

NIH Adopts 8th Edition of the *Guide*: A Discussion

Patricia Brown, VMD, MS, DACLAM
Director, OLAW, NIH
OLAW Online Webinar
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- Oversees the welfare of research animal subjects in PHS-funded activities.
- Compliance with PHS Policy is required if the institution accepts PHS funds



NIH Adopts 8th Edition of the *Guide*

Assured institutions must:

- Base animal care and use program on 8th Edition
- Complete at least one semi-annual program review using 8th Edition by December 31, 2012
- Develop reasonable plan and schedule by December 31, 2012
 - All changes need not be completed, but plan and schedule must be in place by December 31, 2012
- Verify implementation in 2012 Annual Report to OLAW due January 2013

<http://grants.nih.gov/grants/olaw/2011positionstatement.htm>



Why Adopt?



- The 8th Edition of the *Guide* empowers continued advancement in the humane care and use of vertebrate animals in research, research training, and biological testing
- Using performance standards, IACUCs are able to meet their responsibility to ensure humane animal care and use while advancing quality scientific research



Impact of Implementing



Implementation is expected to have a minimal impact on institutions currently using well-developed performance standards. These may not need to be revised as part of the institution's implementation.

Institutions that do not have performance standards are expected to use *Guide* benchmarks to develop them.



Guide is Guidance, Not Regulation

“This [PHS] Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* and that they comply with the applicable regulations issued by the USDA under the Animal Welfare Act.”

PHS Policy Page 9, Footnote 2

<http://grants.nih.gov/grants/olaw/references/phspol.htm>

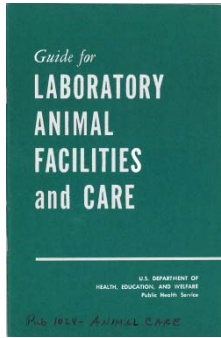


OLAW Website: Updated to 8th Edition

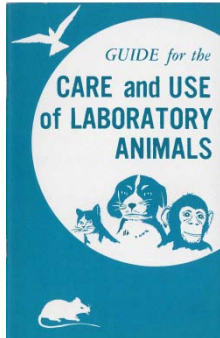
- Frequently Asked Questions
- OLAW Tutorial on PHS Policy
- Sample Documents:
 - Annual Report to OLAW (to be revised for 2013)
 - Animal Welfare Assurances (Domestic, Foreign, Interinstitutional)
 - Semiannual Program Review and Facility Inspection Checklist (Checklist)
 - Semiannual Report to the Institutional Official
 - Animal Study Proposal



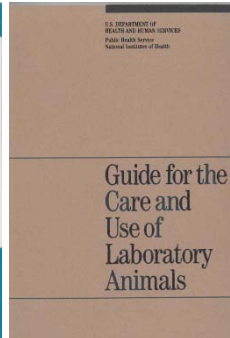
The *Guide* is a Living Document



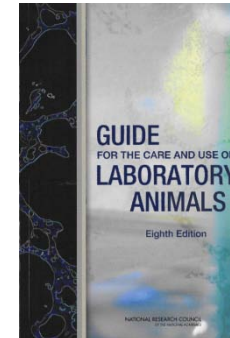
1965



1972



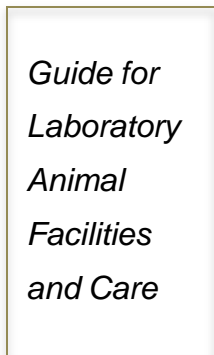
1985



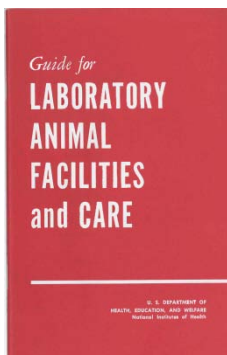
2011



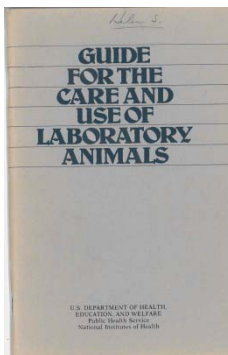
1963



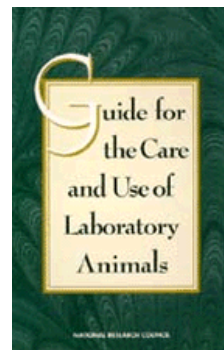
1968



1978



1996



Guide Authorship

- National Academy of Sciences, Institute for Laboratory Animal Research (ILAR) *ad hoc* committee recommended update in 2006
- 13 member expert committee appointed in 2008
 - Scientists: representing biomedical research
 - Veterinarians: representing the animals
 - Non scientists: representing ethics and public interest in animal welfare
- NIH was one of ten funders



NIH Solicited Public Comments

- 797 comments from 137 institutions, organizations:
 - Assured institutions (32)
 - Professional organizations (24)
 - Animal advocacy organizations (4)
 - Individuals (600)
 - 276 comments appear to have originated from four form letters
- Comments posted on OLAW website
 - Nonresponsive and duplicates removed
 - Names removed from personal comments
 - Organizational affiliations displayed



NIH Issues Position Statements

- OLAW developed Position Statements on areas of concern in public comments
- Position Statements posted on OLAW website:
 - Explain how NIH expects institutions to implement the 8th Edition
 - Comments on performance and practice standards
- 60 day public comment period regarding understanding the Position Statements,
 - Comment period ends January 30, 2012
 - OLAW may further clarify position statements

<http://grants.nih.gov/grants/olaw/2011positionstatement.htm>



Performance Standard Criteria

Performance standards are the most important infrastructure component of PHS oversight at Assured institutions. OLAW expects Assured institutions to apply professional judgment and experience to the challenges inherent in developing policies and procedures to maintain a quality program that provides humane care to vertebrate animals.

Performance standards:

- Supports scientific objectives
- Supports the health and welfare of the animal
- Includes a justified performance index
- Includes associated outcome criteria



Departures from the *Guide*

- IACUC must review and approve departures from the minimum standards (PHS Policy IV.B.3)
- OLAW considers *Guide* “must” statements minimum standards required of Assured institutions
- *Guide* “should” statements involve performance standards
- Established performance standards are not a departure from the *Guide*



Alternative to *Guide* Recommendations

- OLAW supports the *Guide*'s approach:
 - Applying performance standards to achieve specified outcomes
 - Allowing individualized applications of the standards at the local level
- Alternative must satisfy PHS Policy requirements



Position Statement Topics

- Cost
- Housing
 - Nonhuman Primate Housing
 - Environmental Enrichment
 - Rodent Housing
 - Rabbit Housing
- Non-Pharmaceutical Grade Substances
- Food and Fluid Restriction/Use of Preferred Foods
- Multiple Surgical Procedures
- Agricultural Animals

<http://grants.nih.gov/grants/olaw/2011positionstatement.htm>



Cost

- Cost cannot be overriding factor in decisions related to animal welfare
- Achieve compliance using teamwork, professional judgment, and experience
- OLAW supports the *Guide's* approach in allowing individualized applications of the standards at the local level
- Alternatives must satisfy PHS Policy requirements



Housing

- Use outcome-based performance standards in evaluating cage or pen space
- *Guide* space recommendations are a starting point
- Performance standards allow flexibility



Nonhuman Primate Housing

- Nonhuman primates must be socially housed
- Exemptions to social housing must be based on:
 - Scientific justification approved by the IACUC
 - Veterinary medical reason
 - Behavioral reason
- Compliance with USDA regulations is required
- Single housing limited to minimum period
- Determination of cage size is not based on body weight alone
- Professional judgment is paramount



Environmental Enrichment

- Purpose is to enhance animal well-being
- Must be species-specific and appropriate
- Devices that animals climb on or through, perch on, or nest in contribute to the living space and need not be subtracted from floor dimensions
- Avoid using items that are distressing to some species or individuals



Rodent Housing

- *Guide's* space recommendations are starting point
- Adjustments may be made by the IACUC using outcome-based performance standards and indices:
 - Health
 - Reproduction
 - Growth
 - Behavior
 - Activity
 - Use of space



Rodent Housing: Breeding Management

- Commonly used rodent cages may be appropriate for trio breeding
- IACUCs may consider adequacy of cage space:
 - Average litter size of the strain(s)
 - Multiple litters present
 - Difference in age of litters
 - Growth rate
 - Need for cross-fostering
 - Management and husbandry practices
- Must ensure animal well-being and avoid overcrowding



Rabbit Housing

- Meet physical, physiologic and behavioral needs
- Take into account typical posture and adequate clearance
- IACUC may consider 14 inch high rabbit cage appropriate using performance indices
 - Hold ears upright
 - Ears not forced to be folded over by contact with cage ceiling



Non-pharmaceutical-grade Substances

- Pharmaceutical-grade substances, when available, must be used to avoid toxicity or side effects
- Frequently it is necessary to use investigational compounds, compounded drugs, and Schedule I controlled substances in research activities
- IACUC must evaluate potential adverse consequences:
 - May consider a number of factors in making its evaluation (listed in the position statement)
 - May establish acceptable scientific criteria in lieu of case-by-case review
 - Cost saving alone is not adequate justification
 - Agents for sedation, analgesia, anesthesia or euthanasia must be pharmaceutical grade, unless justified and IACUC approved



Food and Fluid Restriction

- Record amount of regulated item given during testing and freely given to meet minimum daily requirements
- Monitor both food and fluid if one influences the consumption of the other
- IACUC may approve scientific justification for departures
- IACUC must evaluate:
 - level of restriction
 - potential adverse consequences
 - methods to assess well-being
 - assure hydration, maintenance of body weight, behavioral, and clinical health



Multiple Surgical Procedures

- Define surgical procedures as major or minor and determine impact
- Multiple procedures that may induce pain or impairment must be scientifically justified and IACUC-approved
- Multiple major surgical procedures are acceptable if:
 - Essential component of single project/proposal
 - Scientifically justified
 - Necessary for clinical reasons
- Cost savings not adequate reason



Agricultural Animals

- *Guide* applies to agricultural animals used in biomedical research including those in farm settings
- 2010 Ag Guide is a useful resource
- Information on environmental enrichment, transport and handling may be helpful



Questions?

Please submit questions using the Go-To-Webinar question window.

