An ethical framework for stem cell research in the European Union

DOI:

[10.1007/s10728-005-6439-7](https://doi.org/10.1007/s10728-005-6439-7)

[Link to publication record in Manchester Research Explorer](#)

Citation for published version (APA):

Harris, J., Bortolotti, L., & Irving, L. (2005). An ethical framework for stem cell research in the European Union. *Health Care Analysis*, 13(3), 157–162. <https://doi.org/10.1007/s10728-005-6439-7>

Published in:

Health Care Analysis

Citing this paper

Please note that where the full-text provided on Manchester Research Explorer is the Author Accepted Manuscript or Proof version this may differ from the final Published version. If citing, it is advised that you check and use the publisher's definitive version.

General rights

Copyright and moral rights for the publications made accessible in the Research Explorer are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

Takedown policy

If you believe that this document breaches copyright please refer to the University of Manchester's Takedown Procedures [<http://man.ac.uk/04Y6Bo>] or contact uml.scholarlycommunications@manchester.ac.uk providing relevant details, so we can investigate your claim.

An Ethical Framework for Stem Cell Research in the European Union

John Harris,^{1,2} Lisa Bortolotti,¹ and Louise Irving¹

The European Union is a nightmare from the perspective of the ethics and regulation of science. A hitherto insoluble problem has been the task of drafting ethical principles which do not founder on the radically different attitudes taken to the question of the moral status of the human embryo. Following the conclusions reached in an international project, EUROSTEM, we suggest that this problem can be solved by concentration on the scope of principles and we emphasize that European research should be funded in a way that does not discriminate between individual states and researchers in the EU. Finally, we observe that the availability of any eventual embryonic stem cell therapies will pose a dilemma for those countries and those people that have declared stem cell research to be unacceptable.

KEY WORDS: ethical framework; embryo research; stem cells; research ethics; respect; solidarity; protection of researchers.

INTRODUCTION

In this paper we report on the drafting of an ethical framework for stem cell research as part of the EU funded project EUROSTEM. We outline the main original contributions of the ethical framework and encourage responses and further development from a wider audience. Clearly the European Union must maintain a viable research environment in spite of the significant differences in the cultural views and national legislation of the member states. EUROSTEM makes some clear recommendations as to how this goal can be achieved. First, we note the clear moral imperatives that support what can be termed “medical

¹Centre for Social Ethics and Policy, The School of Law, University of Manchester, UK.

²Correspondence should be directed to John Harris, Centre for Social Ethics and Policy, The School of Law, University of Manchester, UK; e-mail: john.m.harris@manchester.ac.uk.

research as a social institution.” We aim be convincing on the necessity for general agreement on basic ethical principles while respecting the autonomy of individuals and member states. We believe this can be achieved by recognising the necessity of all to respect differences in the scope of application of our guiding principles. We highlight the importance of protecting individual researchers from the risks that differences in legislation across the European Union generate.

THE CHALLENGE OF AN ETHICAL FRAMEWORK FOR STEM CELL RESEARCH IN THE EU

The European Union is at first sight a nightmare from the perspective of the ethics and regulation of science. The more so in the controversial field of stem cell research. A number of factors render the ethical issues raised by stem cell research difficult to address at the level of the European Community. First, there are elements of cultural diversity and diversity of religious and political views that coexist on the European scene. Moreover, there are often inconsistencies in the legislative environment of many member states, and finally, there is a constant tension, within member states and across the EC, between the requirements of freedom of research and of movement and the duty of governments to serve the health needs of their citizens on the one hand, and the protection of moral values and interpretations of basic rights on the other.

The differences in legislation across the member states of the EU are striking. The UK and Belgium have legally permitted the creation of human embryos for research purposes, while states such as France and Denmark allow stem cell research on supernumerary embryos (under certain conditions). At the other end of the spectrum, countries such as Germany, Austria and Ireland explicitly prohibit stem cell research on supernumerary embryos and the creation of human embryos for research. Then there are some member states that have no specific legislation applicable to human embryonic stem cells. Some—such as Portugal and the Republic of Cyprus—have signed the Oviedo Convention (1997) against the creation of human embryos for research and are likely to have laws constraining or prohibiting embryonic stem cell research in the future. In other states the legislation on stem cell research is only partial. Sweden, for instance, allows stem cell research on supernumerary embryos but is silent on the creation of embryos for research. A revision of the current legislation is underway and it is expected that producing fertilised eggs for research purposes will not be prohibited.

In spite of these differences, and the difficulties that they generate, there is a joint interest in supporting scientific research and pursuing research through open collaboration and the European Commission has been a leader in promoting these ideals through its various research programmes. In particular, there is an interest in the potential benefits deriving from the outcomes of stem cell research. A first step towards the development of a common approach to the responsible pursuit of stem

cell research is to agree on an ethical framework that embraces all the common values while respecting the differences. The attempt to create such a framework has been the task of one EU funded project—EUROSTEM and we report here the first draft of such an attempt.

THE MORAL BASIS OF STEM CELL RESEARCH

In the ethical framework of EUROSTEM we start by highlighting the powerful obligation we have to pursue, support and participate in scientific research. Such an obligation stems from a number of independent considerations. First, medical research is a necessary component of the rule of rescue—our duty to help those in need. Moreover, according to the “Do-No-Harm” and “Beneficence” principles we have a moral obligation to further medical research for its potential benefits to those affected by diseases and those who care for them. We accept in our lives the benefits derived from past medical research and basic fairness suggests that we should, for our part, continue to contribute to that social practice, (in this case, medical research) which is likely to produce similar benefits in the future. Finally, we derive a more general benefit from living in a society that pursues and actively accepts the benefits of research and where research and its fruits are given a high priority. The knowledge that research is ongoing into diseases or conditions from which we do not currently suffer but to which we may succumb makes us feel more secure and gives us hope for the future, for ourselves and our descendants, and others for whom we care. However, freedom of research is not unlimited and it should be undertaken responsibly in accordance with accepted moral principles.

In the context of stem cell research a major, and hitherto insoluble problem has been the task of drafting ethical principles which do not founder on the radically different attitudes taken to the question of the moral status of the human embryo. Positions diverge dramatically on this issue, as some regard the early embryo as simply a cluster of cells whereas others conceive it as a human being worthy of the dignity and status granted to other human beings. No ethical framework could hope to square this circle, but in identifying basic principles on which we can agree despite disagreeing on the status of the embryo we can, we believe, achieve a workable and tolerant research environment. To do this we need to think carefully about scope.

THE SCOPE OF ETHICAL PRINCIPLES

Disagreements over the moral status of the human embryo are often framed in terms of human rights and human dignity, such ideas in one form or another command almost universal respect. What is seldom noticed is that while human

rights and human dignity find few detractors there are always disagreements about the scope of such principles. In this context scope concerns the class of individuals covered by the principles and the precise nature of the protections the principles afford. Differences over whether or not embryos and fetuses are included within the scope of "human persons" and over whether a right to life or the obligation to respect the sanctity of life permits war or capital punishment have always existed alongside almost universal respect for "the sanctity of life." Acceptance of basic principles and agreement about the scope of the principles are always distinct issues. Those disagreeing about the moral status of the embryo do not usually disagree about the ethics of murder. They differ, rather as to whether or not a particular case is in fact a case of murder, or whether the individual killed was a person in the relevant sense.³

Within the proposed ethical framework EUROSTEM has formulated a principle of respect for persons, which can be cashed out in terms of respect for the autonomy of the individual and concern for the welfare of persons. How this principle is to be applied will depend on the scope of the term 'person.' The notion of scope can thus be used as a conciliatory mechanism to allow a number of basic principles to be widely accepted by individuals who have radically different views on the status of the early embryo. Two widely accepted principles, "Do-No-Harm" (beneficence) and "Respect for Persons," are based on the idea that persons are morally valuable. They indicate that we should avoid causing harm to persons and we should always treat them in morally appropriate ways (e.g. by respecting their autonomy).

If we believe that the early embryo is a person, then research might be permitted only on adult stem cells or cord blood derived stem cells (Kogler et al., 2004) or be permitted on embryonic stem cells only when it is non-destructive. A good example of this approach is the legislation adopted by Germany, where there is an Embryo Protection Law according to which the instrumentalisation and destruction of human embryos is deemed impermissible.

If we believe that the early embryo is not a person, we will not constrain stem cell research on early human embryos and will have different interpretations of the scope of the principles of "Do-No-Harm" and "Respect for Persons." For instance, we might believe that these principles apply only to sentient fetuses or to human beings after birth. Belgium is one of the two states in which the creation of human embryos for the procurement of stem cells is permitted by law.

It is important to allow for such differences in the EU and that is why the notion of scope is valuable in creating some bases for agreement while respecting the autonomy of the individual states. In the framework, we identify the importance

³A recent case turning on the status of the human embryo in the European Court of Human Rights concerned just this question of scope. See The European Court of Human Rights [CASE OF *Vo v. FRANCE* (Application no. 53924/00) Strasbourg 8th July 2004]. One of the present authors has recently discussed the issue of scope. See Harris and Sulston (2004).

of toleration and pluralism. There are many good reasons for supporting toleration as a guiding ideal, particularly within bioethics. It promotes the sense of humility required to refrain from imposing one's own judgments and beliefs on others and it incorporates the virtues of cooperation and goodwill.

PROTECTION OF INDIVIDUAL RESEARCHERS

The situation we have described, with significant differences in legislation across the EU, inevitably creates dangers for the individual researchers that engage in collaborative work. It would be consistent with the Treaty of Rome (1957), which promotes freedom and safe conditions for workers, that researchers in one member state are given the opportunity to cooperate with researchers in another member state without the risk of criminal liability for their involvement in research that might be forbidden by one national legislation but not by another.

The ethical framework includes radical recommendations in relation to the protection of individual researchers. To the extent that national laws prevent cooperation and collaboration between researchers, nation states and the European Commission should work actively to find solutions for this problem, as the solutions cannot be the responsibility of individual researchers. We conclude that no one working in the EU should be punished or rendered liable to prosecution, restriction or discrimination for undertaking research that is permitted in that country. Moreover, European research should be funded in a way that does not discriminate between individual states and researchers in the EU.

AVAILABILITY OF THERAPIES

A final crucial issue concerns the availability of any eventual stem cell therapies. We noted at the start the duty of governments to serve and protect the health needs of their citizens. The European ideal, no less than basic decency, requires that any therapies developed from stem cell research be made generally available in the EU and indeed throughout the world. It is this requirement and indeed the inevitability of this process that will eventually lead to a real consensus on stem cell research. For if, as most stem cell researchers expect, there will indeed prove to be important stem cell derived therapies and if these in part flow from research or cell lines that are embryo derived, then not only will the pressure to make these therapies generally available be morally overwhelming, it will also be politically decisive. Those countries and those people that have declared embryonic stem cell research to be unacceptable seem not to have taken on board the dilemma that will arise if such therapies are proved. Does the unacceptability of the research entail the unacceptability of the therapies? If it is true that those who will the end will the means also, then we can look forward to a harmonious research environment

in Europe. If not then the free movement guaranteed by the Treaty of Rome will take on new importance and therapeutic tourism will become a permanent feature of the European scene.

ACKNOWLEDGMENTS

Work on this paper and the EUROSTEM ethical framework to which it refers was funded by a project grant from the EC—DG research “Quality of Life and Management of Living Resources Programme.” The full draft text of the EUROSTEM ethical framework can be found at: <http://www.eirma.asso.fr/eurostem.html>.

REFERENCES

- Harris, J., and Sulston, J. (2004) Genetic Equity. *Nature Reviews Genetics* **5**, 796–800.
- Kogler, G., Sensken, S., Airey, J.A., Trapp, T., Muschen, M., Feldhahn, N., Liedtke, S., Sorg, R.V., Fischer, J., Rosenbaum, C., Greschat, S., Knipper, A., Bender, J., Degistirici, O., Gao, J., Caplan, A.I., Colletti, E.J., Almeida-Porada, G., Muller, H.W., Zanjani, E., and Wernet, P. (2004) A New Human Somatic Stem Cell from Placental Cord Blood with Intrinsic Pluripotent Differentiation Potential. *Journal of Experimental Medicine* **200**(2), 123–135.
- Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human embryonic stem cell research and use (2004) Vol. I, edited by Line Matthiessen-Guyader, Directorate E, Biotechnology, Agriculture and Food.
- Treaty of Rome (1957) <http://www.hri.org/docs/Rome57/>.