

**Elanco's Animal Care and Use Expectations for Third Parties Organizations (TPO)
(Contract Research Organizations, Animal Suppliers and Transporters, etc.)**

The ability to perform animal research is a privilege. Elanco Animal Health recognizes that everyone working with research animals has an ethical and scientific obligation to ensure their appropriate use, care and treatment. The expectations set forth in this document provide the framework for animal work initiated by Elanco and performed by third party organizations. This includes animals to be used in research, such as suppliers and transporters, as well as those used in research studies, such as Contract Research Organizations (CROs), universities, governmental institutions, and organizations supplying custom animal derived biologics.

This document does not apply to client-owned animals or studies using an Elanco product according to the approved label in that country.

Core Expectations of Third Parties include:

- Having provisions in place to provide adequate veterinary care with appropriate experience and oversight to ensure good animal health.
- Reporting all incidents that negatively impact study integrity or animal welfare within Elanco studies to the study sponsor representative within one business day.
 - This would include but is not limited to any animal illness, disease outbreaks, or any significant (i.e., reportable to a government authority) non-compliance with any country or local animal welfare laws, regulations, or standards.
- Complying with regulatory requirements relating to the care and/or use of animals.
- Providing trained and proficient staff for the job tasks assigned, including documentation.
- Ensuring provisions in place to identify and mitigate hazards to animals and employees.
 - Employees are informed and have procedures in place to manage these risks.
- Having a mechanism in place for reporting and investigating animal welfare concerns.
- Having written husbandry and housing procedures that promote good health and psychological well-being.
- Having defined standards that meet or exceed those defined in the "Guide for the Care and Use of Laboratory Animals¹" (Guide) and/or the "Guide for the Care and Use of Agricultural Animals in Research and Teaching²" (Ag Guide) or equivalent standards.
- Euthanasia methods that comply with local regulations and/or the AVMA guideline for euthanasia.
- Seeking continual best practices through promoting the 3Rs (Replace, Reduce, Refine), conducting frequent literature reviews, attending continued educational meetings, etc.
- Being proactive in maintaining study integrity in the event of emergencies with a Business Continuity Plan, as well as a Disaster Plan to minimize pain/suffering in the event of a catastrophic event.
- Protecting Elanco intellectual property with confidentiality agreements in place for all staff working with an Elanco Study.
- Providing appropriate security of the site based on the species of use, the types of studies conducted and the public threat for activist activity.

Elanco actively encourages TPOs to obtain and maintain AAALACi accreditation as an internationally recognized standard of research animal care and use.

Ethical Review Process

An ethical review for merit of the activities is expected for all animal studies regardless of the species used. TPOs with their own ethical review committee will also be assessed to ensure they are equivalent to Elanco reviews.

Organizations approved by Elanco without an ethical review process will have an ethical review conducted by Elanco's internal committee for studies placed at these facilities.

Animal Welfare Assessment of TPO

Third parties using animals for Elanco are required to complete a Pre-Audit Animal Welfare Questionnaire to obtain key information relating to the above expectations. TPOs must allow an in-person animal welfare audit conducted by Elanco's Global Animal Welfare Department. The facility will be assessed against the standards defined the "Guide" and "Ag Guide" and provided approval for use if they meet these or equivalent standards. All TPOs are reassessed periodically for renewal of use.

1 [Guide for the Care and Use of Laboratory Animals, 8th edition. National Academies Press \(nih.gov\)](#)

2 [Ag_Guide_4th_ed.pdf \(adsa.org\)](#)