

UFAW UFAW Animal Welfare Series

The Welfare of Animals Used in Research

Practice and Ethics

Robert C. Hubrecht



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The Welfare of Animals Used in Research: Practice and Ethics

Robert C. Hubrecht

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The Welfare of Animals Used in Research

The Universities Federation for Animal Welfare

UFAW, founded in 1926, is an internationally recognised, independent, scientific and educational animal welfare charity that promotes high standards of welfare for farm, companion, laboratory and captive wild animals, and for those animals with which we interact in the wild. It works to improve animals' lives by:

- Funding and publishing developments in the science and technology that underpin advances in animal welfare;
- Promoting education in animal care and welfare;
- Providing information, organising meetings and publishing books, videos, articles, technical reports and the journal *Animal Welfare*;
- Providing expert advice to government departments and other bodies and helping to draft and amend laws and guidelines;
- Enlisting the energies of animal keepers, scientists, veterinarians, lawyers and others who care about animals.

Improvements in the care of animals are not now likely to come of their own accord, merely by wishing them: there must be research...and it is in sponsoring research of this kind, and making its results widely known, that UFAW performs one of its most valuable services.

Sir Peter Medawar CBE FRS, 8 May 1957

Nobel Laureate (1960), Chairman of the UFAW Scientific Advisory Committee (1951–1962)

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Foreword

As a longstanding (that means quite old) biomedical researcher who has worked with cells, animals and patients throughout my research career, I am delighted to provide the Foreword to this important and long overdue book.

Animals are used in research to understand biological and disease processes, to develop new markers of disease progression, medical devices and new drugs, and to then test these discoveries before they are tried in humans. The latter is a regulatory requirement by governments across the world.

Experimental and regulatory use of animals has been core to the development of new medicines for many decades, and overall it has been very successful. But it is a highly sensitive issue on which views are diverse and often radically polarised. This is the perfect recipe for entrenchment. Those most strongly opposed to research using animals can participate in quite extreme acts of terror, while the scientists involved in the research retreat behind their bunkers, fail to engage in the research and worse still, do not participate in the critical debate about how to limit the use of animals and ensure the welfare of those that are used.

Thus, there is an urgent need for a text that covers the range of issues related to animals used in research. This book provides such a text and its author Robert Hubrecht commands great respect for his unswerving support for animal welfare, his balanced and open approach and the fact that he has facilitated delivery of major benefits to those animals on which experiments are performed.

The book covers the range of important issues-why and how animals are used, public opinion and concerns, the arguments for and against the use of animals (including the practical, the philosophical and the emotional), how we judge the harm to animals versus the likely benefits of research or testing, how we control and regulate the use of animals and how we move forwards-in partnership.

Robert Hubrecht notes how attitudes have changed. This is true not just in research but more widely in our relationship with animals. As a society we are now much more concerned about the welfare of farm animals, pets and of course animals in research. While some of this can be ascribed to a shift in general societal

values, the change in welfare standards for animals used in research owes much to animal welfare scientists such as Robert Hubrecht, who has argued the case while maintaining the respect of scientists who use animals in their research. No mean task.

For me, as a researcher, the most important chapter is that which deals with the '3R's'- the replacement, reduction and refinement of animals in research. First proposed over 50 years ago, Russell and Burch's ideas gained rather modest interest for some time. The 3R's are now absolutely mainstream thinking, at least in the UK and are fundamental to every researcher who uses animals.

Most importantly this book is sensitive to the diversity of opinion, and the arguments are based on evidence-which should sit well with any scientist.

Robert Hubrecht's book will certainly be required reading for any student of staff member who works with me and deploys animals in their research. I am sure it will attract a much wider audience.

I hope that within my life time we will have made advances such that we no longer need to use animals to make major discoveries and to develop important new medical advances. In the meantime this book will help us to think very carefully about why, how and when we use animals. Rightly so.

Professor Dame Nancy Rothwell DSc, FRS, FMedSci, FSB
President and Vice-Chancellor The University of Manchester

Preface

Since prehistory, humans have exploited animals, first hunting them as a source of food and clothing but in more recent years to satisfy other desires. We keep animals as companions, modifying them in the process through domestication or through surgical interventions; we rear them in farms for food and for other products; we use them in sport, as purpose-bred animals such as racehorses, greyhounds or pheasants; and they continue to be used, in small numbers, for entertainment in circuses, stage acts, and in films. Finally, we use them in research as models of disease to test the efficacy of drugs, to test the safety of products, or for the advancement of knowledge. The use of animals in research is probably the most controversial of all these practices. On one side of the argument, pressure groups and organisations, some of which count doctors and veterinarians and philosophers in their number, campaign against animal research, both on ethical grounds and arguing that their use is scientifically flawed. On the other side, there are organisations, often counting in their membership doctors, veterinarians, philosophers and distinguished scientists, that are dedicated to protecting animal research because of the benefits that are seen to flow from it. Most of us in the developed world will depend at some time on medicine, and many of us owe our lives or health to it and thus bear at least some responsibility for the use of animals in research. In addition, in a democracy scientists carry out their work with the permission of the public and if there was a sufficient feeling that animal research could not be justified, then it would be outlawed. So all of us, whether involved in research on animals or not, and whether we agree with it or not, bear part of the responsibility for the continuation of the practice.

The views held by those either for or against animal experimentation are often extremely strongly held and I do not intend to add to the heat of that debate. Unfortunately, it is probably an impossible task to write a book on the welfare of animals used in research that is completely unbiased, so to help readers judge any bias that I might have, it seems right that I should briefly describe my background. I was trained as a research scientist and spent many years studying the behaviour,

and sometimes the physiology, of animals in laboratory settings and in the field. I then moved to the Universities Federation for Animal Welfare, an organisation that uses science to advance our understanding of how best to improve the welfare of sentient animals whenever they are harmed as a result of human activities. Undoubtedly my career has affected my views but it has also provided me with relevant experience.

Animals are used in research to benefit humans, and sometimes also other animals, but their use can cause harm to the animals involved, and on occasion is likely to cause considerable suffering. It is therefore right that, whenever animals are used in research, the case for their use should be critically examined to ensure that there are no alternatives, that the numbers used should be kept as small as possible, and that any harm caused to the animals involved should be kept to a minimum. In other words, that the 3Rs principles of replacement, reduction and refinement should be fully implemented, which can only be achieved with a good understanding of the issues.

My aim has been to produce a resource that will be a useful introduction to the issues involved in laboratory animal welfare for those who intend to pursue, or are pursuing, a biological or medical career that involves the use of animals in research. I hope that it may also prove useful to prospective animal care staff and animal welfare scientists, and to those involved in ethical review or otherwise working to improve the welfare of animals used in research. It may also help inform debate amongst those who are not involved in experimentation but who are interested in the issues. Laboratory animal welfare is a very wide-ranging subject with many areas of specialist interest, and to deal with each topic in depth would require more space than I have here. I have therefore tried to provide an informative introduction to the welfare and ethical issues that arise from using animals in research, in the process drawing attention to innovative ideas and research and to sources of information. The animal welfare issues involved in research on animals cross national boundaries but the implementation of measures to address these varies. I have therefore not attempted to produce a guide that explains how research is controlled and should be carried out in one particular jurisdiction, but rather tried to concentrate on principles, where necessary illustrated by national examples. I hope that that this has resulted in a book that will help improve the welfare of animals used in research wherever that occurs.

Robert Hubrecht, UFAW
September 2013

Dedication

To Diana

Acknowledgements

Over the years I have absorbed many ideas during discussions with others working in the field of animal welfare science. Those that I have not acknowledged will, I hope, forgive me. I am very grateful to those who have given me advice on various sections or chapters of the book, or provided me with material, and in particular to Joanne Zurlo, Michael Balls, Ngaire Dennison and Jeff Everitt. I should also like to express my thanks to those who gave permission to use images, including those who did not wish to be acknowledged. I am indebted to Liz Carter who took a great weight off my shoulders by dealing with permissions for images and other material, to Eleanor Hubrecht who read and commented on early drafts and provided encouragement, and to Wendy Goodwin for her help with references. I am particularly grateful to James Kirkwood and Manuel Berdoy for their generosity in providing very detailed comments and suggestions on all of the chapters.

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Introduction

1

In this chapter I outline how animals have been used in history to advance human knowledge, how animals are used in research today, where research is carried out, how many animals are used, and the extent of various types of harm caused to them. This leads on to the need on ethical grounds to reduce harm to a minimum, public attitudes to research on animals, and the public's role in permitting research on animals.

1.1 Reasons for Using Animals in Research

The history of the use of animals to advance human knowledge is long. Even in prehistory, the butchering of animals must have provided some insights into human anatomy and disorders for those who were wise enough to see. However, our earliest records of animal studies date back to the ancient Greeks. Aristotle pioneered the experimental method and carried out dissections some 300 years BC, but he was certainly not an experimental scientist as we would recognise one today, his biological works being described by the Nobel Prize-winning scientist Peter Medawar as 'a farrago of hearsay, imperfect observation, wishful thinking and credulity amounting to downright gullibility'¹. Alcmaeon of Croton, while in Alexandria (305–240 BC), dissected a living animal to demonstrate the importance of the optic nerve for vision² and Erasistratus, a prominent physician in Alexandria

¹ Medawar and Medawar (1985).

² Maehle and Tröhler (1987).

(third century BC), used vivisection to distinguish between the sensory and the motor nerves. In the second century AD, Galen of Pergamum, a famous physician who became doctor to the emperors Marcus Aurelius and Commodus, used dissection to study the continuity of the nervous system. The experience that he gained from these studies on animals led him to diagnose loss of feeling in the fingers of a patient as being caused by an injury to the spine. This was probably the first time that it was realised that neural problems could be referred from the actual point of injury.

With the arrival of the Renaissance and its associated flowering of scientific endeavour there was a renewed interest in animal experimentation that has continued to the present day. The following are just a few historical examples of the use of animals in studies on anatomy and physiology. William Harvey used living animals (including shrimp, eels, fish, pigeons, dogs and other mammals) to demonstrate the circulation of blood and, in 1661, Marcello Malpighi saw the capillaries as predicted by Harvey in dissected preparations of the frog lung and urinary bladder. In the 1800s, Claude Bernard studied glycogen and its relationship to diabetes, and Sir Charles Bell and Eduard Hitzig studied the nervous system. Incidentally, Bell was extremely reluctant to carry out his experiments, which, like others of the time, must have resulted in extreme animal suffering as this was before the discovery of anaesthesia³. More recently, animals have been used in research into the immune system, and in the development and treatment of diseases such as anthrax, poliomyelitis, influenza, asthma and tuberculosis, blood transfusion, various cancer treatments, muscular dystrophy and neurological disorders such as Alzheimer's and Parkinson's disease amongst many others⁴. In addition, animals have been, and are, used in a wide range of fundamental research including studies to gain knowledge about animal or ecological systems, and ways of improving animal health, welfare, productivity or performance⁵. Animals are also used in the safety testing of pharmaceutical and household products as well as environmental safety testing of chemicals, the legal requirement for which, in Europe, depends on the tonnage of the chemical produced per annum⁶.

Today published statistics provide an overview of the types of research in which animals are used. For example, UK statistics on animal use for 2011⁷ show that fundamental biological research accounted for 35% of the total procedures carried

³ Lapage (1960); Sechzer (1983).

⁴ Lapage (1960); Smith and Boyd (1991), p. 27. See also the Understanding Animal Research website www.understandinganimalresearch.org.uk, accessed 8 May 2013.

⁵ A comprehensive list of various uses to which animals are put as models for various diseases can be found in Hau and Schapiro (2011).

⁶ The European Community REACH regulation (2007) deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances and includes regulations on the testing of chemicals, see http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm. For the USA, see The Toxic Substances Control Act (1976) at <http://www.epa.gov/lawsregs/laws/tsca.html>, accessed 8 May 2013.

⁷ Home Office (2012).

out on animals⁸, applied human medicine 13%, applied veterinary medicine 5%, and protection of humans, animals or environment 3%. Only 1% of procedures were used in the direct diagnosis of conditions while 43% involved animals in breeding programmes, a category that includes harmful mutant animals and genetically modified animals⁹. The development of genetic modification and mutant techniques has resulted in greater numbers of animals, particularly mice and fish, being used in fundamental research aimed at elucidating gene function and the control of genetically mediated disease. This has been a contributing factor to the reversal of the downward trend in the use of animals in research in the UK seen in the mid 1990s¹⁰. However, the UK statistics have recorded all animals bred with a genetic modification unless the researcher can prove over two generations that there is no welfare impact. In practice this means that all have been recorded, even though some are simply used for breeding purposes, are not used directly in research and may not show any ill effects (possess a harmful phenotype). Some have argued that this practice artificially increases the statistics of animal use, but others have pointed to the various harms caused in the production of genetically modified animals. However, implementation of European Directive 2010/63/EU will change the reporting requirements so that those shown not to possess a harmful phenotype will not need to be reported¹¹.

1.2 Where Animal Research is Carried Out

There are various types of institution in which animal research is carried out. Universities and non-profit organisations use animals in fundamental studies, or work in collaboration with pharmaceutical companies. Academic research includes areas such as neurobiology, gene function, and metabolism, but animals are also used in more applied settings such as studies on Parkinson's or Alzheimer's disease. Academic research also includes studies of behaviour or animal welfare that may sometimes be carried out outside the laboratory. Pharmaceutical companies use animals in the research and development of medicines. In these studies animals are

⁸ Regulated procedures prior to January 2013 were defined as 'any experimental or other scientific procedure applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm'. The implementation of European Directive 2010/63/EU resulted in a revision of this definition (see Glossary and <https://www.gov.uk/research-and-testing-using-animals>, accessed 8 May 2013).

⁹ See Glossary for definitions of genetically altered (GA) and genetically modified (GM) animals.

¹⁰ The UK statistics show a fairly regular increase in the number of genetically modified and harmful mutant animals from 1995 to 2010. However, the 2011 figure was slightly lower than that in 2010 due to a 6% reduction in the breeding of harmful mutants, partially offset by a 3% increase in the numbers of genetically modified animals.

¹¹ Commission Implementing Decision of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes, available from http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm, accessed 3 April 2013.

used in trials of efficacy of potential drugs and to assess their likely toxicology. Some of this research, typically the efficacy studies, is usually done in-house by the company developing the medicine, while the toxicology studies necessary to obtain a licence from the drug regulators¹² to market the drug may be carried out by independent contract research organisations (CROs). However, there has been an increasing trend for contracting laboratories to offer more and varied research services to the pharmaceutical companies. In addition, CROs carry out safety and environmental toxicity testing of non-pharmaceutical chemicals. Organisations that breed animals for research may also carry out certain types of research, and have begun to offer some of the services traditionally provided by CROs. A further category of research institution is government or other public research facilities. These include establishments whose function may be to monitor and provide advice on serious health risks to the population, monitor and control the standards and quality of biological products, research into agricultural or pest-related issues, or counter defence threats.

1.3 Numbers of Animals Used

The number of animals used in experiments is not trivial. Statistics from the UK¹³ show that, in 2011 for example, over 3.79 million procedures were started that were likely to cause pain, suffering, distress or lasting harm to animals (this figure is more than the 3.71 million animals used as some re-use of animals is permitted); 77.5% of these procedures were carried out on mice, rats or other rodents, while other mammals (a category that includes dogs, primates, cats, ferrets, etc.) accounted for only 2% of procedures and fish were used in 15% of procedures. As we shall see in Chapter 6, despite a fall in animal use in the 1980s and 1990s, the development of genetic modification technologies has resulted in increased use of certain animals, particularly mice.

This, however, is only one country. Unfortunately, as the Nuffield Council on Bioethics¹⁴ points out, statistics for other countries can be hard to come by and are not necessarily equivalent. For example, the Animal and Plant Health Information Service (APHIS) of the United States Department of Agriculture publishes statistics on the numbers of animals used in research in the USA in each state by fiscal year (Table 1.1), but the numbers used seem very small (approximately 1.1 million animals per annum) compared with equivalent statistics for the UK. The discrepancy between the UK and US figures is, however, easily explained. In the USA the Animal Welfare Act excludes birds, rats of the genus *Rattus* and mice of the genus *Mus*

¹² There are various regulatory bodies that license medicines: e.g. in the USA the Food and Drug Administration (FDA); in the UK the Medicines and Healthcare products Regulatory Agency (MHRA); and within Europe the European Medicines Agency (EMA).

¹³ Tables and graphs can be found in Home Office (2012), available from <https://www.gov.uk/research-and-testing-using-animals#publications>, accessed 3 April 2013.

¹⁴ Nuffield Council on Bioethics (2005).

Table 1.1 United States Department of Agriculture Animal and Plant Health Information Service (APHIS) Annual Report on Animal Usage by Fiscal Year. Fiscal Year 2010, published 27 July 2011.

Cats	21 578
Dogs	64 930
Guinea pigs	213 029
Hamsters	145 895
Marine mammals	126
Non-human primates	71 317
Other farm animals	38 008
Pigs	53 260
Rabbits	210 172
Sheep	13 271
All other covered species	303 107
Total	1 134 693

Source: http://www.aphis.usda.gov/animal_welfare/efoia/7023.shtml,
http://www.aphis.usda.gov/animal_welfare/efoia/downloads/2010_Animals_Used_In_Research.pdf, accessed 13 May 2013.

bred for use in research. As these in the UK account for just over 87% of the total procedures, a more reasonable estimate of the animals used annually in the USA might be 8.6 million. Using available statistics and estimates of this sort, it has been estimated that fewer than 60 million animals are used worldwide in research¹⁵. Whatever the exact figure, it is clear that a significant number of animals are used for research purposes and that this justifies serious ethical consideration. However, it is easy to be seduced by numbers, especially when you have nothing with which to compare them. So to provide some perspective, let us turn to the food industry. Many of the animals produced for food suffer some welfare compromise in the processes of breeding, production, transport and slaughter, and the number that we use is truly astonishing. To take just one animal that we breed and kill for food: in 2011, provisional figures suggest that 931 million broiler chickens were slaughtered in the UK¹⁶, and many broiler birds suffer welfare problems such as lameness and ascites¹⁷. Does this then mean that we should ignore the issue of animals in research? I would argue not. Numbers can be a useful tool to target and prioritise resources effectively, but it would be wrong to use the fact that more animals are used in the food industry to suggest that the laboratory animal issue is less important. After all, for each animal, it is the personal experience that is important, not the numbers of its fellow sufferers.

¹⁵ Understanding Animal Research <http://www.understandinganimalresearch.org.uk>, accessed 28 March 2012. Taylor *et al.* (2008). See also Knight *et al.* (2008) for suggestions that the number of animals used worldwide is much larger.

¹⁶ Department for Environment, Food and Rural Affairs www.defra.gov.uk/, accessed 22 October 2012.

¹⁷ For example Julian (1998); Butterworth *et al.* (2002); Knowles *et al.* (2008).