



# P.I.E. Guidelines: Ethical boundaries in animal research









# **Practice Guidelines**

Please read the declaration at the end of this document before applying these guidelines





# Introduction

It is well known that animals have been used in research for many years, contributing to the successful implementation of life saving procedures and medications for humans. Many existing medical techniques have been greatly enhanced through research involving animals. However, an ethical debate surrounds the subject of research involving animals, which embraces the wider moral implications. Allegations of malpractice and abuse of animals has also frequently been reported, whether suspected or proven.

The more serious moral philosophy attached to this contentious issue surfaced during the 20th century. Prior to this time, the treatment of animals was given scant attention in terms of moral or ethical consideration; philosophical perspectives hinged on reasoning that was based on the difference between animals and humans, rather than the consideration of an animal as a sensory creature.

Whilst the general consensus of agreement is that humane treatment should be given to animals involved in research, different assumptions regarding 'humane treatment' have arisen. Various notions about pain and distress, morality, breeding for research, sensory reactions to different stimuli, duty of care and responsibility, animal sentience as well as differing contexts within these fields, have given rise to further argument and moral considerations.

The responsibility towards animals that a researcher should implement when conducting experiments contributes to further contentious discussion: why individual animals from the same species may be given different treatment from a moral standpoint. To illustrate this, one may consider the contradiction of using pesticide to eradicate mice from a building whilst feeding mice used in research projects. The argument stretches further when using animals in research causes emotional distress to a human; the consideration then centres upon causing pain to a human without moral justification or ethical reason, regardless of the peripheral issues. Whereby an animal experiences unnecessary suffering or has been used in research without due requirement, this may be enough to cause human emotional pain.

However, if animals are used with due care, accorded respect, and distress is minimised, human suffering is thereby also minimised within the boundaries of justification. It can therefore be established that best practice is ascertained by following appropriate rules and regulations, based upon majority national interest: namely, to use animals for research in such cases where an alternative does not exist, and where suffering, pain and distress to the animal is minimal or non-existent.

# Main considerations in animal welfare

# 1 Pain, suffering and distress

- 1.1 If animals are sentient creatures, capable of experiencing pain or distress, it is in the public interest that rules and regulations are followed for implementation of humane treatment. If this is not the case and animals have no sensory feeling, concern about the effects of research would be eliminated.
- 1.2 During the 17th century, the French philosopher, Rene Descartes, argued that animals were organic machines that did not feel pain and that were not capable of rational thought. As a result, extreme suffering was caused to animals undergoing scientific experimentation and it carried full justification.
- 1.3 However more modern philosophers have expounded the theory that: 'as pain is the body's representative in the mind's decision-making process, without pain, the mind would imperil the body...but without the rational decision-making mind, pain is superfluous. Therefore animals have no rational or moral considerations which might overrule the needs of the body.' The conclusion of one such contemporary philosopher, P. Harrison, is that animals do not experience what humans would call pain.
- 1.4 The sentience of an animal or non-human being can never really be truly ascertained. However the ability of animals to respond to either harmful or pleasant stimuli is assumed by the majority of researchers to be true.



1.5 The philosopher and physiologist, Bernard Rollin, points out: "as soon as one has admitted that animals can be hurt in ways which matter to them...or that unnecessary animal suffering is wrong, one has implicitly but inescapably presupposed that animals are in the moral arena, that one can be morally wrong in how one uses or treats animals..."

## 2 Definition of humane treatment

2.1 This can be classified as the optimum procedure for elimination of pain and distress to the highest possible degree, thus minimising suffering when full elimination is not possible. For the purpose of experimentation, pain is defined as the "awareness of discomfort".

Pain may be divided into two key types. 1) Acute pain: this is associated with sharp pain of short duration. 2) Chronic pain, on the other hand, continues over a long period.

The term 'distress' represent physical or mental stress that can result from emotions as in anxiety or fear. Pain can also lead to distress.

2.2 Evidence of distress may be seen in abnormal behavior patterns whereby an animal is unable to adapt to the experimental or environmental phenomena in which it is placed.

It may manifest itself in inefficient reproduction, abnormal feeding or postprandial grooming.

Furthermore, distress can be associated with various pathologies including tumours, chronic conditions, and immunosuppression.

- 2.3 This gives rise to the theory that an animal may be under distress, even if no pain is evident. There needs to be understanding that tranquilisers can relieve distress, but do not relieve pain.
- 2.4 Researchers are required to justify their deployment of animal experimentation by the following application: replacement, reduction, and refinement. By decreasing the number of animals used, pain and distress will decrease.

# 3 Alternative procedures

- 3.1 Replacement: whenever feasible, researchers should choose computer models, in vitro samples of cell cultures instead of whole animals, human volunteers, animals with lowered sentience, microorganisms or plants. Investigators should also provide existential evidence that alternative methodology has been considered.
- 3.2 Reduction: animals that are being euthanised whilst under anaesthetic should not be used for a second experiment, unless specifically named in the approved research protocol with one aim is to obviate the need for two animals to be used. Data gained from an animal could be used more than once. Group crossover and sequential testing can reduce animal numbers, improving data analysis and sharing information with other researchers. When healthy animals are used there is less risk of loss from disease, weak samples or illness; more efficiency prior to research can also avoid repetition of data. Improved animal husbandry and experimental techniques can limit other risks.
- 3.3 Refinement: experiments need to be devised whereby, the appropriate species is used, and with minimal distress to animals throughout the whole process and euthanasia techniques are humane and appropriate to different species.

# 4 Ethical considerations

- 4.1 Investigators using animals for biomedical research should be guided by certain ethical principles which constitute a working model for humane treatment of animals. Each authorised person of a research programme or faculty and those working under them has a moral duty to ensure all animals are treated in a humane manner, regardless of species.
- 4.2 During procedures whereby pain, distress or comfort is likely, all possible measure to alleviate this are employed: anaesthetic and analgesic drugs. Whereby experimental procedures are likely to cause pain, discomfort or distress to get valid results, these must be of the shortest possible duration. If an animal displays severe pain or distress during research and it cannot be alleviated by analgesics, it must be euthanised immediately.



# P.I.E. Guidelines: Ethical boundaries in animal research

- 4.3 When quality of data is insufficient, deployment of experimentation cannot be justified if an animal exhibits suffering or distress.
- 4.4 Whereupon the objectives are to investigate pain mechanisms and administering pain relief would interfere with the resultant findings, then experiments involving pain or distress without analgesic relief may be proposed.
- 4.5 Whereby deprivation of food or water constitutes part of the research, normal development and health of the animal should not be impeded.
- 4.6 If physical restraint is used, it must not be done so as a substitute for anaesthesia. It should be used only to relieve suffering or to eliminate any abnormal physiological changes; the exception is if such changes are required for research aims.

# 5 Funding resources

- 5.1 Sufficient funding must be available in order for correct animal husbandry to be in place and to include the use of animals in experimental procedures.
- 5.2 Whereby a designated methodology has been chosen for convenience to the investigator, this is unjustifiable if it causes increased pain or suffering to the animal and an alternative procedure that may be more inconvenient to the investigator has been rejected.
- 5.3 Any animal breeding programme must prevent reproduction of an excessive number of animals which is above the capacity to implement sufficient standards of care.
- 5.4 Before animal research commences, the senior investigators should exhaust all the potential options before using animal models.
- 5.5 The preservation of animal wellbeing must spearhead all aspects of care before, during and after research. Any specific environmental or behavioural factors should be addressed appropriately.

- 5.6 Animals' care should be paramount during the research study.
- 5.7 If reasonable substitutes exist such as videos, tapes, films, preserved specimens; these should be utilised rather than live animals. If no other substitute is identified, then the use of live animals for teaching purposes may be authorised.
- 5.8 Academic tutorials should incorporate a limited number of live animals to give maximum learning, under supervision, to each group of students. Teacher—assistant ratios should be monitored and accurately assessed by departments to impart humane methods of handling and animal use to students in their training and impress upon them the importance of such methodology.
- 5.9 Full postoperative care must be administered whereby it is necessary for an animal to regain consciousness. Suitable pain relief must be administered during recovery, after which humane euthanasia is conducted after the necessary results are obtained.
- 5.10 It is unethical practice to conduct painful or uncomfortable experiments or research for the sole purpose of instructing students in scientific knowledge.

### 6 Drug safety and animal experiments

- 6.1 It is commonly expressed by scientists that a ban on using animals in experimental research procedures would lead to using humans for testing drug safety and an end to the testing of new drugs, on the grounds of risk.
- 6.2 Experimentation and research using animals should not be conducted in order to show only that drugs are also safe and effective for humans. If a drug passes the test stage on an animal as being safe, it is then tested on a controlled group of humans (pilot study) before larger scale clinical trials are conducted.

#### 7 Regularity of reviews

7.1 Research methodology and facilities should be given periodic review.



# P.I.E. Guidelines: Ethical boundaries in animal research

- 7.2 The review should include inspection of facilities used for animal research programmes.
- 7.3 Any concerns arising from such reviews should be reported. These may involve animal care concerns within the research areas; they may arise from public complaint or from personnel and individuals working within the research facility. They may also be associated with training methods.
- 7.4 Recommendations should be made to address concerns and modifications or corrective action implemented.

#### Contributors

- Colin Hopper
- Waseem Jerjes
- Hiang Boon Tan
- Ramin Carbiner
- Zaed Z R Hamady

#### Declaration

The Publication Integrity & Ethics and the contributors to these guidelines acknowledge that many institutes and universities around the world have their own guidelines that deal with research ethics. These establishments expect their researchers to follow their guidelines and comply with them. The Publication Integrity & Ethics confirms that its guidelines on research ethics should not replace any existing guidelines of any establishment nor be followed by any of its researchers. However, P.I.E. is happy for any institute or university in the world, with existing guidelines on research ethics, to adapt part or all of the P.I.E. guidelines if the head of that establishment decides to do so and proper acknowledgement of P.I.E. is given.

The Publication Integrity & Ethics recognise that many institutes and universities in the developing world lacks guidelines on research ethics. P.I.E. is happy for any institute or university, who lack these guidelines, to construct their own guidelines based on this document as long as the head of that institute or university approves this decision and proper acknowledgement of P.I.E. is given.

Please note that you may require contacting the Medical, Dental or Pharmacy Council or the Department of Health in your country to seek approval before using these ethics research guidelines.

© The Publication Integrity and Ethics www.integrity-ethics.com

No permission is required for non-commercial use or redistribution of any part of these guidelines as long as a complete citation is provided.

While every effort has been made to make these guidelines accurate and comprehensive, research integrity and publication ethics are extensive disciplines and these guidelines make no claim to be exhaustive, nor should they be taken as legal advice.