NIH-USDA-FDA 21st Century Cures Act Listening Session on Animal Research

January 29, 2018 | AAALAC International Council Meeting[1]

Agency Representatives (via call-in/webmeeting)

- Pat Brown, VMD, OLAW, NIH
- Betty Goldentyer, DVM, Animal Care, APHIS, USDA
- Estella Jones, DVM, FDA

Background

- Pat Brown gave a short slide presentation about the 21st Century Cures Act, agency actions to convene a working group, and plans for public request for information (RFI) in early 2018.

Comments from Council Members

- The PHS Animal Welfare Assurance is lengthier than the IRB Assurance. Consider approaches to reduce this task.
- Question: What is the difference between regulations, policies, laws, and guidance? Regulations are required as written in the law and not optional (e.g., AWA). Agencies develop policy to inform the community of specific guidance pertaining to implementation of the regulations. In response to the Cures Act, agencies can change policy or regulations. However, it is a long process for changing regulations and changes to laws require Congressional action.
- Semiannual program review and facility inspections every 6 months could lead to complacency. Suggest that this could be more effective every 12 months.
- Question: What is the status of the update to the GLPs as there could be redundancy with another agencies guidance? The original GLPs are over 30 years old. FDA is currently revising the GLPs with plans to incorporate provisions of the PHS Policy and AWA. FDA legal counsel is reviewing 3500+ comments on the proposed rule. Final rule is expected in late 2019.
- Ensure consistency among agencies in interpretation of regulations and policies. OLAW FAQs seem to over-interpret the *Guide*.
- Having to include written justifications and descriptions of methods, procedures, and sources for the AWA requirement for alternative search requires time and effort with seemingly minimal benefit to animal welfare.
- The time and effort needed to obtain and retain IACUC approval is burdensome. Suggest a risk-based review and approval process along the lines of the Common Rule as an extension of DMR and VVC methods of approval.
- Suggest requiring reporting of programmatic concerns to OLAW rather than individual / single event issues.
- Suggest changing IACUC protocol approvals from 3 years to 5 years to match NIH grant funding lengths.
- Suggest aligning review periods (i.e., annual reviews) among the agencies.
- Question: The Cures Act provides for a 2-year period. What is the proposed timeline for the agencies? The deadline required by law is December 2018 and the agencies expect a final report to address concerns raised and proposed actions by December 2018.
- NIH grant proposals have moved away from documenting every animal used, but OLAW seems to be requiring institutions to document all animals whether used or not. Institutions expend significant time tracking rodent and fish animal numbers and use various methods that may result in inconsistency in totals tracked.
- Reconsider the need for annual USDA inspections for AAALAC-accredited institutions. USDA Response: USDA is exploring ways to incentivize compliance and give credit for 3rd party-accreditation.
- Expanding on the topic of inspections: Recommend reciprocity where reviews by one agency would satisfy inspection requirements of another agency.
- Recommend developing a single form (e.g., annual report) that would be accepted by all agencies.
- Consider updating the *Guide* more frequently.
- Various guidance is published as FAQs, commentary, etc., consider if this means of establishing agency expectations is necessary.

[1] The comments made, and questions posed reflect points raised by the individual volunteer members of the Council on Accreditation.