

NIH Rigor and Reproducibility: Use of Animals in Research February 18, 2016 §

This session will be a discussion of the factors contributing to variability of data associated with animal studies. With the new NIH requirements to address rigor and reproducibility in grant applications, we will discuss how investigators might approach the requirement with respect to explaining the conditions around which studies are conducted.

Visit the National Institutes of Health website for background information on [Rigor and Reproducibility](http://grants.nih.gov/reproducibility/index.htm) @ <http://grants.nih.gov/reproducibility/index.htm>.

General parameters to be considered for *in vivo* work:

Animal Information:

1. Complete nomenclature for animals used (strain, stock or line name)
2. Vendor (name and catalog number)
 - a. Vendor housing conditions
 - b. Shipping/transportation mode
 - c. Breeding paradigm, weaning schedule
 - d. Housing/cage density
3. Pathogen status/microbiome
4. Sex
5. Age
6. Weight
7. Diet (source and content)
8. Water (acidified, tap, DI, autoclaved) (Bottles or automatic)
9. Bedding type
10. Enrichment
11. Confirmatory genotyping
12. Immune status

Health Profile of Animal Colony:

1. Descriptions of health screening program and parameters
2. Quarterly Health Screening: soiled bedding sentinels- serology for rodent viruses and pathogens endemic to the facility (i.e. *Helicobacter*, murine norovirus are common); bacterial strains
3. Annual Health Screening: contact sentinels with PCR sampling, serology + necropsy+ microbiology- viruses, bacteria, parasites
4. Quarantine period: exclusion list for pathogens (facility pathogen specific)

Animal Micro-Environment (at the CAGE level) and Macro-Environment (at the ROOM level)

1. Sterile or non-sterile caging

2. %Cage space requirements (include cage size and animal density)
3. %Social or individual housing
4. %Individually ventilated or static caging
5. %Cage components, materials, opacity
6. %Room temperature
7. %Relative humidity
8. %Cage change cycle
9. Light cycle %
10. Acclimation period %
11. Air exchange or flow rate in cages and rooms %
12. Caretaker gender, training, technical competency %
13. Microbiota (animal, room, facility, support areas) %
14. Cleaning chemicals and pest control measures %
15. Intracage measurements (e.g., ambient ammonia levels) %
16. Quarantine period (separate location, microbiota, etc) %

Technical Procedures:

1. %Route (intraperitoneal, subcutaneous, intravenous, intramuscular, oral delivery)
2. %Volume
3. %Dosage
4. %Collection time points and frequency
5. %Anesthetics (route of administration, technical verifications such as vaporizer calibration for gas delivery)
6. %Euthanasia method (if post-sampling conducted)
7. %Sample collection and preparation (include manufacturer and catalog numbers for all reagents, potentially supporting SOPs for preparation steps)
8. %Surgical interventions and modifications
9. Drugs administered for medical reasons (e.g., pinworm, analgesics) %
10. Relevant physiological parameters (if measured) %

Materials:

1. %Description of drugs, diluents, buffers, medias, cells, etc. (manufacturer and catalog numbers)
2. %Cell lines tested for rodent pathogens or contamination
3. %Reliance on ARRIVE guidelines

REFERENCES + RESOURCES:

- ILAR. 2011. Guide for the Care and Use of Laboratory Animals, 8th Edition. The National % Academies Press, Washington, D.C. %
- ILAR Roundtable Workshop: Reproducibility Issues in Research with Animals and Animal Models, June 4-5, 2014 (<http://nas-sites.org/ilar-roundtable/roundtable-activities/reproducibility/>)
- *Nature* (multiple articles): <http://www.nature.com/nature/focus/reproducibility/index.html>.
- APS Symposium <http://www.the-aps.org/mm/SciencePolicy/Agency-Policy/Reproducibility>
- Institute for Laboratory Animal Research. Guidance for the Description of Animal Research in Scientific Publications. 2011. The National Academies Press
- http://www.faseb.org/Portals/2/PDFs/opa/2016/FASEB_Enhancing%20Research%20Reproducibility.pdf