

Scottish Council on Human Bioethics

15 Morningside Road, Edinburgh EH10 4DP, SCOTLAND, UK

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Regulation of Hybrids and Chimera Embryos

Consultation response on behalf of the Scottish Council on Human Bioethics:

The Science and Technology Committee has decided to hold an inquiry into the Government's proposals for the regulation of the creation of animal/human hybrid and chimera embryos for research purposes. The inquiry will focus upon the appropriateness of the proposals for legislation in this area as set out in the Government's recent White Paper, Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos) (CM 6989) and on the impact of these proposals upon stem cell research in the UK.

Executive Summary:

- 1. The Scottish Council on Human Bioethics (SCHB) agrees that new legislation addressing the creation or prohibition of human-nonhuman embryonic combinations is necessary. However, this should not be undertaken at the expense of a full and extensive public debate.***
- 2. The SCHB considers, in this regard, that the Science and Technology Committee public consultation lasting a total of 12 days (representing 8 working days) is completely insufficient and does not appropriately serve the democratic process.***
- 3. The SCHB believes that the creation of certain kinds of human-nonhuman embryonic combinations could seriously undermine the whole concept of human dignity as defined by the United Nations Universal Declaration of Human Rights. This affirms in its Preamble "the inherent dignity and ... the equal and inalienable rights of all members of the human family" as "the foundation of freedom, justice and peace in the world".***
- 4. Finally, if a combination is considered as a human embryo, then it would come under the Council of Europe's Convention on Human Rights and Biomedicine (CETS No.: 164). This Convention has already been ratified by 20 European States (with another 14 having signed their intention to ratify) and states in Article 18 that "The creation of human embryos for research purposes is prohibited."
Thus the SCHB would like to call on the UK government to sign and ratify this Convention, as soon as possible. If this is not undertaken, the SCHB believes that the UK would begin to be seen as an 'ethically isolated and rogue' state by its neighbours.***

Scottish Council on Human Bioethics Response:

Necessity of public debate

- 5. For all involved in the human-nonhuman combination debate, it is vital to examine the grounds in favour of and in opposition to creating such entities.
In addition, informed public opinion needs to be given the necessary and appropriate information in order to coordinate a genuine debate about current attitudes towards human-nonhuman combinations, animal issues and human concerns. Openness in the activities of the regulatory bodies, advisory groups and working parties especially in relation to the scientific issues of risks,**

benefits, safety and monitoring of humans and nonhuman animals is a vital part of providing a framework within which proper informed debate may take place.

6. If the technology is to be accepted and used, it should be demonstrated that:
 - there is a genuine biomedical need for human-nonhuman combinations;
 - there are no appropriate alternative options which are available;
 - the technology is efficacious;
 - the highest possible levels of safety for patients and the wider human population can be guaranteed;
 - all issues of nonhuman animal husbandry, care, welfare and use can be properly dealt with; and
 - there are realistic benefits for patients, families and society and not just for the commercial companies who stand to make a profit from this procedure.

Ethical Perspectives

7. To many people, the resulting human-nonhuman entities created by crossing the species barrier would give rise to grave and complex ethical concerns. In crossing the species barrier, the general understanding of what it means to be a human person would no longer be clear cut. Indeed, any ethical appraisal of crossing this barrier should ultimately address the question of whether the combinations of human and nonhuman parts modifies the identity and the rich meaning of what is understood to be human or nonhuman. This is because human beings are generally considered to have a specific human dignity which nonhuman animals do not have.

Human Dignity

8. Like many other terms in ethics and philosophy, 'dignity' has often been used as an empty slogan, or a cover for intellectual undress. Indeed, it cannot be fully accounted for by other concepts such as respect and autonomy, beneficence, non-maleficence or justice. But this does not invalidate the basic idea.
9. In the Oxford English Reference Dictionary, 'dignity' is defined as the '*state of being worthy of honour and respect*'¹. In other words, it incorporates aspects of 'honour' and 'respect' but also of 'value' and 'worth'.
10. In this regard, it should be remembered that the concept of human dignity is not a scientific one. No individual will ever be able to prove whether or not a person possesses human dignity. From a scientific perspective, a human being is made up of a 'large pile of cells' containing about 70% water and a few other chemical compounds who will eventually become, with time, a handful of dust or ashes. Thus one of the problems about bestowing human dignity to others or to oneself is the circular nature of this process. Scientifically, the assignment of human dignity from a 'pile of cells' to another or the same 'pile of cells' does not have any meaning!
11. Because of this, it should be noted that secular human dignity can only be considered as a *belief*, a belief which is somewhere 'out there' (but cannot be proved scientifically). And in our modern societies, this important belief in human dignity has also become a belief in which most agree should always be believed is found in everyone to an equal extent. This universal nature of human dignity has arisen in order to address the unacceptable abuses which took place in the past history of humanity.

¹ *The Oxford English Reference Dictionary, Second Edition*, Edited by Judy Pearsall and Bill Trumble, Oxford University Press, 1996.

12. It should also be noted that the moral difference between human and nonhuman animals has been presumed throughout the history of law. This is one of the reasons for which nonhuman animals can be killed and used for food or other uses without the killing being considered as murder.
13. Of course, human dignity is compatible with a kind of respect toward nonhuman animals, even if one does not express it with the notion of 'rights'. To uphold that human beings deserve unconditional respect does not inevitably lead to an irrational exploitation of nature. Respect of human beings and respect of nonhuman animals and plants, even at different levels, are not opposing ideas. But the nature of this respect is different in both cases, and that difference (absolute respect in the first case, relative respect in the second) is precisely what makes human dignity. If all animals - including humans - are equal, no one has a dignity, because the notion of dignity implies precisely an intrinsic distinction between the human realm and the nonhuman realm².

Biomedical risks

Risks of biological developmental problems

14. In the first reproductive cloning experiment, in February 1997, Dolly the sheep was created after 277 nucleus fusions took place, whereby 8 embryos were obtained giving only one viable lamb³. In the creation of animal-human combinations, especially at the embryological level, it would be expected that a far greater number of pre- and post-natal developmental biological problems would occur.

Risks of creating new diseases

15. It is well known that many animals may harbour in their organs, cells and genome, microbiological and other entities which may cross the species barrier and develop in the host. Unfortunately, the appearance of new diseases resulting from such a crossing over of the species barrier is not a myth. For example, prion diseases, such as Creutzfeldt-Jakob disease, can be contracted by humans by consuming material from animals infected with the bovine form of the disease. Moreover, the HIV virus is very probably of simian origin, and is the cause of a pandemic, in which the animal has ceased to play any part.
16. The infectious risk is sufficiently serious to induce physicians and biologists to publicly raise the question of whether it is ethical to allow humankind to run the risk of devastating and uncontrollable pandemics since human-nonhuman combinations will never concern more than a limited group of procedures. In other words, the procedure may bring about a period of uncertainty (knowing hazards but not the probability relating to their occurrence) and even ignorance (hazards occurring that one did not even envisage) as to the possibility of spreading new diseases.

Legal Perspective:

17. From a legal perspective, it would be useful to consider whether a created human-nonhuman entity would come under animal or human legislation or something more specific and in between.
18. If an entity is considered as a human embryo or fetus, then existing UK legislation, such as the ***Human Fertilisation and Embryology Act 1990***, would generally be applicable.

² Roberto Andorno, The Paradoxical Notion of Human Dignity, <http://www.revistapersona.com.ar/Persona09/9Andorno.htm>

³ Ian Wilmut *et al.*, *Nature* 385, 810-13, 1997

19. However, it should be noted that under the **Scotland Act 1998**, Schedule 5 (Reserved Matters), Part II (Specific Reservations), Head J (Health and Medicines), J3 (Embryology, surrogacy and genetics), the following are reserved matters to the **UK Parliament**:

- The subject-matter of the Human Fertilisation and Embryology Act 1990, and
- Human genetics.

In other words, matters arising that do not come under the terms of reserved matters, such as animal embryology and genetics, can be legislated upon in the **Scottish Parliament**.

20. Interestingly, after having sought clarification from the **Scottish Parliament** on whether it had jurisdiction over the creation of some human-nonhuman entities, it did not mention the fact that the subject-matter of the **Human Fertilisation and Embryology Act 1990** was reserved to Westminster. This may be because “*The 1990 Act does not control the mixing of animal eggs with other human cells*”⁴ as indicated in the UK Chief Medical Officer’s report entitled **Stem cell research: Medical progress with responsibility (2000)**.

21. This uncertainty with respect to legislation in the field of human-nonhuman embryonic entities is confirmed, in the report prepared in 2005 by the **House of Commons Science and Technology Committee** entitled **Human Reproductive Technologies and the Law**⁵ which indicated that the consideration of human-nonhuman embryonic mixtures is made difficult by the lack of legal definitions.

This is because the **Human Fertilisation and Embryology Act (1990)** does not, unfortunately, provide adequate clarifications concerning the specific status and nature of the created human-nonhuman embryonic entities.

Moreover, in the **Human Fertilisation and Embryology Authority’s** own words, this sort of research would only “potentially” fall within its remit.

22. Thus, the **Scottish Parliament’s** response regarding its remit over human-nonhuman embryonic combinations was to emphasise that since some of these combinations “*related, in part, to human genetics*” they were the reserve of the **Westminster Parliament**.

23. But questions remain as to the meaning of the term “*in part*”. Would this mean, for example, that if some animal genes were found to be identical to those of humans, then these animals would no longer be the responsibility of the **Scottish Parliament**?

Furthermore, would the transplantation of human cells into a nonhuman Scottish animal take this animal away from the remit of the **Scottish Parliament**?

24. In addition, the varying percentages of animal or human genes in these new biological entities may be less relevant to their status than the fact that they have been created by elements of two different species. For example, the claim that some hybrids created through the use of animal eggs and a human nucleus will be, from a genetic perspective, 99.9% human and 0.1% animal⁶ does not have any real meaning. Indeed, the genetic makeup of a human being is over 98% the same as that of a pygmy chimpanzee. Moreover, somatic human cells are 100% human but do not have any specific moral value.

⁴ Recommendation 6, Stem cell research: Medical progress with responsibility (2000), UK Department of Health, http://www.dh.gov.uk/AboutUs/MinistersAndDepartmentLeaders/ChiefMedicalOfficer/ProgressOnPolicy/ProgressBrowsableDocument/fs/en?CONTENT_ID=4108203&chk=25Wb7v

⁵ House of Commons Science and Technology Committee, Human Reproductive Technologies and the Law, Fifth Report of Session 2004-05, Vol.I, p 30-32. <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/702.htm>

⁶ Ian Sample, Stem cell experts seek licence to create human-rabbit embryo, The Guardian, 5 October 2006, <http://www.guardian.co.uk/genes/article/0,,1887689,00.html>

Thus it is not only the genetic material that matters but the animal egg as well. Indeed, without this egg, no living entity would ever be created.

Philosophical Perspective:

25. From a philosophical perspective it is also possible to consider human-nonhuman combinations from different perspectives which may reflect the debates which have already taken place with regard to early human life. And in this regard, it should be noted that the UK has not reached any agreed consensus on this matter.

Early human-nonhuman embryonic combinations

26. The early human-nonhuman combination can first be considered as just a pile of cells without any moral value whatsoever because, amongst other factors, it is not self-aware and cannot support the concept of autonomy. This may be because:

- The combination is not considered as being an embryo of any sort, or
- The combination is considered as - or given the benefit of the doubt of - being an embryo but is still accepted as having no moral value.

27. Secondly, it may be possible to consider early human-nonhuman embryonic combinations as - or given the benefit of the doubt of - being embryos endowed with a 'special status'. This would be somewhat similar to the manner in which many consider the moral status of an early human embryo. If this is the case then there may be an argument for them to be protected in certain circumstances.

28. Finally, it may be possible to consider early human-nonhuman embryonic combinations as - or given the benefit of the doubt of - being persons endowed with the same moral value as other human persons. If this is the case, then it is suggested that they should be given the same protection as any other person in society.

Later embryonic, fetal and postnatal human-nonhuman combinations

29. With regard to later embryonic, fetal and postnatal human-nonhuman combinations, again different positions can be considered if they are not accepted as having full human dignity as soon as they are created. Thus they may be considered as:

- gradually being endowed with an increasing amount of moral value in relationship to their prenatal development.
- having full moral value immediately after birth.
- gradually being endowed with an increasing amount of moral value in relationship to their postnatal development.
- never having any moral value even after birth.

Conclusion

30. For those who believe that an early human-nonhuman embryonic combination is not a person but just a pile of cells without any moral status or human dignity, then their creation should not result in many new ethical problems. This position would be similar to the view which argues that human embryos cannot have any significant moral value before 14 days of development.

31. However, for those who believe that human-nonhuman embryonic combinations cannot be assimilated to 'piles of cells' (and who represent a significant cross-section of the general public in the UK), the creation and destruction of these entities may give rise to profound ethical problems. For them, the mixing at a very intimate level of human and nonhuman biological material may begin to undermine the whole distinction between human and nonhuman animals for which a different understanding of dignity exists. As a result, this may undermine the whole concept of human identity, human dignity and human rights. A blurring of the important differences between what makes human and nonhuman life would be taking place.
32. In addition, uncertainty even exists towards the entity's moral status and whether it is even entitled to full dignity. Thus, for some, the promised biomedical benefits that may result from the creation of such entities do not compensate the risks of destroying entities with full or partial moral status.

Recommendations of the Scottish Council on Human Bioethics:

General Recommendations

1. *In so far as it is possible, a decision should be taken to determine whether a created human-nonhuman entity should come under human or nonhuman animal legislation.*

Human-Nonhuman Transgenesis

2. *The creation of transgenic nonhuman animals in which some foreign human genes are deliberately inserted into the genome of nonhuman animals should only proceed with extreme caution.*
3. *The creation of transgenic human beings in which some foreign nonhuman animal genes are deliberately inserted into the genome of these human beings may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modifications in the genome of descendants.*

Human-Nonhuman Gestation

4. *The placing of a live human embryo into a nonhuman animal should be prohibited.*
5. *The placing of live human sperm into a nonhuman animal should be prohibited.*
6. *The placing of a live nonhuman embryo into a woman should be prohibited.*
7. *The placing of live nonhuman sperm into a woman should be prohibited.*

Human-Nonhuman Hybrids

8. *The creation of an embryo containing cells made up of both human and nonhuman chromosomes should be prohibited.*
9. *The mixing of human and nonhuman gametes should be prohibited.*

Human-Nonhuman Somatic Cell Nuclear Transfer

- 10. *The insertion of a human cell nucleus or chromosomes into a nonhuman egg stripped of its chromosomes enabling an embryo to exist should be prohibited.***
- 11. *The insertion of a nonhuman cell nucleus or chromosomes into a human egg stripped of its chromosomes enabling an embryo to exist should be prohibited.***

Human-nonhuman Chimeras

- 12. *The incorporation of human stem cells into post-blastocyst stages of nonhuman embryos should only take place if it can be demonstrated that they cannot contribute to the germline or brain cells of the nonhuman animal.***
- 13. *The incorporation of nonhuman stem cells into post-blastocyst stages of human embryos should only take place if it can be demonstrated that they cannot contribute to the germline or brain cells of the human being.***
- 14. *The incorporation of human pluripotent or totipotent stem cells into a nonhuman blastocyst or its preliminary embryonic stages should be prohibited.***
- 15. *The incorporation of nonhuman pluripotent or totipotent stem cells into a human blastocyst or its preliminary embryonic stages should be prohibited.***