NABR Comments on the March 1, 2015 Stakeholder’s Announcement regarding Revision of the APHIS Animal Welfare Inspection Guide

1. **New instructions for inspecting research facilities which have not engaged in regulated activities in the prior two years [Chapter 4; page 25]**

   The heading on page 25 has been changed to read Inactive Research Facility or Research Facility with No Activity for Two Years—Inspection. This change clearly delineates a facility which has formally requested and been placed on inactive status from a facility which has made no such request but has not been active for two years. This can be because the facility has either not conducted any activity for the past two years or has only been conducting uncovered activity for the past two years.

2. **A more consistent procedure for reporting exceptions and exemptions on the Annual Report [Chapter 7; page 26]**

   The change in language as it relates to reporting exceptions and exemptions is consistent with the interpretation that NABR has been espousing for several years and which was discussed during the 2014 Q & A with the USDA webinar. The current language recognizes that where the regulations or standards provide the IACUC with a mechanism for approving a specific activity either as an exception to the regulations and standards or as an exemption provided for in the regulations and standards, that an explanation for this approval should not be included in the annual report. This includes approval of multiple major operative procedures under one protocol, exemptions to the plans for exercise for dogs or environmental enhancement of nonhuman primates, short term food and water restrictions and deviations from the methods of euthanasia as defined in the AWA regulations.

3. **Properly handling significant changes to research protocols – to better align with current guidance issued by the Office of Laboratory Animal Welfare [Chapter 7; page 27]**

   This change provides the VMOs with guidance that aligns the USDA inspection process with the recently released OLAW guidance on handling of significant changes to protocols. If institutions take advantage of this change through the development of SOPs, guidance documents and formularies, they will reduce the administrative burden for the IACUC and the investigator. If an institution implements these changes and develops a system to keep protocols current with the changes made, it will minimize the chance that the facility will be cited for lack of congruence between the ongoing activity and an approved protocol.

4. **New instructions on reviewing research protocols during inspections [Chapter 7; page 29]**
The revisions to this section of the AWIG in response to a suggestion contained in the OIG Audit report to provide guidance to the VMO on how to select and review various types of protocols and should be carefully reviewed by those involved with the management of the IACUC and the inspection response program. An issue of concern that arose out of the OIG report was the recommendation that VMOs document and maintain a record of the protocols reviewed and the rational for selecting them. The concern was that maintaining records which identify specific protocols could be subject to FOIA and when those protocols were from public institutions, subject to state open records acts and thus place the investigator at risk of harassment. The Research Facility Protocol Selection Worksheet developed by APHIS can be found on page 7-59 of the AWIG. It contains five categories of reasons for selecting a protocol and a column for indicating how many protocols were selected for each of those categories. The individual protocols are not identified.

5. **Regulating non-farm animals that are used to develop and test vaccines for farm animals [Chapter 7; page 36]**

   This topic was addressed in the 2014 Q&A with the USDA Webinar and the changes in the AWIG change the answer that was provided at time, so that rabbits used for the development or testing of agricultural products and/or production of serum are now covered by the AWRs and subject to inspection. If your facility uses non-farm animals to develop and test products for farm animals, you should carefully read this revised section.

6. **Updated guidance for completing the Annual Report [Appendix A; pages 35, 39 and 41].**

   The changes made to these supporting documents, that are included in the annual report packet, correct language that was not consistent with that contained in the regulations.