

# Human embryo research in Belgium: an overview

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**Objective:** To present an overview of the numbers and types of human embryos used in research projects in Belgium from 2007 to 2015.  
**Design:** Analysis of all research proposals approved by the Federal Commission for Medical and Scientific Research on Embryos In Vitro.

**Setting:** Not applicable.

**Patient(s):** Not applicable.

**Main Outcome Measure(s):** Number of embryos used for research, number of embryos created for research, and areas of embryo research.

**Result(s):** Since 2007, 15,811 embryos were used for 36 research projects. In total, 10,492 (66%) fresh supernumerary embryos (unfit for transfer or freezing) were used, 4,083 (26%) frozen supernumerary embryos (donated by parents whose child wish was completed or abandoned), and 1,236 (8%) embryos created for research. Most projects focused on research into embryo development. Fresh supernumerary embryos were mainly used for human embryonic stem cell (hESC) research. Frozen supernumerary embryos were almost exclusively used for research into embryo development and for hESC research. Embryos created for research were used for research into embryo development, oocyte research, research into cryopreservation of oocytes, and hESC research.

**Conclusion(s):** Having concrete data on embryo research is crucial for an informed debate. Moreover, these data are necessary to find out trends in research such as the numbers of embryos needed and the areas of research. Data collection requires a sufficiently clear definition of “research” and “embryo.” These conceptual questions frequently reveal lack of clarity in legislation. (Fertil Steril® 2017; ■:■-■. ©2017 by American Society for Reproductive Medicine.)

**Key Words:** Embryo research, ethics, human embryo

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**R**esearch on human embryos has always been much debated and is highly likely to remain controversial in the near future. Whereas some people regard the embryo as a mere cell aggregate with no special moral status, others regard it as the most vulnerable form of human life which should not be instrumentalized for research purposes, regardless

of the potential benefits. This huge difference in viewpoints is illustrated by the very diverse laws across the world.

Although many countries allow embryo research under strict conditions, there is little empirical information on the research carried out on human embryos. No country is systematically making public any overview of the embryo research performed on its

territory, making it very difficult to obtain hard data needed to answer questions in this context. Fragmentary data can be obtained from countries such as the United Kingdom and France, but for many other countries it is impossible to obtain data, either because they are not collected or because they are not accessible by the public. What types of embryos are used? What kind of research is performed? Is there an increase in the number of embryos used for research? At the moment, no one is able to answer these questions. Yet, we think that transparency in scientific research is a prerequisite to maintain the trust of the public and in particular of the patients who have to dispose of their

Received February 5, 2017; revised April 29, 2017; accepted May 3, 2017.

G.P. has nothing to disclose. S.S. has nothing to disclose. S.D. has nothing to disclose. B.H. has nothing to disclose. V.K.-D. has nothing to disclose. U.P. has nothing to disclose. H.v.V. has nothing to disclose. A.v.S. has nothing to disclose. H.M. has nothing to disclose.

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Fertility and Sterility® Vol. ■, No. ■, ■ 2017 0015-0282/\$36.00  
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<http://dx.doi.org/10.1016/j.fertnstert.2017.05.003>

embryos. Research has shown that patients' willingness to donate their embryos for scientific research depends largely on their perception of science and scientists (1). Based on this insight, the Belgian Federal Commission for medical and scientific research on embryos in vitro decided to develop a system of data collection that could generate unique information and thereby answer the main questions raised by the public and policy makers. In this context, Belgium can serve as a case example for countries that, for example, consider allowing embryo creation for research purposes. Our system of data collection requires some clarifications of basic terms (such as "embryo" and "research") and a clear view on the actual practice of handling embryos in both IVF clinics and research laboratories.

In this paper, we will refer to three types of embryos that can be used in research: fresh supernumerary embryos, cryopreserved supernumerary embryos and embryos created for research. Fresh supernumerary embryos are embryos that have been labeled as unfit for transfer or freezing owing to, for example, chromosomal abnormalities, abnormal fertilization or, predominantly, inferior quality. Frozen supernumerary embryos are embryos that have been cryopreserved with the aim of future transfer but where the parental project is either accomplished or abandoned or the legally determined period of cryopreservation has expired. Finally, embryos created for research were never part of a parental project.

## POSITION OF BELGIUM WITHIN THE EUROPEAN CONTEXT

The European Convention on Human Rights and Biomedicine (also known as the Oviedo Convention) formulates principles and prohibitions about research on human embryos. Article 18 of the Convention prohibits the creation of human embryos for research purposes, and "[w]here the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo" (2). The Convention, however, allows nations to make reservations for certain provisions of the Convention "to the extent that any law then in force in its territory is not in conformity with the provision" (2).

Of the 47 members of the Council of Europe, 35 have signed the Convention and 29 of those have also ratified it. Signing the Convention expresses interest and intention to become a party to the treaty, but only ratification expresses definitive consent to be bound by it. Italy, Luxembourg, the Netherlands, Poland, Sweden, and Ukraine have signed the convention without ratifying it. The Convention has been neither signed nor ratified by Andorra, Armenia, Austria, Azerbaijan, Belgium, Germany, Ireland, Lichtenstein, Malta, Monaco, Russia, and the United Kingdom. (2).

The reason why the Belgian government neither signed nor ratified the Convention was that it regarded it as too restrictive on the subject of embryo research. Belgium, Sweden, and the United Kingdom are the only European countries that allow the creation of embryos for research purposes under certain conditions. Most European countries only allow research on spare IVF embryos, and a small minority of countries prohibit all research on human embryos. Still others do not have any legislation in place regarding research on

human embryos. In short, great diversity remains in how European nations address research on embryos (3).

In Belgium, embryo research is regulated by the Law on Research on Embryos In Vitro (4). This law established the Federal Commission for Medical and Scientific Research on Embryos In Vitro (hereafter referred to as the Federal Commission), which evaluates the research projects. It is their task to guarantee the application of the law and to formulate recommendations for law-making initiatives as well as for the application of the law by the local Ethics Committees. The Federal Commission is composed of 14 members: four medical specialists, four scientific specialists, two legal scholars, and four specialists in ethics and social sciences.

The law stipulates the conditions under which embryo research is permitted (5). It also lists a number of applications that are forbidden, such as reproductive cloning, eugenics, sex selection for nonmedical reasons, implantation of human embryos in animals, and creation of chimeras or hybrids. Research on embryos is allowed for up to 14 days (freezing period excluded) and must be based on the most recent scientific findings and conducted according to the appropriate scientific methods. The research must be performed in a laboratory of a university that is recognized as a center for reproductive medicine. No other research method can be equally effective to obtain the same results. Embryos subjected to research must be destroyed unless the research had a therapeutic goal for the embryo, or when it concerns mere observation that does not harm the embryo's integrity (Art. 5, 2°).

The Belgian initiators of the bill denied a fundamental moral distinction between research embryos and supernumerary embryos (6). Article 4, §1 of the law forbids the creation of embryos for research except when the research goal can not be achieved by other means (including supernumerary embryos). This article deviates from Article 18 of the European Convention mentioned above.

The disposition of supernumerary embryos created in the context of assisted reproduction is regulated by the 2007 Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes (7). Patients who do not wish to keep their embryos for their own reproduction have three options: donation to others, destruction, or donation for research. This decision is fixed in a contract before the start of the IVF/intracytoplasmic sperm injection (ICSI) treatment, but patients may change the destination of their embryos at any time, as long as both partners agree (Art. 7–8).

For those who are donating fresh supernumerary embryos, a specific consent, mentioning the research project for which the embryos will be used, must be obtained. This is, however, impossible for those who want to donate their frozen supernumerary embryos at the end of the legal storage period (5 years with one possible extension if requested), because one can not foresee what projects will be active at that time. The Federal Commission therefore decided that a generic consent suffices for cryopreserved embryos. The centers for reproductive medicine that perform embryo research each have a form or brochure dedicated to embryo research. This document explains the research performed in that center (see below). If several lines of research are performed, the

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