

# Chapter 10

## The Use of Non-human Primates in Research

Kate Chatfield and David Morton

**Abstract** The use of non-human primates in biomedical research is a contentious issue that raises serious ethical and practical concerns. In the European Union, where regulations on their use are very tight, the number of non-human primates used in research has been in decline over the past decade. However, this decline has been paralleled by an increase in numbers used elsewhere in the world, with less regard for some of the ethical issues (e.g. genetic manipulations). There is evidence that researchers from high-income countries (HICs), where regulations on the use of non-human primates are strict, may be tempted to conduct some of their experiments in countries where regulation is less strict, through new collaborative efforts. In collaborative ventures, equivalence in the application of ethical standards in animal research, regardless of location, is necessary to avoid this exploitation.

**Keywords** Animal experimentation • Animal ethics • The three ‘Rs’  
Non-human primates

### Area of Risk of Exploitation

This case study applies both to academic researchers and to political entities supporting such research. Many areas of research using animals cause public concern, but none more so than those involving non-human primates. European Union Directive 2010/63/EU (EU 2010) imposed several stringent conditions on their use in research, including their acquisition, scientific reasons for their use, husbandry and housing conditions, and record keeping, restricting the overall severity of the procedures carried out, and care of the animals during an experiment. Non-human primates are used in a number of research fields, including neurological research

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K. Chatfield (✉)  
University of Central Lancashire, Preston PR1 2HE, UK  
e-mail: kchatfield@uclan.ac.uk

D. Morton  
School of Biosciences, University of Birmingham, Birmingham B15 2TT, UK

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that involves advanced brain responses which can be tracked in various ways, safety testing for novel medicines and new batches of vaccines, defence studies and studies that may benefit wild animals. While in most areas of research the animals concerned might not suffer extremes of pain, in some they are caused significant mental distress.

Certain types of work envisage substantial human benefits (e.g. defence strategies and antidotes), and this may impel some researchers to seek collaboration abroad to carry out work that might be limited or severely curtailed in their own countries. They might also accept compromises in the acquisition of experimental primates: for instance, wild-caught animals, often seen as local pests, could be used instead of purpose-bred animals. Furthermore, the application of the “Three Rs” – replacement, reduction and refinement<sup>1</sup> – is likely to be less stringent, particularly regarding refinement strategies in the housing and husbandry of the animals, and even more so in the experimental design of studies (e.g. the implementation of severity limits and humane endpoints).

## Animal Research Worldwide

Animal experimentation is used for many biomedical research activities, including pharmaceutical studies, basic scientific research, biotechnology and traditional medicine research. We cannot determine the exact number of animals used worldwide in research, but there is an estimate of between 50 million and 60 million animal procedures per year, with rats and mice by far the most commonly used species (Understanding Animal Research 2015).

It is estimated that non-human primates represent a very small proportion of the total number of animals used in experiments: fewer than 1 in 1,000 in the EU and approximately 3 in 1,000 in the US (SCHER 2009). Worldwide, however, the number may be more than 100,000 each year.

The wide variety of non-human primate species used in research can be divided into New World species such as marmosets (e.g. the common marmoset, *Callithrix jacchus*), and Old World species such as the long-tailed or cynomolgus or crab-eating macaque (*Macaca fascicularis*) and the rhesus macaque (*Macaca mulatta*). In addition, baboons, another Old World primate of the genus *Papio*, are occasionally used.

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<sup>1</sup>The “Three Rs” are the underpinning requirements of most policies and regulations in animal research:

- Replacement: Methods that avoid or replace the use of animals.
- Reduction: Methods that minimize the number of animals used per experiment.
- Refinement: Methods that minimize suffering and improve welfare.

Non-human primates are highly valued in biomedical research because of their genetic similarity to humans,<sup>2</sup> which means they can be especially useful for testing the safety of new drugs and studying infectious diseases, and in neurophysiology, where they can be trained to respond to external stimuli and their central nervous system responses monitored or followed in some way.<sup>3</sup> However, their similarity to humans also raises specific ethical concerns about their use in scientific experiments (SCHER 2009).

In the EU, animal experiments are governed by Directive 2010/63/EU (EU 2010) on the protection of animals used for scientific purposes, which required member states to apply the provisions of the directive through their national legislation from 1 January 2013. According to the directive, the use of non-human primates demands special attention and certain requirements have to be met:

Due to their genetic proximity to human beings and to their highly developed social skills, the use of non-human primates in scientific procedures raises specific ethical and practical problems in terms of meeting their behavioural, environmental and social needs in a laboratory environment. Furthermore, the use of non-human primates is of the greatest concern to the public (EU 2010: art. 17).

Consequently, the use of non-human primates is strictly controlled and the purposes for which they can be used require rigorous scientific justification:

Therefore the use of non-human primates should be permitted only in those biomedical areas essential for the benefit of human beings, for which no other alternative replacement methods are yet available. Their use should be permitted only for basic research, the preservation of the respective non-human primate species or when the work, including xenotransplantation, is carried out in relation to potentially life-threatening conditions in humans or in relation to cases having a substantial impact on a person's day-to-day functioning, i.e. debilitating conditions (EU 2010: art. 17).

There are additional requirements on the provision of life histories and severity monitoring that add further criteria to try to ensure that the science is of the highest quality and that animal welfare is not avoidably compromised (EU 2010: art. 30, 39).

With increased scrutiny and regulation, and in response to public opinion, there has been a marked reduction in the number of non-human primates being used in research. Figures show that approximately 6,000 were used in scientific procedures in the EU in 2011, compared with almost 10,000 in 2008 (SCHEER 2016). Furthermore, some institutions are no longer using primates, such as the Harvard Medical School, which closed its affiliated primate facility in 2015. Others are

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<sup>2</sup>For example, baboons have a 91% DNA similarity (see also Wong 2014).

<sup>3</sup>Safety testing of new drugs, substances and devices, especially those intended for human medicine and dentistry, accounts for approximately 67% of the non-human primates used in research. Fundamental biological research accounts for a further 14% and the research and development of medical and dental products and devices for humans for about 13% (SCHER 2009).

reviewing their primate use: for instance, the US National Institutes of Health announced recently that it would review all non-human primate research that it funds (Cyranoski 2016).

In light of this trend, the European Commission's Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) announced in June 2016 that it was seeking more information to update the EU directive on the use of non-human primate research. In particular, it is seeking opinion on areas of research and testing where non-human primates continue to be used, possibilities to replace their use, and the potential implications for biomedical research, as well as the question of whether the use of non-human primates should be banned altogether in the EU (SCHEER 2016). In Europe, researchers say, the climate for such research is growing colder (Cyranoski 2016).

While the decrease in the number of non-human primates used in the EU may be welcomed and regarded as a beneficial impact of Directive 2010/63/EU, there is rising concern that this decrease has coincided with an increase in the use of non-human primates elsewhere. There is also concern from some in the scientific community that the opportunity to gain valuable insights into certain human diseases will be lost.

Hau et al. (2014) describe how, due to political pressure and the introduction of the new EU directive, biomedical research with non-human primates is increasingly difficult to carry out in Europe. Consequently, European scientists are seeking collaboration with non-human primate centres outside of Europe (Hau et al. 2014).

This has also been noted by Cyranoski (2016), who explains that non-human primate research increasingly faces "a tangle of regulatory hurdles, financial constraints and bioethical opposition" (Cyranoski 2016:300). As a result, some researchers have stopped trying to do such work in the West, and he quotes one neuroscientist as saying that "red tape drove her to China" (Cyranoski 2016).

There is a long tradition of collaboration between European academic institutions and those in the US and Canada, but the network of collaborating institutions is becoming increasingly globalized (Macy 2011). This is highly positive in many respects, but if animals are to be used in collaborative research, the attention to ethical concerns, animal welfare and the quality of the research must be equivalent among research partners around the globe<sup>4</sup> (Bayne et al. 2015). However, regulations, norms, practices and standards in animal research are not currently harmonized, as is clearly illustrated by the following case.

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<sup>4</sup>The EU have already taken steps towards this end. International projects that are supported by EU funding, such as the Horizon 2020 funding programme, must ensure that all collaborators in the project comply with EU laws in their project activities.

## Specific Case and Analysis

In 2013 a report in the British press alleged that an academic from a UK university was bypassing British law in his research with wild-caught baboons in Nairobi (Macrae 2013). A professor of movement neuroscience, part of a team investigating methods to treat conditions affecting the brain such as stroke, spinal cord injury and motor neurone disease, was accused of exploiting a cheap and plentiful source of animals in Nairobi.

The accusation followed an undercover investigation by the British Union for the Abolition of Vivisection (BUAV), which had covertly obtained photos and video footage of the baboons at the relevant institute in Nairobi. BUAV contended that the images revealed disturbing welfare standards and that UK researchers should not accept lower standards when carrying out research at non-UK facilities.

The UK professor was quoted as saying that while animal welfare standards were not as high in Nairobi as in the UK, they had improved greatly during his time there, and that the institute was committed to making further improvements. In addition, he accepted that the experiments would not be permitted in the UK, but argued that it was better to capture wild baboons, who had lived for four or five years in the wild, rather than breed them in captivity. Experiments on wild-caught animals are not normally permitted in the UK, but he claimed that the reasons behind the ban on using wild-caught primates in the UK did not apply to his experiments in Africa.

In a subsequent article in the Kenyan press, the institute in Nairobi denied reports that the facility was being used to conduct harmful research on baboons, claiming that the studies were aimed at advancing medical research for the benefit of Kenya and the world. It added that out of Kenya's 13 non-human primate species, only the two most abundant species (baboons and African green monkeys, another Old World primate) were being used for biomedical research and that, far from being endangered, baboons were considered pests in the wild and those being used in the experiments would otherwise have been killed (Kariuki 2014).

This story received significant coverage in the British media, with celebrities adding their voices to the protests (Nelson 2013). A petition was launched by the students' union at the UK university to persuade the university to end such experiments and, following public pressure, the university decided to halt the baboon experiments in 2014.

There are two immediate concerns that arise from this case: first, that the standards of animal welfare in Kenya may have been lower than the standards required in the EU, and second, that the baboons had been taken out of the wild.

It is not possible to make judgements about the equivalence of standards of animal care without all the facts of the case. However, it is perfectly clear that these experiments would not have been permitted on wild-caught animals in the UK. Of the 2,466 non-human primates used in experiments in the UK in 2014, none had been taken from the wild (Home Office 2015).

It would appear that for many researchers concerns about the equivalence of standards in animal research are fundamental. As Niemi (2011) points out, with an unprecedented level of scrutiny of research possible via the internet, the negative consequences of mere allegations of animal mistreatment are greater than any theoretical advantage to be gained by conducting animal research in a less rigorous environment. This sentiment is echoed by Ogden (2011), who maintains that pharmaceutical and biotech companies do not want to be perceived as using outsourcing in order to bypass standards of humane care and use. Generally, it is acknowledged that the pharmaceutical industry has a vested interest in the promotion of high-quality animal care and facilities and high-quality research outputs (Medina et al. 2015).

However, even for those with the best of intentions, there are challenges for collaborative animal research that stem from a lack of consensus on what should be considered best practice across different cultures. In addition, regulations on animal research and welfare differ from country to country and are subject to change (Landi 2011).

In China, for example, there does not appear to be the same degree of public opposition to the use of non-human primates in research, and many new non-human primate research centres are being established. Some advertise themselves as “primate-research hubs”, encouraging researchers to fly in and out and make use of their extensive facilities (Cyranoski 2016).

In Africa, non-human primates are used in research in a number of countries including Kenya, South Africa and Ethiopia. Some Old World primate species and baboons are considered agricultural pests in many parts of Africa, and legislation governing their use in research is generally lacking (Hau et al. 2014).

Most African countries lag behind high-income countries (HICs) in regard to the existence or adequacy of national and/or institutional policies and guidelines on the use of animals in research. While some African countries have been developing ethical or legal frameworks aimed at safeguarding the welfare of animals used for research, in most African countries there is a serious lack of information in the public domain. Consequently, some researchers from (HICs) may be tempted to export their research activities to collaborating African institutions where ethical and legal frameworks on the use of animals may be less stringent (Nyika 2009).

In 2011, Kimwele, Matheka and Ferdowsian published results from their survey of 39 highly ranked academic and research institutions in Kenya aiming to identify those that used animals, their sources of animals, and the application of the Three Rs. At that time, 28 (71.8%) institutions had no designated committee to review or monitor protocols using animals. Only two of the institutions with an established animal care and use committee referred to documented guidelines, and neither documented the composition of their committees (Kimwele et al. 2011).

Across Africa as a whole, the absence of legal and ethical frameworks and committees to review protocols that involve animals in research means that animal protection could be severely compromised, as well as the validity of the scientific outcome data. In addition, the lack of institutional animal ethics committees

promotes the outsourcing of animal research to these unregulated institutions (Nyika 2009).

This situation is compounded by the fact that most Western academic institutions do not have much experience with local animal care and use regulations in other countries (Macy 2011). Hence, a double ethics review, where the Western committee also provides an ethics opinion, is not a solution.

## Recommendations

- The overarching requirement for avoiding exploitation in animal research is a global code of conduct for research involving animals. There are moves towards this outcome, but it is currently far from resolved. In recent years there have been attempts from different organizations to develop global frameworks. In 2012, the International Council for Laboratory Animal Science and the Council for International Organizations of Medical Sciences updated their International Guiding Principles for Biomedical Research Involving Animals (CIOMS and ICLAS 2012). These principles incorporate the Three Rs and are intended to serve as a framework of responsibility for all countries, including those with emerging research programmes.
- In the absence of a global code of conduct, there will inevitably be variations in standards, regulations, legislation, scientific integrity, data validity and humane practices. In light of this concern, researchers from HICs engaging in collaborative research have an obligation to ensure the application of the same standards that are upheld in their home nations and home institutions.
- For residents of the EU, this entails full compliance with Directive 2010/63/EU (EU 2010) in a manner that is both transparent and auditable. Partner institutions must therefore also be transparent and auditable in the application of principles that are equivalent to those specified in the directive. This must be a requirement even when local legislation and regulation are different or less strict.
- In practice this may entail much closer collaboration with partners on the ground, working together with local representatives to ensure equivalence in all activities such as animal housing and care, as well as experimental procedures.
- European funders of research involving animal experimentation have a particular responsibility to ensure that full compliance with Directive 2010/63/EU is a necessary condition for their support.

## Conclusion

Although non-human primates constitute a small proportion of the animals used in research worldwide, their use raises particular ethical concerns. In the absence of a global code of conduct for animal research, animals in countries where regulations and legislation are less well formulated are at risk of exploitation in research. For collaborative ventures, it is vital that institutions from HICs apply precisely the same standards as are required in their home countries and institutions. This may entail close working relationships with local partners to ensure equivalence in standards and some investment to achieve that goal.

For non-human primates, the application of equivalent standards may result in a reduction in the numbers used in collaborative biomedical research, but it will also result in more rigorous science and improved welfare standards and a better application of the Three Rs.

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## Author Biographies

**Kate Chatfield** is a social science researcher and ethicist. She is a senior research fellow and Deputy Director of the Centre for Professional Ethics in the School of Health Sciences at the University of Central Lancashire, UK.

**David Morton** is professor emeritus of biomedical science and ethics at the University of Birmingham. He was, until his retirement in 2012, a member of the European Food Safety Authority scientific panel on animal health and welfare. He was a government adviser on the UK Animals (Scientific Procedures) Act of 1986. He was prime author of the Guidance Document on the Recognition, Assessment, and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation produced by the Organisation for Economic Co-Operation and Development.

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