

## Commentary: Should the Belmont Report Be Extended to Animal Research

BERNARDO AGUILERA and DAVID WENDLER

In “A Belmont Report for Animals?” Hope Ferdowsian, *et al.* offer an important contribution to the burgeoning literature on animal ethics, focusing on the complex issue of animal research regulation.<sup>1</sup> As the authors note, current animal regulatory schemes and guidelines have important gaps and inconsistencies, while the most influential framework, the ‘three Rs,’ (i.e., Replacement, Refinement, and Reduction) is outdated and has fallen behind growing public concern regarding the appropriate treatment of animals.<sup>2</sup> Perhaps the primary flaw in current animal research regulation, they argue, is the “general assumption that, when in conflict, human interests outweigh animal interests,” thus giving researchers leeway to justify the use of animals in a broad range of burdensome and painful experiments, including experiments that offer little benefit to human beings.

In the authors’ view, this assumption ignores the fact that animals and human beings have equal moral status, in the sense that “animal interests should be given approximately equal moral weight as human interests.” The authors then consider how the regulations for animal research need to be revised to be consistent with this view. They propose to extend the influential principles for human research formulated in the Belmont Report, *viz.*, respect for persons, beneficence and justice, to cover research with animals. Based on this approach, they argue for three important claims: (1) harms to animals should be weighted equivalently to relevantly similar harms to humans, leading to similar protections, (2) animals should be considered vulnerable to the extent that it is unfair to use them for research that does not offer potential net-benefit to them, and thus (3) animals’ enrollment in research should generally be avoided.

The authors’ analysis leads to a largely abolitionist view of research involving animals, at least as we know it. More precisely, they claim that consistent extrapolation of the Belmont Report points to a regulatory scheme that restricts research to nondissenting household animals diagnosed with a condition or disease, enrolled in studies that offer net-benefit, and based on the permission of an appropriate surrogate decisionmaker.

There is much debate over whether human beings and animals have equal moral status. We believe there are plausible grounds for this view, and we will not question it. Instead, we discuss three implications that Ferdowsian, *et al.* draw from this view. First, we evaluate the claim that the Belmont Report, a framework developed for human subjects research, offers appropriate guidance for

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animal research. Second, we consider whether giving approximately equal moral weight to animal interests supports an essentially abolitionist regulatory scheme. Third, and finally, we argue that the authors' proposal appears to be most consistent with a rights-based view of animal ethics. However, a rights-based view, at least to the extent that rights are understood as protections of the right holders' fundamental interests, does not appear to support a largely abolitionist regulatory scheme. In sum, we agree with the authors that there is a pressing need to reconsider the regulations for animal research in light of current thinking regarding animals' moral status, and they deserve credit for highlighting this challenge. Our analysis suggests there is significant work to do in terms of identifying the appropriate protections for animals, and determining how best to implement them.

### Can the Belmont Report be Applied to Animals?

We agree with Ferdowsian, *et al.* that there are inconsistencies among current animal research regulations and a need to replace the three Rs. For example, it is widely agreed that the risks of animal research should be justified by the social value of the information to be gained, a requirement that is not included in the three Rs.<sup>3</sup> We are also sympathetic to the idea that a principle-based approach might be helpful in updating and reformulating animal research ethics. However, we question whether directly applying the principles of the Belmont Report to animal research is the best way to promote this goal.

The Belmont Report is a work of the National Commission, which was founded in response to public disclosure regarding the Tuskegee syphilis study, and was charged with identifying ethical principles to govern the conduct of research involving human subjects. To try to ensure that their recommendations received widespread support, the Commission did not attempt to derive these principles from general moral theory, but pursued a different approach. They attempted to find consensus by grounding their recommendations for human research in "values generally accepted in our cultural tradition."<sup>4</sup> They believed this would be the best way to overcome substantial disagreement regarding moral values and moral theories. Take, for example, one of the preliminary analyses prepared for the Commission's meetings:

If we focus our attention rather on particular, more narrowly defined problems, or groups of issues, it would be much easier to get some common measure of understanding or agreement. As we shall in fact see, the state of apparent disarray on the philosophical front is quite compatible with substantial agreement about the Commission's own specific field of ethical concern: viz., human experimentation.<sup>5</sup>

As a result, the Belmont Report is based on consensus with respect to a particular context or subject matter. The authority of the principles contained in the Belmont Report is thus circumscribed within the limits established by this agreement, namely, research with human subjects. Consensus regarding the principles appropriate for this context does not imply consensus regarding whether the same principles apply to a different, even if related, context.

In response, the claim that the Belmont Report can be extended to animal research might be defended by either of two arguments. First, it might be defended

on the grounds that there is widespread agreement regarding the appropriate principles for animal research. However, it is unclear whether there is sufficient agreement in this regard. For example, the authors cite one survey that suggests Americans are divided with respect to whether animals should be used in research. Another survey found that one in three Americans believe animals should be given the same rights to be free of harm and exploitation as human beings, a view that might support extrapolation of the Belmont Report, but two in three believe animals deserve fewer protections.

Alternatively, one might argue that the Belmont Report can be extended to animal research based on the claim that animals and human beings have equal moral status. Consistent with this approach, Ferdowsian, *et al.* claim that we can deduce from the Belmont Report that animals should be given special protections because they constitute a vulnerable population:

Though vulnerable human populations, including children and prisoners, are protected [by the Belmont Report] as a result of their compromised abilities to provide informed consent, animals are currently excluded from similar protections despite possessing similar vulnerabilities.

As the authors rightly point out, the Belmont Report offers no definition of vulnerability that would exclude animals, and it clearly regards as vulnerable, and deserving of special protections, individuals with compromised capacity to provide informed consent. Specifically, the principle of respect for persons articulated in the Belmont Report protects the autonomy and personal dignity of individuals capable of informed consent, while offering additional protections to individuals with diminished capacity to consent. So, the argument might go, animals, like children, and adults with severe dementia, have diminished capacity to provide informed consent and therefore are entitled, according to the principles articulated in the Belmont Report, to the same protections.

This argument does not depend on consensus regarding the protections appropriate for animal research. Hence, it would avoid the previous objection by interpreting the Belmont Report as leaving conceptual space for expanding the class of vulnerable individuals beyond humans to all individuals who cannot give their own informed consent. Unfortunately, this strategy faces a significant challenge. It is true that animals, children, and adults with severe dementia are unable to provide informed consent. But, the Belmont Report specifies special protections for individuals with *compromised* capacity to consent. Only in the case of human beings is the inability to consent properly described as the result of diminished or compromised capacity.<sup>6</sup> Animals simply cannot satisfy the standards of informed consent set by the Belmont Report. Admittedly, animals typically possess lower degrees of autonomy and understanding than human beings, but this does not trace to an impairment or defect. Indeed, it would be a categorical mistake to say that animals have compromised ability to provide informed consent, in the same sense as it would be wrong to say that humans have compromised or impaired capacity to fly.

This is not to deny that, given their inability to consent and protect themselves more generally, the notion of vulnerability could be applied to animals in the context of biomedical research. Indeed, the authors take steps in this direction and

propose, for example, that conditions such as captivity and complete dependence on their captors expose animals to situational vulnerability. Developing a positive account of the vulnerability of animals in research, and the protections it merits, is extremely valuable. However, this account would no longer be an extension of the Belmont Report, and would need an independent justification.

### Experiential Welfare and Equal Consideration of Interests

According to Ferdowsian, *et al.*, the main reason why the ethical principles stated in the Belmont Report apply to animals is that they have equal moral status as humans, which the authors spell out in terms of animal interests having approximately the same moral weight as relevantly similar human interests. The authors develop this position in support of their further claim that a Belmont Report-inspired regulatory scheme for animal research would give animals similar (or even greater) protections than those present in the corresponding regulations for human research. In this section we argue that the principle of equal consideration of interests does not warrant a generalization of this sort, since the interests of animals under similar research contexts might not be comparable across different animal species, including humans.

It is fairly uncontroversial that animals have welfare interests. As Ferdowsian, *et al.* note, “humans and other animals have interests in self-preservation, living free of unnecessary constraints, and meeting their basic and complex needs.” This seems right, but somewhat similar claims can be made for plants, e.g., they have interests in obtaining sufficient water and sunlight. So it will be useful to distinguish between *biological* and *experiential* welfare interests. Experiential interests are specific to creatures who are sentient, i.e., can consciously experience pain or pleasure. Biological interests, in contrast, apply (trivially) to biological organisms in general. This distinction is important because there are reasons to believe that sentient creatures count morally in ways that nonsentient creatures do not. Sentient creatures can have a subjective take on the harms inflicted on them, in the form of pain and suffering, which is intrinsically bad. In this sense, sentient creatures have experiential interest in not being harmed, suggesting that painful or burdensome treatment, including the kind of treatment that is often present in research studies, is morally problematic.

Meeting the challenge the authors have presented us—developing guidelines for animal research that acknowledge the equal moral status of animals and humans—requires figuring out how to compare the experiential welfare interests of animals with human interests.<sup>7</sup> The authors’ claim that animal interests should be given approximately equal moral weight by means of “[...] a principle of equal consideration of interests [that] would require that harms to animals should be weighed equivalently to relevantly similar harms in humans,” is in stark contrast with an *unequal consideration* principle according to which moral status admits of degrees, in the sense that the interests of some creatures carry greater moral weight than the similar interests of others. For example, an unequal consideration principle might suggest that it is generally worse to cause a given amount of suffering to humans than it is to cause the same amount of suffering to mice.

The principle of *equal consideration* applies when the human and animal interests are comparable in a *relevant* sense. As David DeGrazia puts it, having relevantly comparable interests means “having roughly the same thing at stake from

the standpoint of one's overall well-being or interests."<sup>8</sup> Now consider Ferdowsian, *et al.*'s claim that "[...] human subjects are commonly protected from serious harms including severe pain, psychological distress, permanent disability, suffering, death and prolonged captivity—factors which are commonly experienced by many animals used in research." Granting that animals can experience these harms, how do they compare to the analogous harms in human research?

We cannot assume that because an interest in *X* is very important for human beings, an interest in *X* has the same importance for some animals, let alone that it is equally important for all animal species. For example, the importance for a human person in not being held captive or disabled is influenced by her beliefs, plans, and relationships in a way that differs significantly from most animals. To illustrate the point, imagine laboratory animals confined for several months in a relatively ample space with adequate food, shelter, and environmental enrichment to stimulate their natural behaviors. Now imagine using a comparable form of confinement to hold university students captive for purposes of an experiment. This would frustrate many of their goals, such as attending class, graduating, and going to law school, that do not arise in the case of animals. Moreover, captive students will recognize what their professor is doing to them, thus dramatically altering and undermining their relationship with the professors. It seems fair to assume that captivity does not pose the same harms to a rat or a zebrafish.<sup>9</sup>

In a similar vein, a given sensory input or set of environmental conditions may not generate comparable overall suffering in humans and animals, or between different animal species. Even though there is agreement that primary forms of sensory and affective consciousness are present in many animal species, few animals other than humans have higher-order forms of consciousness, which involve referral to the contents of primary consciousness, a sense of self, and the ability to reflect on past and future events.<sup>10</sup> Arguably, more sophisticated forms of conscious experience can give rise to interests that are not present in animals who lack those experiences. This suggests that, in many cases, the same input or conditions will set back the interests of humans significantly more than the interests of animals. Being held captive in a comfortable environment may nonetheless destroy a human being's career, while having little negative effect on many animals.

We note that the reverse is also possible. The cognitive differences between humans and animals may result in an input being unproblematic for human beings, but very harmful to animals. A person who is motivated to help others by volunteering to participate in research might regard the loud noises emanating from an MRI machine as highlighting the importance of the study and easily tolerate them, while the same noises may be terrifying to an animal who does not understand them, and does not know when they might end.

Some might argue that captivity and enrollment in research are harmful to animals, even when they do not lead to aversive experiences. For example, some commentators argue that animals have an interest in living a life that is typical for their species. Captivity and participation in research are not characteristic of animals' lives, hence, on this view, they necessarily set back animals' interests in living a flourishing life. The question of what, if anything, beyond positive experiences is part of a flourishing life for animals is important and difficult, and comprehensive assessment of the proper regulations for animal research will need to address it. Because the Belmont Report was intended for human beings, it fails to address this question, highlighting another way in which developing regulations for

animal research that are consistent with their equal moral status will need to go beyond the Belmont Report.

To sum up, Ferdowsian, *et al.* appear to endorse a principle of equal consideration, on which animals have moral status and their interests matter to the same extent as relevantly similar human interests do. While this is an important starting point, there is conceptual and empirical room for the possibility that the impact of certain research procedures on humans may differ dramatically from their impact on different animal species. Treatments and experiments that are morally problematic for human subjects do not necessarily provide a reliable guide for determining which treatments and experiments are morally problematic for animal subjects.

While we agree with the authors' claim that harm/benefit analyses done in animal research often exaggerate human benefits and ignore animal harms, we believe that the principle of equal consideration is consistent with scenarios in which the same research procedure yields distinct harm/benefit assessments between humans and some animals. Studies involving comfortable captivity might pose minimal risk to zebrafish, moderate risk to dogs, and significant risk to humans. Therefore, the protections that would result from applying the Belmont Report to animals might not be equivalent to the protections it confers on humans. Taking these differences into account likely will require a more complex regulatory scheme which offers different sets of protections depending on which animal species is being used in the research. We return to this point at the end of this commentary.

### Grounding Regulations in a Rights-based View?

In the previous section we tackled Ferdowsian, *et al.*'s claim that animals have equal moral status as humans in light of the principle of equal consideration of interests, arguing that it fails to ground a largely abolitionist proposal for animal research. However, there may be another way to ground an extrapolation of the Belmont Report to animals that would bring them protections comparable to those of human research. One approach follows. The protections for human beings enumerated in the Belmont Report are justified on the basis that they offer a way to ensure that, in conducting research, investigators respect the relevant rights of their human subjects. If we assume that animals have the same moral status as human beings, it might be thought to follow that they have the same rights, and these rights have the same strength. This would suggest that animals deserve at least equal research protections as human beings. Moreover, it might be the case that the same rights imply that animals deserve greater protection since, as the authors point out, they are more susceptible to having their basic interests discounted.

Although Ferdowsian, *et al.* do not explicitly endorse a rights-based view to animal ethics, they come close to such a view when they apply the Belmont Report's principle of justice to animals: "[...] a just approach [to animals] necessitates that their fundamental needs are treated as similar to those of humans—with full and equal consideration. Treating animals otherwise, simply because of their easy availability and convenience, undermines obligations of justice." It is also worth noting that the author's interpretation of the Belmont Report results in strong restrictions on the use of animals for research that come close to the

abolitionist approach common in rights-based views (here the *locus classicus* is Tom Regan's *The Case for Animal Rights*).<sup>11</sup>

This is not the place to discuss the merits of a rights-based view to animal ethics. But it is important to note that the process of specifying what rights animals might have is controversial at best. One might grant that rights 'co-travel' with moral status, and further grant that animals have equal moral status to human beings, but nonetheless be uncertain, or even dispute whether animals have the same rights as humans.<sup>12</sup> In particular, one might grant that animals have fundamental negative rights, like the right not to be caused to suffer, but refrain from ascribing them positive rights, such as a moral entitlement to certain goods or services.<sup>13</sup> A future challenge, then, will be to determine whether there are compelling reasons to think that animals have such positive rights.

Given that Ferdowsian, *et al.* ground the moral status of animals in the possession of interests, it seems plausible to construct their view of animal rights in terms of an interest-based theory, for example, saying that animals' right to not suffer traces to their *interest* in not suffering. However, such a view does not seem to support a largely abolitionist stance with respect to animal research. To see why, one needs to recognize that interests come in different strengths and that only sufficiently strong interests can plausibly support the generation of rights and corresponding duties to those who possess the interests. Take the interest in not being killed. While we may grant that this interest is shared by all sentient animals, the added capacities and sophistication of human experience arguably lead to a stronger interest in continued life, than that present in cognitively less-complex animals. Thus, the fact that fish have the same moral status as human beings does not imply that fish necessarily have a right, much less the same right, against being killed, even if we grant fish an interest in not being killed. How strong an interest must be in order to ground a right not to be killed is an open question, but an interest-based theory of rights seems consistent with the claim that the interest of some animal species in not being killed is not strong enough to ground a corresponding right.

Given that different animal species have different interests by virtue of their different capacities, we would expect that animal rights will vary between species. Consider the interest-based view of animal rights put forward by Alasdair Cochrane,<sup>14</sup> according to which animals have rights not to suffer and not to be killed. However, captivity does not violate the rights of most animals and so they can be used for experimentation, provided it does not result in suffering or death. He arrives at this conclusion by observing that most (if not all) animals lack a full-fledged capacity for autonomy, and thus do not possess an interest in leading a freely-chosen life. Of course, some forms of captivity happen to be harmful, but such harm would be caused by the suffering of the animal and not by the lack of freedom itself. According to Cochrane, animals that are not autonomous have no interest in freedom, and so are not harmed by captivity as such. For purposes of the present discussion, our point is that, even when construed as a rights-based view, the claim that animals have equal moral status does not seem to support a largely abolitionist proposal for animal research. In response, the authors may want to endorse a rights-based view that derives a whole set of rights from the possession of moral status, without depending on the specific capacities and interests of the individuals in question. But this would be a very different proposal that takes further steps away from the Belmont Report.

Overall, Ferdowsian, *et al.*'s paper offers an insightful discussion of the ethics of animal research, motivated by the need to revise the normative backbone of current regulatory schemes and guidelines for animal research. Learning from parallel efforts made in the context of human research regulation, such as the use of principle-based approaches, seems useful. However, drawing norms directly from the Belmont Report to animal research does not strike us as the best strategy. To take one more example of the pitfalls of such direct application, consider the principle of justice in the Belmont Report:

The principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects. Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research.

It strikes us as an interesting and important question whether justice as a principle applies in the context of animal research, and, if so, whether it has similar implications. The fact that group preferences are generally problematic in the context of human subjects research does not imply that similar preferences are problematic, much less equally problematic, in research with animals. Is there something problematic about reserving the slots in beneficial studies for animals that are similar to us, like great apes, or for animals that we happen to like, say dogs, and focusing the riskier studies on others, perhaps snakes or spiders? These are important questions for which the Belmont Report offers little guidance.

In any case, we agree with the authors that current regulations for animal research are wanting, and that recognition of the view that animals have equal moral status implies that guidelines and regulations for animal subjects are in need of revision. At a minimum, there is need to take seriously the pain and suffering of animals, to ensure that it is justified by the value of the research, and to consider the need for caps on the level of permissible pain and suffering. Beyond that, evaluation of the extent to which animals should be afforded protections similar to those in human regulations will need to take into account the fact that animal species have different cognitive capacities that underlie different sorts of interests. These differences highlight the need for empirically informed regulatory schemes that take account of these differences when determining the appropriate regulations for animal research. There is much work to do in this regard, and we have the authors to thank for highlighting the importance of doing it.

## Notes

1. Ferdowsian H, Johnson SM, Johnson J, Fenton A, Shriver A, Gluck J. A Belmont Report for animals? *Cambridge Quarterly of Healthcare Ethics* 2020;29(1):19–37. Throughout this paper, we use 'animals' to denote non-human animal species.
2. Russell WMS, Burch RL. *The Principles of Humane Experimental Technique*. London: Methuen; 1959. Replacement refers to methods that avoid or replace the use of at least some animals in an area where those animals would otherwise have been used. Reduction refers to any strategy that will result in fewer animals being used. Refinement refers to the modification of procedures to minimize pain and distress.



3. See LaFollette H. Animal experimentation in biomedical research. In: Beauchamp TL, Frey RG, eds. *The Oxford Handbook of Animal Ethics*. New York: Oxford University Press; 2011:797–825.
4. Beauchamp TL. The Belmont Report. In: Emanuel E, Grady C, Crouch RA, Lie R, Miller FG, Wendler D, eds. *The Oxford Textbook of Clinical Research Ethics*. New York: Oxford University Press; 2008:149–55, at 152.
5. Georgetown University. The Archival Collection of the National Commission of the Protection of Human Subjects of Biomedical and Behavioral Research. Box #4, Meeting #15. February, 1976:13–6, at 6.
6. The authors also use the term “impaired,” which denotes the same idea of something that is unable to function according to a relevant standard.
7. Hereafter, we refer to “experiential welfare interests” just as “interests.”
8. DeGrazia D. *Taking Animals Seriously: Mental Life and Moral Status*. New York, NY: Cambridge University Press; 1996, at 187.
9. Some animals may experience considerable harms as a consequence of being captive. Great apes and dolphins, for example, may have the cognitive sophistication to have some of their desires frustrated by otherwise comfortable captivity.
10. Seth AK, Baars BJ, Edelman DB. Criteria for consciousness in humans and other mammals. *Consciousness and Cognition* 2005;14:119–39. See also Boly M, Seth A, Wilke M, Ingmundson P, Baars B, Laureys S, Edelman DB, Tsuchiya N. Consciousness in humans and non-human animals: Recent advances and future directions. *Frontiers in psychology* 2013;4:625; and Panksepp J, Lane RD, Solms M, Smith R. Reconciling cognitive and affective neuroscience perspectives on the brain basis of emotional experience. *Neuroscience & Biobehavioral Reviews* 2017;76:187–215.
11. Regan T. *The Case for Animal Rights*. Berkeley, CA: University of California Press; 2004.
12. Beauchamp TL. Rights theory and animal rights. In: Beauchamp TL, Frey RG, eds. *The Oxford Handbook of Animal Ethics*. New York, NY: Oxford University Press; 2011:198–227.
13. Cavalieri P. *The Animal Question: Why Nonhuman Animals Deserve Human Rights*. New York, NY: Oxford University Press; 2001.
14. Cochrane A. Animal rights and animal experiments: An interest-based approach. *Res Publica* 2007;13:293–318.