

May 14, 2014

Office of Laboratory Animal Welfare  
National Institutes of Health  
9000 Rockville Place, Bethesda, MD 20892

Dear Sir/Madam:

Thank you for giving us the opportunity to comment on proposed guidance regarding significant changes (Notice Number: NOT-OD-14-063). SRI's IACUC would like to offer our comments as follow:

<b>Language from OLAW draft guidance</b>	<b>Comment</b>
A. Significant Changes (may have/have direct impact on animal welfare) include:	
<ul style="list-style-type: none"><li>• in frequency, interval, type, number, or anatomical location of:<ul style="list-style-type: none"><li>○ procedures; and</li><li>○ substances delivered to the animal</li></ul></li></ul>	Does OLAW mean an increase in frequency, shorter interval and greater number? An example for each type of change would be helpful.
B. Significant changes that may/may not have direct impact on animal welfare:	
<ul style="list-style-type: none"><li>• in animal numbers (see <a href="#">Guide for the Care and use of Laboratory Animals, p. 25</a>) or species;</li></ul>	Need clarification from OLAW as to what is meant by this item. Page 25 of the Guide says that an increase in animal numbers should be statistically justifiable. Does OLAW mean any change in animal numbers such that the new number is not statistically justifiable is a significant change? Such a change should not be approved by the IACUC at all, correct?

<p>C. Insignificant changes that may be handled by IACUC staff without IACUC review and approval (but IACUC still needs to be notified of changes after approval):</p>	
<ul style="list-style-type: none"> <li>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</li> </ul>	<p>Why the phrase “not regulated by USDA”? So if not a regulated species, greater than 10% increase is significant and up to 10% increase is considered a minor change meanwhile ANY increase in number is considered significant for regulated species? Need clarification from OLAW.</p>
<ul style="list-style-type: none"> <li>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</li> </ul>	<p>Need clarification from OLAW Since in most institutions, this is a vivarium-management function, not the IACUC’s (i.e. no protocol amendment is required when animals are moved from housing room A to housing room B or when procedure room 1 is used instead of procedure room 2. This kind of change is mostly driven by space availability and is assigned by vivarium management.)</p>
<ul style="list-style-type: none"> <li>contact information updates</li> </ul>	<p>Need OLAW to clarify whether a change in contact number requires a protocol amendment. Currently, the protocol is not necessarily amended when contact numbers change since a current phone list is already being maintained by vivarium management and is posted throughout the animal facility.</p>

Should you have any questions on SRI's comments, please feel free to contact me at (650)859-2412 or [sherry.hanen@sri.com](mailto:sherry.hanen@sri.com).

Sincerely,



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 Director, Corporate Regulatory Compliance  
 IACUC Chairperson  
 SRI International (Assurance #A3025-01)