



Position paper:

Criteria for pre-embryo research

Executive summary

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The views expressed in this position paper are those of the author and do not necessarily reflect the views of the Centre for International Political Studies or the University of Pretoria.

EXECUTIVE SUMMARY

Introduction

Pre-embryo experimentation is a highly topical and controversial issue worldwide. Initially, pre-embryo experimentation focused on solving reproductive problems, but these limited aims were completely transcended by the advent of embryonic stem-cell research, the revolutionary aims of which include creating substitute organs and limbs. As the massive medical and economic potential of stem-cell research became apparent, countries began to promote this research through research-friendly regulatory regimes and other incentives such as grants and subsidies.

As in several other jurisdictions around the world, pre-embryo experimentation in South Africa is subject to a legal-ethical regime that narrowly demarcates permissible embryo experimentation and strongly regulates such experimentation. This paradigm is premised on the value of 'respect for the pre-embryo'. This value will constitute the point of departure for this position paper.

Problem statement and objective

The National Health Act is mainly silent on the crucial issue of substantive criteria for allowing pre-embryo research. It is therefore imperative that the regulations that are currently being drafted should fill this lacuna left by the legislation. The objective of this position paper is to address the problem by developing a *comprehensive set of substantive criteria* to be incorporated in the regulations. This is done by first analysing the value that justifies and informs the regulatory paradigm, namely respect for the pre-embryo; and secondly by a comparative legal analysis.

The respect-doctrine

There are two dimensions of respect for pre-embryos – one relating to the *ends* of pre-embryo research, the other relating to the *means* of such research:

- *The ends of pre-embryo research:* Respect is a relative value and therefore not equal to the absolute value of human dignity. Being of relative value, respect for the pre-embryo must compete with other interests in a balancing process. If such another interest, such as medical research, qualifies as a worthwhile purpose, the destruction of the pre-embryo in pursuit of such purpose would be ethically justified.
- *The means of pre-embryo research:* The respect-doctrine requires not only that pre-embryo research must be for good ends, but also that the use of pre-embryos as means must reflect the (relative) value of the pre-embryo. This means that a worthwhile purpose does not give researchers carte blanche in the use of pre-embryos, but rather that pre-embryos should be used in a judicial fashion.

Comparative legal analysis

The comparative legal analysis includes three foreign jurisdictions, namely the United Kingdom, the Netherlands and Belgium. All three of them share South Africa's alignment to the doctrine of respect, but are ahead of South Africa in embodying the values associated with the respect doctrine as specific substantive criteria in their law. The analysis demonstrates how the statutory instruments of the three comparative jurisdictions give direct expression to the ethical values associated with the respect doctrine. In addition, the statutes add a good measure of practicality by including criteria that pertain to good scientific practice. The subsequent concrete policy recommendations encapsulate concisely the essence of this comparative legal analysis:

Policy recommendations

Medical scientific purpose

The proposed research must have a medical scientific purpose.

No equally effective alternative

There must be no alternative to the proposed research methodology that will not entail the use of pre-embryos and still be equally effective in achieving the purpose of the proposed research.

Good scientific practice

The proposed research must be aligned with good scientific practice, measured by the following criteria:

Sound methodology

The proposed research must have a sound research methodology. This entails inter alia that:

- the research methodology must entail the destruction of the smallest possible number of pre-embryos necessary to achieve the research purpose without compromising the efficacy of the research; and
- the research methodology must be based on the latest literature.

Expertise of researchers

The key research team members must have the expertise necessary to conduct the proposed research.