

Classification System for Degree of Animal Harm

by *F. Barbara Orlans*, Scientists Center for Animal Welfare,
4805 St. Elmo Avenue, Bethesda, Maryland 20814, USA.

Introduction by *Karl Johan Öbrink*, president of Scand-LAS.

Dr. Barbara Orlans, who is the founder of the "Scientists Center for Animal Welfare" in the United States, has adopted the category system for animal experiments that was first used in Sweden in connection with the ethical committees. She has elaborated on the system and no doubt improved it. I believe that the ethical work does benefit from it. I agree with Dr. Orlans that the "active involvement of investigators in assessing of the degree of animal harm or distress involved in their experiments can serve a useful educational function".

It is regrettable that Sweden has abandoned the system, but we will follow the development and experiences in the US with great interest.

Justifying Animal Experiments

It is the consensus view that all biomedical experiments involving harm to the experimental subject need to be justified. This is as true for experiments involving animal subjects as it is for those involving humans. An experiment cannot be justified if it is trivial in nature. There must be significance to the expected results. In the United States and elsewhere of laboratory licies governing the welfare of laboratory animals incorporate this view.

Harming animals is, as a general rule, undesirable. It is not a desirable end in itself. It can only be justified if the social good derived from this activity outweighs the negative aspects of harming a sentient creature. Animal experiments can be sanctioned if there is no alternative means of achieving the same scientific or educational objectives, and if the benefits to society outweigh the costs in terms of animal harm.

* This paper is based on remarks made at the 3rd Bengt Gustafsson Seminar held August 15-16, 1985 at Uppsala University, Sweden.

To apply these concepts, two scales need to be drawn up, one for the degree of cost (pain or harm inflicted on a sentient creature) and one for the social good. These two scales are then weighed against each other and a judgment call is made as to whether the benefits outweigh the costs. The social benefits derived from animal experiments are very evident but hard to quantify. A scale for such benefits has not been devised. However, a scale for costs can reasonably be established and is presented in Table 1. Even though this provides only half of the needed assessment, it is at least a start in developing concepts for addressing the ethical dilemmas of animal experimentation.

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In Table 1, the costs range from zero or minimal in Category A, to great in Category E. A step-wise progression of increasing harm is described for each category. Specific examples to illustrate each category A-E are provided. Each category may not be sharply delineated from the

Table 1. Categories of biomedical experiments based on increasing ethical concerns for non-human species.

Category	Examples and comments
<p>Category A Experiments involving either no living materials or use of plants, bacteria, protozoa, or invertebrate animal species.</p>	<p>Biochemical, botanical, bacteriological, microbiological, or invertebrate animal studies, studies on tissues obtained from autopsy or from slaughterhouse, studies on embryonated eggs. Invertebrate animals have nervous systems and respond to noxious stimuli, and so must also be treated humanely.</p>
<p>Category B Experiments on vertebrate animal species that are expected to produce little or no discomfort.</p>	<p>Mere holding of animals captive for experimental purposes; simple procedures such as injections of relatively harmless substances and blood sampling; physical examinations; experiments on completely anesthetized animals which do not regain consciousness; standard methods of euthanasia that induce rapid unconsciousness, such as anesthetic overdose or decapitation preceded by sedation or light anesthesia.</p>
<p>Category C Experiments that involve some minor distress or discomfort (short-duration pain) to vertebrate animal species.</p>	<p>With anesthesia, exposure of blood vessels or implantation of chronic catheters; behavioral experiments on awake animals that involve stressful restraint; food/water deprivation for short periods (a few hours); noxious stimuli from which escape is possible; surgical procedures under anesthesia that may result in some minor post-surgical discomfort. Category C procedures incur additional concern in proportion to the degree and duration of unavoidable distress or discomfort.</p>
<p>Category D Experiments that involve significant but unavoidable distress or discomfort to vertebrate animal species.</p>	<p>Deliberate induction of behavioral stress in order to test its effect; major surgical procedures under anesthesia that result in significant post-operative discomfort; induction of an anatomic or physiological deficit that will result in pain or distress; application of noxious stimuli from which escape is impossible; prolonged periods (up to several hours or more) or physical restraint; maternal deprivation with substitution of punitive surrogates; induction of aggressive behavior leading to self-mutilation or intra-species aggression; procedures that produce pain in which anesthetics are not used, such as toxicity testing with death as an end point, production or radiation sickness, certain infections, and stress and shock research that would result in pain approaching the pain tolerance threshold. Category D experiments present an explicit responsibility on the investigator to explore alternative designs to ensure that animal distress is minimized or eliminated.</p>
<p>Category E Experiments that involve inflicting severe pain near, at, or above the pain tolerance threshold of unanesthetized, conscious animals.</p>	<p>Use of muscle relaxants or paralytic drugs such as succinyl choline or other curariform drugs used alone for surgical restraint without the use of anesthetics; severe burn or trauma infliction on unanesthetized animals; attempts to induce psychotic-like behavior; killing by use of microwave ovens designed for domestic kitchens or by strychnine; inescapably severe stress or terminal stress. Category E experiments are considered to be highly questionable or unacceptable irrespective of the significance of anticipated results.</p>

neighboring category – obviously it is a continuum. This classification system has several practical applications which will be described below.

Use of Classification System

During these last few years, several U.S. research institutions have adopted such a classification system for use by their institutional oversight committee for animal experiments. These committees in the U.S. are charged with review of animal experiments to ensure compliance with national standards of humaneness. Some institutions use Table 1 without change; others have modified it by adding examples of specific procedures encountered in their own research facilities. Such modification is beneficial because, in this way, the classification system has relevance and immediate applicability to the local situation.

The oversight committees that use this classification system usually require investigators to classify their own projects prior to formal submission of the protocol for committee review. This follows the pattern established originally in Sweden for protocol review by regional review committees. This active involvement of investigators in assessing of the degree of animal harm or distress involved in their experiments can serve a useful educational function.

Committees that use a classification system often incorporate some form of expedited review for certain minimally in-

vasive animal procedures. For instance, experiments falling within categories A or B are sometimes either exempt entirely or reviewed by only a subset of the full committee membership. Categories C, D and E, receive full committee review. The higher the category, the greater the intensity of review.

Student Use of Animals

In addition to the above applications, Table 1 provides a conceptual basis for addressing student use of animals. Beginning students in high school and introductory college biology courses should start with Category A projects. Only as their comprehension of basic biological principles, commitment to a career in science, skills, and educational needs increase, should they progress to Category B or higher categories of experiments. Unfortunately in the United States, high school students frequently attempt highly invasive animal procedures falling in Categories D and E for science fair competitions. In the author's opinion, such projects are not ethically justified and should be prohibited.

In summary, a classification system based on increasing ethical concerns has several practical applications. It can be used a) in developing concepts on the justification of animal experiments; b) in review procedures of experimental protocols, and c) in addressing student use of animals. The system has potential for more widespread incorporation into national policies.