

The following tips are provided for consideration by those engaged in biomedical research governed by the Animal Welfare Act, the Health Research Extension Act of 1985, and related amendments, regulations and guidance from USDA and NIH but do not constitute legal or veterinary advice.

- The key to compliance is understanding what the federal laws require (these tips are limited to federal authority), but also, how they have been interpreted by federal agencies and specific individual animal health officials, including inspectors (with emphasis on USDA, APHIS, Animal Care Inspectors).
- Respecting and developing a cordial professional relationship with federal animal health officials is key.
- Understand that the role of federal animal health officials is to enforce the laws governing federally protected animals in research, and they must perform that role objectively and without bias.
- In addition to knowing what the laws require, consider reviewing the following guidance:

Animal Welfare Inspection Guide available at

<https://www.aphis.usda.gov/sites/default/files/animal-care-inspection-guide.pdf>

The Inspection Guide is not a Regulation or Standard and does not rise to the level of policy.

Updated regularly

OLAW- Departures from the Guide available at

<https://olaw.nih.gov/guidance/departures-from-the-guide.htm>

NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

POLICIES, GUIDELINES, SOPS

- Documents that specify the conduct of research are confidential and must be protected as such to protect the integrity of the research facility.
- Documents should be internally consistent.
- Wording is critical.
- Procedures to identify and investigate potential noncompliance, adverse events, expected outcomes, unexpected outcomes must be carefully drafted to protect integrity of IACUC and IO while addressing any issues identified.
- Investigations are confidential, preliminary and must protect employees.
- Examples of confidential documents:
 - Physical observations of animals
 - Veterinary treatments
 - Toxic profiles of compounds under study
 - IACUC minutes discussing specific protocols
 - Proprietary animal enclosures
 - SOP's

METHODS TO PROTECT CONFIDENTIAL INFORMATION.

“At least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is “confidential” under FOIA exemption for confidential commercial information, abrogating National Parks and Conservation Ass'n v. Morton, 498 F.2d 765 (D.D.C. 1972).”
Food Mktg. Inst. v. Argus Leader Media, 588 U.S. 427 (2019).

- Designate any and all documents as “Confidential and Proprietary” as applicable.
- Require and maintain confidentiality agreements between vendors, licensees, and employees.
- Minimize employee access to Confidential Information.
- Execute confidentiality agreements with employees and contractors, as well as non-disclosure agreements with its customers, auditors, investors and prospective investors and prohibit partners and customers from publishing information;
- Limits access to the information on a “need-to-know basis”;
- Maintain a company-wide confidentiality policy and program for training employees on the confidentiality of the information, how to guard it, and how to report suspected and actual breaches;
- Create the position of a privacy officer responsible for overseeing the protection of confidential information;
- Physically safeguard hard-copy materials;
- Password-protect electronic materials;
- Maintains industry standard network security;

Redact or don't provide the following information

- Social Security Numbers
- Birthdates
- Home addresses and phone numbers
- Sources and amounts of pending support
- Sources of private support
- Portions of videos that display individual likeness.
- Photos of private individual's face.
- Driver's license number and date of birth.
- Names, professional titles and a signature of third-party individuals.
- Familial titles, telephone numbers, email addresses and veterinary license numbers, of private third-party individuals.
- Records that disclose private telephone numbers, private, non-public addresses and email addresses.
- Signatures of third-party individuals and licensees.

Control content of confidential documents

- Original drafts of documents should minimize or eliminate names, locations, identifiers.
 - Use titles or employee codes instead of names.
 - Exclude contact information in SOPs unless needed (e.g., contingency and emergency plans).
 - Use confidential attachments if contact information is required.
- Minimize information in official documents-limit to required information.
 - E.g., IACUC minutes, Assurance.
- Redact trade secret, confidential and private information not required for agency review.
- SOPs, protocols, guidance and policy statements are the trade secrets or confidential information of the facility that differentiates it from similarly situated competing facilities.

PREVENTABLE USDA CITATIONS

Review citation reports of other research facilities and avoid similar issues

HIGH RISK CATEGORIES

- Study protocol review
- Scientific justification
 - Animal numbers
 - Specific procedures
 - 3Rs
- Identify text that indicates painful procedure or impact to animal welfare
 - Database review for alternatives for each term identified
- Incorporate by reference SOPs
 - Identify requirements in SOPs and provide to PI team prior to study initiation
- Contingency plans
- IACUC meeting minutes content
- PAM
- Adverse event reporting
 - No assumptions. Report observations.
- Internal coordination-husbandry team, veterinary team, research team
- USDA inspection discussions

PREPARATION FOR USDA INSPECTIONS

- Research particular preferences and concerns of your USDA inspector.
- Not all questions should be answered-there are often questions about adverse events-these should be referred to determination by IACUC.
- Consider jurisdictional issues when documents are requested-e.g., OLAW and AAALAC correspondence; confidential preliminary reports.
 - Inspector may believe that any document may be requested, but there is a limitation. May require input from attorney.

- Any noncompliance or adverse event previously identified-be prepared to discuss whether a citation should issue and if so, what regulation should be cited.
- Provide corrective action, even if no errors occurred.
- Any documents requested or photos taken-redact all confidential information prior to submission (if not, such protection could be waived).
- Request photos are deleted if not needed for citation.
- Exit interview
 - Request narrative if citations are issued.
 - Requirement to consider requested revisions of narrative.
 - Should citation have been issued? Make all arguments during exit interview and preserve right to appeal. Provide additional documents or information.
 - Is it the proper citation?
 - If designated “critical” is that accurate?
 - If designated “repeat” is that accurate?
 - Are facts correct?
 - Are there duplicate citations? Same facts used in more than one citation.
 - Review animal inventory carefully.

USDA APPEAL

Consider appeal if applicable.

IES INVESTIGATION

Must have legal representation for all officials and staff. Do not proceed alone.

Minimize email correspondence with federal officials. Subject to FOIA requests.



**WORKING WITH ANIMALS TO
FIND MEDICAL CURES IS
CHALLENGING.**

WE HEAR YOU.

Fox Rothschild's Animal Law attorneys understand the issues that the biomedical research community faces due to the increasing influence of animal rights activists.

With our in-depth experience and national involvement, we help our clients avoid obstacles and solve problems so they can focus on what is most important: achieving medical breakthroughs for humans AND animals.

 **Fox Rothschild** LLP
ATTORNEYS AT LAW

950 attorneys nationwide

Nancy E. Halpern, DVM, Esquire
Partner and Chair, Animal Law Practice
nhalpern@foxrothschild.com | 609.844.7404

Princeton Pike Corporate Center
997 Lenox Drive, Building 3
Lawrenceville, NJ 08648
www.foxrothschild.com

For more information, contact:

Nancy Halpern, DVM, Esq.
Chair, Animal Law Practice Group

Fox Rothschild LLP

609.844.7404

nhalpern@foxrothschild.com