Anonymous #26

The use of animals in research is a lawful activity in the United Kingdom, regulated under the Animals (Scientific Procedures) Act (1986). Under the terms of this Act, all scientists conducting research on protected animals are required to hold a personal license which governs the types of research they are permitted to conduct, a project license which specifies the particular projects they are permitted to conduct (with detailed specifications about the procedures involved and the animal care and welfare aspects of the research), and are accountable to the local certificate holder. The certificate holder is responsible to the Home Office inspectorate under the act for all research conducted on the site. All research is supervised by a Named Veterinary Surgeon and a Named Animal Care and Welfare Officer. All research projects are reviewed by an ethical review process, as required by the Act, with any research involving greater than mild severity being reviewed by the Central Ethical Review process for the site. This committee is composed of lay people, veterinarians, animal care and welfare officers, and research scientists, including scientists expert in the design of experiments using methods of investigation using alternatives to animals. At Imperial College London, one of the lay members, of the Central Ethical Review process is not an employee of the College, providing an independent voice as a senior member of a totally unrelated profession.

Scientists don't *want* to use sentient animals in reseach where non-sentient alternatives exist. *No* scientist would rather experiment on an animal if there is an alternative; *no* medical research scientist wants to cause pain to a living creature. Aside from moral concerns, in nearly all cases, except analgesiometry, this adversely affects the scientific results. However, there is often a lack of satisfactory alternatives or possibly an awareness that they exist. Full cost recovery by the animal research facility of the direct costs to the scientist's grant remains the most potent

driver for using less expensive and more controllable alternatives. The scientific community in general believes that animal experimentation can normally be conducted in a way which causes no or very little suffering to animals, but that there are exceptions. In those exceptional cases, the justification of this research is the importance of the insights that can be gained into the mechanisms of disease which cause real human suffering. If these insights cannot be gained in an ethical way from research on human subjects, then our alternatives are either experimentation in animals, experimentation in non-animal alternative models, or no experimentation at all. If there are no scientifically validated non-animal models, the scientific community in general believes that animal experimentation is preferable to not conducting research at all, if that means human misery goes unexplained and untreated into the indefinite future. This implies that the use of animals in experiments is an unfortunate necessity. Even then, every effort is made, and under the law every effort must be made, to conduct this research in a way which minimises the pain and suffering caused to the animals.

The crucial moral questions ethical review of research is required to ask involve: is this research important? Is it well designed? Is it necessary to use animals at all (Replacement)? Is it necessary to use so many animals (Reduction)? Can the experiment be Refined so as to use procedures which have less impact on the welfare of the animals?

*What are your views about the use of genetically modified animals in research?*

The use of GM animals has opened up many new possibilities in science. For example, use of genetic knock out mice has allowed scientists to more accurately pinpoint disease pathogenesis and to mimic human disease. However, GM animals are often regarded as a special case for the ethics of research with animals. Concerns are raised that animals are treated as mere experimental tools.

However, in most cases, the concerns voiced about the use of GM animals apply as much to non-GM animal. For example, concerns over the effect of caging on restricting the normal activity of animals applies to all animals regardless of genetic status. There appears to be a general public perception that all or most GM animals suffer some elements of pain, distress, suffering or lasting harm. In the majority of cases this is not true. Many GM animals have normal lifespans and suffer no ill effects as a result of the presence of a transgene. Some GM animals do suffer as a result of their genetic modification but again in many cases this is less than the alternative methods of generating a similar "model" through surgery or chemical

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Refinement and reduction in production of genetically modified mice Lab. Animal. 37: S1:1-S1.51.

The use of GM animals, such as the pig, for "organ farming" for xenotransplantation is often presented as the most controversial issue. It is being considered as the demand for organ transplants in human medicine, for example heart transplants, far exceeds the supply from human donors. It could be argued that the use of pigs as organ donors differs little from farming of pigs for meat. Those who consider eating meat unethical are likely to regard xenotransplantation in a similar light. However for those who do eat meat, the ability to save lives is surely more important that the use of pigs for pork and bacon. There are concerns about viral diseases moving from animals into humans, but these issues are not specifically about animal experimentation.

3. *What is your view about the use of alternatives?*

The use of alternatives is commendable, provided they are scientifically valid and can accurately generate the knowledge required which can then be reliably extrapolated. A fundamental problem is that for many diseases there are still no alternative models to whole animals, which accurately reproduce the disease process in the laboratory. It is important that further research and development be done to overcome this. However, there is relatively little funding for this type of research. One suggestion would be that charities interested in reducing or banning animal vivisection should perhaps fund research in this area, as a constructive way of moving forward with the scientific community. In general, it is clear that for alternatives to animal research to progress there does need to be a continuing commitment to change, but there also needs to be recognition that even into the medium term future it will be impossible to replace animal experimentation completely.

It is not necessary for animal tissues to be identical to human for useful results to be obtained; sometimes the differences can be as informative. For example, the human heart responds to adrenaline through two different membrane proteins. The balance of these proteins varies between species, and the differences in response to adrenaline between species have given us a great deal of information about why the high adrenaline levels in heart failure contribute to the deterioration of the heart.
The donation of human tissue has declined due to adverse media attention and cultural differences. The scientific lobby should suggest that people may reduce the use of animals in research by considering tissue donation routinely (as in blood) or when they are about to undergo a surgical procedure.
The use of human stem cells could be highlighted as a way of reducing animal use. If these cells can be obtained in an ethically acceptable way and if a cellular model only is sufficient (rather than testing in a whole living organ or organ system in a living animal), then this would be preferable. This may be particularly important in cases where a genetically modified animal would suffer unacceptably poor quality of life or the transgene would be lethal to the animal.

4. *What is your view about ethical issues relating to the use of animals in research?*

The nature of animal suffering is complex, and varies from species to species, but we know more about it now than in the past – ironically, through conducting experiments on animals. (Likewise, much of what we know about treating animal disease comes from animal experimentation). Many of these questions are very difficult to answer, and the practical issue concerns how – if at all – we can give a meaningful sense to "cost-benefit" analysis of animal suffering in animal experimentation. We believe that the 3Rs approach remains the best guide here, but it is a very pragmatic approach, and there are many open questions in philosophy here. Fundamentally, needless or callous cruelty cannot be defended, but careful approaches which ensure that any suffering caused is of as short a duration as possible, and in as few animals as possible can be justified in terms of the benefits to humans.

5. *What is your view about the UK regulations on research involving animals in the UK?*

The UK may have the strictest regulation on research invoving animals world wide. However, a lot of the regulation is only as good as the people doing it. For example, there should be some standards about the minimum number of NACWOs and NVSs to work at institutions. Some ERP committees meet far less frequently than others. Some places may be more willing to "rubber stamp" things than others. However, we believe that the UK's regulations are sufficiently flexible and sufficiently carefully applied to cope with changing situations. Increased regulation could push the work abroad; indeed this is already happening. Work that could not get through the ERP system in the UK is being performed in Europe. This may make things even worse because control over the work has been lost. There needs to be greater effort towards harmonising international regulation along the lines of the UK regulation.

Areas that could be improved –

- Speed up administration, but without compromising the review of the proposed work.
- The basis of the cost: benefit analysis. Current regulation relies on the researcher to provide the information to the ERP and the Home Office. Especially for novel work, it can be difficult to determine the cost:benefit analysis on this information. It can be difficult to make decisions if not an expert in that field. Also, if the information is inaccurate it could be misleading. These hurdles may be overcome

**by the quality and availability of the professional advisers in the Institution. The ERP provides the forum.**

**We suggest that the ERP can take more responsibility for the regulation of research, on the model of Institutional Animal Care and Use Committees in the USA, to drive the adoption of "best practice". This would avert the current obsession with adopting linguistic compliance with fashionable phraseology or individual Inspectors' whims rather than real improvement in practice.**

6. *What do you think about the information that is available to the public about research involving animals?*

There isn't enough information about the benefits provided to medical care through research involving the use of animals. People seem ambivalent or uninformed about the ways in which animals are used in research. One way to increase awareness would be to link funding bodies (including charities), the ERP and institutional openness under the Freedom of Information Act. This would enable funders to get a clearer idea of how their moneys are used, and to inspect the progress of research they fund through inspection of ERP interim reports. It might also ensure that ERPs are properly resourced, if the costs of personal and project licenses are factored into research grants – currently these costs are not allowable by medical research charities including the Wellcome Trust.