

Global Work Instruction for Use of Animals in Laboratory Research and Training Activities

1. PURPOSE

The purpose of this global Work Instruction (WI) is to identify the process for the use of animals in connection with laboratory research and/or training in support of Teleflex products.

Teleflex is committed to ensuring the ethical treatment of animals used in laboratory and educational settings to advance patient safety and well-being, as well as compliance with all applicable laws and regulations (for example: Directive 2010/63/EU, USDA AWA/AWR, NRC Guidelines) and our Code of Ethics. Teleflex operating companies have policies that include, among other things, guidelines regarding ethical use and humane treatment of laboratory research animals and promote use of non-animal alternatives whenever feasible.

Teleflex:

- Is committed to the principles of replacement, reduction and refinement (as defined in Article 4 of Directive 2010/63/EU, NIH Guide to the Care & Use of Laboratory Animals):
 - Replacement - using alternative non-animal systems in place of live animal utilization whenever possible;
 - Reduction - using the minimum number of animals possible to achieve maximum information without compromising animal welfare; and
 - Refinement - continually modifying procedures to limit the discomfort and distress to animals.
- Does not use live animals for training sales associates.
- Does not test cosmetic or personal care products on animals anywhere in the world except in the rare situation where it is required by law or governments.

2. SCOPE

This global WI applies to the following activities conducted in support of Teleflex products:

- The use of animals in connection with laboratory research activities;
- In vivo research investigations utilizing an animal testing model; and
- The use of animals in connection with customer training or education activities.

3. RESPONSIBILITIES

Appropriate Teleflex personnel are responsible for maintaining and ensuring compliance with this global WI.

Use of animals in connection with laboratory research and education will be managed by one of the following functions:

- Clinical and Medical Affairs (CMA).
- Business Unit (BU) Research and Development (R&D) Teams.
- Global QARA Biocompatibility Team.

4. DEFINITIONS

- AAALAC – Association for Assessment and Accreditation of Laboratory Animal Care International
- Animal Investigation Protocol – Outlines the details of an animal laboratory investigation.
- Animal Laboratory Investigation – Systematic investigation utilizing animal subject(s) as a testing model to develop or evaluate use of Teleflex products.
- Institutional Animal Care and Use Committee (IACUC) – US institutional review committee to oversee and evaluate all aspects of the animal care and use program.

5. CITED DOCUMENTS

Cited documents, including external standards, are explicitly cited within the content of this work instruction.

- DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes.
- Guide for the Care and Use of Laboratory Animals. National Research Council.
- NIH Guide for the Care and Use of Laboratory Animals.
- USDA, AWA/AWR The United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations.
- D0003064 – Records Control Global SOP.

6. INSTRUCTIONS

Academic partners and contract research organizations and laboratories using animals to conduct research or training shall do so in accordance with applicable geographical regulatory governing body regulations and standards. Prior to engaging such organization and laboratories to perform such work, Teleflex personnel responsible for managing and overseeing such work shall take steps to confirm that:

- The academic partners and contract research organizations and laboratories have earned Association for Assessment and Accreditation of Laboratory Animal Care (“AAALAC”) accreditation to demonstrate their commitment to responsible animal use and care; and
- Teleflex is afforded the right to audit such organization and laboratories to ensure their compliance with applicable regional regulations.

6.1 Rationale for Use of Animals in Laboratory Research and Training

Use of live animals in laboratory research should be limited to conducting research and/or training on medical or surgical procedures (including proper product usage) when alternative non-animal models have been deemed inadequate for the purpose. Before engaging in such activities, the responsible party should confirm and document (in the research plan and/or protocol) that there are no alternative methods for generating required data.

6.2 Development and Execution of Laboratory Research

6.2.1 Research Protocol

- Research involving the use of animals will be conducted under a laboratory research protocol that outlines the objectives, endpoints, study procedures and data collection.
- The laboratory research protocol must be reviewed and approved by an IACUC or an equivalent ethical committee(s), as required by institutional and geographical regulatory body regulations applicable to the investigation site.
- The CMA/R&D lead is responsible for development and maintenance of all necessary study documentation according to the requirements of the appropriate IACUC or equivalent for the study site(s) and geographic location(s).

6.2.2 Reporting

The CMA/R&D lead will be responsible for reporting the results of the investigation. Reports will be archived in accordance to D0003064, Records Control Global SOP.

6.2.3 Training, Facilities and Service Provider

- Teleflex personnel managing the research and/or training activities in question shall take steps to ensure that all third party personnel involved with the care and use of animals have been educated, trained, and/or qualified in the principles of animal welfare and compliance to help ensure quality science and animal well-being in accordance to the institutional and/or regulatory governing body regulations.
- When possible, AAALAC accredited sites should be considered for investigation site selection.
- When possible, service providers that are AAALAC accredited should be selected in relation to execution of animal laboratory research.

6.3 Sourcing Animals

- Teleflex personnel managing the research and/or training activities in question shall take steps to ensure that live laboratory animals to be used in connection with laboratory research and training are obtained from accredited sources.