to be considered as significant amendments? The term “substances” is too broad and ill defined, additional clarification or definition is needed.

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

- in animal numbers or species;
- to house or use animals in a location that is not part of the animal program overseen by the IACUC;

University of Texas System Comment:

Since it appears to be the intent of OLAW to clarify the approval of satellite housing locations as defined in the *PHS Policy on Humane Care and Use of Laboratory Animals* or areas where surgery is performed, then the second bullet point should be specific to such locations. Current OLAW guidance documents do not stipulate a particular level of oversight for animal use areas outside of housing, satellite, and surgery locations. Having to approve all animal use locations as significant amendments, regardless of their type of use, represents additional regulatory burden that does not improve animal welfare.

- in the scope of an approved animal activity; and
- in Principal Investigator.

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:

UT System Comment:

Due to the myriad of interpretations of what “...the IACUC is to be informed...” may entail, this should be clarified. To meet the requirement that IACUC members be fully informed while maintaining regulatory flexibility the guidance should be revised to “However, there must be a defined process to keep the IACUC informed of changes handled by the IACUC staff.”

- total increase in animal number for animals not regulated by USDA that does not exceed 10% of the number reviewed and approved by the IACUC;

UT System Comment:

OLAW and the USDA should work to harmonize the expectations of both agencies.

- change that would result in less discomfort or invasiveness to the animal, except the changes described in section A.;

UT System Comment:

The word “discomfort” is not used in existing regulations and guidance documents. Therefore, this should be re-stated as “pain and/ or distress” which would make this proposed guidance consistent with other regulations.

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

UT System Comment:

There is currently no regulatory requirement to track any changes in stock, strain, or genetic modification beyond ensuring that stocks, strains, or genetic modifications that have clinical or veterinary concerns are appropriately handled. Therefore, this proposed guidance would significantly add to current regulatory burden. The ability to simply track the thousands of genetic modifications that occur on a regular basis under approved IACUC protocols much less to review each to determine whether it represents a significant change is an extreme administrative burden for both researchers and IACUCs without providing clear commensurate improvement in animal welfare. The current regulatory requirements for appropriate veterinary oversight are sufficient to ensure animal welfare.

- 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;

UT System Comment:

For larger institutions with multiple animal facilities, this could imply that moving animals from one centrally managed animal facility (vivarium) to another that are part of the animal program now need to be tracked by the IACUC. Typically, this activity is currently tracked by the animal facility management and/or veterinary departments. Adding this tracking could significantly add to regulatory burden and would not improve the oversight of research animal welfare.

- 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.);

- correction of typographical errors;
- correction of grammar; and
- contact information updates.

UT System Comment:

These last three bullet points consist of requirements that appear nowhere else in the regulation or guidance. The requirement for an amendment and to inform the IACUC of such minor changes which have no impact on either the scientific aspect or animal welfare aspect of the protocol represents a significant new regulatory burden that does not advance animal welfare.

We commend the Office of Laboratory Animal Welfare for seeking comment as it develops guidance ensure the humane care and use of animals in PHS-supported research, testing, and training while balancing investigator and institutional burden. Please do not hesitate to contact us for any additional information from the University of Texas System that may assist the task force in this important effort.

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