



Animal Welfare Policy Governing the Use of Animals in Research, Teaching, Testing, and Production at Aragen Life Sciences Limited.

Section Title: Research and Testing: Compliance

Approval Authority: CEO (Chief Executive Officer)

Responsible Authority: Respective Institutional Officer

Responsible Executive: Respective Attending Veterinarian

1. Policy Statement

This policy applies to all research, teaching, testing, or production activities involving vertebrate animals conducted under the auspices of Aragen Life Sciences Pvt. Ltd. AAALACi accredited Vivariums.

The policy provides the following assurances for all procedures using live vertebrate animals:

Procedures involving animals should be conducted only when they will contribute to the advancement of knowledge that is likely to lead to improvement of the health and welfare of animals or human beings, provide a better understanding of the animals themselves, or for the good of society.

Animals involved in any research, teaching, testing, or production procedures receive humane care and treatment. Animal research is conducted in a well-controlled research environment.

Concerns regarding the care and use of animals at Aragen are addressed in a professional and responsible manner.

Research involving the use of live animals is performed in an ethical manner designed to minimize pain and distress and comply with applicable regulations.

2. Reason for Policy

This policy allows Aragen to fulfil its ethical obligations to the community at large and its legal obligations to regulatory agencies. It is not intended to limit the freedom of Scientist, staff, or compliance personnel, but rather to assist in conducting research and testing of the highest quality while adhering to the highest professional standards of their disciplines and regulatory authorities.

3. Who Should Read This Policy

Scientist and staff who use live vertebrate animals for research, testing, or production purposes are required to conform to this policy. They should also be familiar with administrative procedures adopted by Aragen life sciences to ensure compliance with the principles of humane animal care and use, and with pertinent laws and regulations.

To ensure compliance, Scientist and staff utilizing live vertebrate animals are required to obtain the approval from Institutional Animal Ethics Committee (IAEC) prior to such utilization. They are further required to comply with such conditions as may be made by the Committee.

4. Resources

The Aragen embraces the CCSEA (**Committee for Control and Supervision of Experiments on Animals**), Government of India Principles for the Utilization and Care of Vertebrate Animals Used in Testing and Research.

Additionally, the Aragen shall adhere to The National Research Council's Guide for the Care and Use of Laboratory Animals (most current edition) and to the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

The Aragen will adhere to the American Veterinary Medical Association's Guidelines for the Euthanasia of Animals for methods of euthanasia of research animals (most current edition).

5. Definitions

The Guide: Refers to the National Research Council's Guide for the Care and Use of Laboratory Animals

PHS policy: Public Health Service Policy on the Humane Care and Use of Laboratory Animals

Animal Welfare Act: Refers to the Animal Welfare Act administered by the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS)

Attending Veterinarian: The role of the Attending Veterinarian

(AV) is defined in the National Research Council's Guide for the Care and Use of Laboratory Animals as the "veterinarian responsible for the health and well-being of all laboratory animals used at the institution"

CCSEA, Indian Government Principles: Refers to the Indian Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing and Research.

IAEC/IACUC: Institutional Animal Ethics committee/Institutional Animal Care and Use Committee

6. The Policy

A. Introduction

Through its use of animals in research and testing, or production purposes, Aragen incurs certain ethical and legal responsibilities for the humane care and use of those animals. These ethical responsibilities require that Scientist, staff and personnels use care, wisdom, and humane considerations when deciding on the need for animals, the choice of species, and the number of animals, for research, testing, or production purposes. In order to promote the humane care and use of animals, the Aragen Institutional Animal Care and Use Committee/ Institutional Animal Ethics committee (IACUC/IAEC) is charged with the responsibility for ensuring adherence to appropriate CCSEA and other regulatory policies and regulations, and local laws. The Aragen contends that well-conducted research with animals has provided, and continues to provide, information, ideas, and applications that can be obtained in no other way. Medical research produces clear benefits for human health care: Medical advances have contributed substantially to decreased infant mortality and increased life expectancy. In addition, medical and related research also contributes to the quality and length of life for many animals such as pets, zoo animals, and wildlife, including endangered species.

Before any work with animals commences, all procedures using live vertebrate animals, whether new, on-going and irrespective of the source or presence of funding, must be reviewed and approved by a Aragen IAEC/IACUC. This shall include use of animals for research, testing, or production purposes.

In some circumstances, the work may be reviewed and approved by another institution's IAEC/IACUC. Any sub-awards that are given to Aragen Scientists for animal studies will need Aragen IAEC/IACUC approval and oversight. IAEC/IACUC are permitted to make determinations of whether a protocol is required for an activity not clearly involving animal research and testing.

B. Principles Regarding the Use of Animals

I. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

II. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. (The use of statistical models and proper experimental design can help determine the numbers of subjects needed to produce required statistical power. Following such good scientific practice might increase the total number of animals used in a project.) Non-animal methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

III. Proper use of animals, including the avoidance or minimizing of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

IV. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anaesthesia. Surgical or other painful procedures should not be performed on un-anesthetized animals paralyzed by chemical agents.

V. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be humanely euthanise at during the procedure.

VI. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

VIII. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an IAEC/IACUC. Such exceptions should not be made solely for the purposes of teaching or demonstration.

C. Mechanisms for Compliance

To ensure consistent policies and procedures across the Aragen, an IAEC/IACUC Advisory Committee has been established to draft, revise, review, and approve animal care and use policies, guidelines, and Standard Operating Procedures (SOP). Advisory Committee membership may include representatives from administration (the Institutional Official (IO) and/or Research Compliance leadership), the veterinary staff (the Attending Veterinarian or designees), IACUC staff (administrators, IAEC/ IACUC chair, IAEC/ IACUC members.

The IAEC shall be appointed by, and be responsible to, the Executive Office of the Aragen, for monitoring compliance with this policy and with the requirements of applicable laws and regulations. The CEO may delegate to the IO, in writing, the authority to appoint IAEC/IACUC members.

The IAEC/IACUC Committees are authorized to:

1. Review at least once in year Aragen program for humane care and use of animals, using the Guide as a basis for evaluation.
2. Inspect at least every six months all of Aragen animal facilities using the Guide as a basis for evaluation.
3. Prepare reports of IAEC/IACUC evaluations and submit the reports to the CCSEA, Chair, IAEC and IO.
4. Review concerns involving the care and use of animals at the Aragen.
5. Make recommendations to the IO regarding any aspect of the Aragen animal care program, facilities, or personnel training; and
6. Review and approve, require modifications in (to secure approval), or withhold approval of those sections of proposed research or instructional protocols related to the care and use of animals according to the following Public Health Service Policy requirements, and consistent with the CCSEA, Indian Government Principles:

Implementation of the CCSEA, Indian Government Principles:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with solid research design.
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anaesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be humanely sacrificed during the procedure.

d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort.

The housing, feeding, and non-medical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

g. Methods of euthanasia used will be consistent with the recommendations of the most recent edition of the American Veterinary Medical Association's euthanasia guidelines, unless a deviation is justified for scientific reasons in writing by the investigator.

h. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.

i. Suspend any activity involving animals if it determines that it is not conducted in accordance with the specifications set forth in the Animal Welfare Act, the Guide, or the Aragen Animal Welfare Assurance filed with the National Institute of Health's Office of Laboratory Animal Welfare. A suspension may occur only after review of the matter at a convened meeting of a quorum of the responsible IAEC/IACUC, and with the suspension vote of a majority of the quorum present.

j. The Attending Veterinarian or designee has the authority to stop any animal study that is not being conducted in compliance with the regulations or this policy or is not described in an approved IAEC/IACUC protocol, until such time as an IAEC/IACUC investigation can be conducted.

In accordance with CCSEA guidelines, the Institutional Animal Ethics Committees (IAEC) shall consist of five internal members designated by Aragen and four external members appointed by CCSEA, Government of India.