

Case Study: The United Kingdom

Regulation of Stem Cell Research

Based on materials from the Department of Health, the Wellcome Trust, the MRC, and the UK Stem Cell Bank

Overview

The UK Government is supportive of research into all types of stem cells from adults to fetuses, cord blood to embryos subject to carefully prescribed guidelines. Research using surplus human embryos from IVF and embryos created for research, by fertilization, or somatic cell nuclear replacement (cloning) is permitted in the United Kingdom under license from The Human Fertilisation and Embryology Authority (HFEA). As a condition of the license, cell lines established by the research must not be transferred to third parties and must be deposited in the UK Stem Cell Bank. This bank was established in May 2004 and is overseen by an independent committee chaired by Lord Naren Patel. Most funding of UK stem cell research comes from the research councils, notably the Medical Research Council (MRC). Finally, a Local or Multi-centre Research Ethics Committee must also approve any embryonic stem cell research project in the UK.

Human Fertilisation Embryology Authority

The HFEA is a statutory body created in 1991 by the Human Fertilisation and Embryology Act to license and monitor research and fertility clinics in the UK. The HFEA was created in response to public concern about the potential risks of infertility treatments and embryo research. The mission of the HFEA is to address the issues of *in vitro* fertilization (IVF), donor insemination, and more recently embryonic stem cell research. The agency also regulates the storage of eggs, sperm, and embryos, reviews all new developments in treatments and research, and advises ministers. HFEA is actively involved in the public debate on the ethics of IVF and embryo research

In addition, HFEA monitors clinics that do research on or conduct IVF, donor insemination treatments, or human embryo research. The HFEA Code of Practice provides clinics with detailed guidelines. Clinics may be inspected at any time to ensure that they maintain the highest medical and professional standards. The activities of HFEA were designed to safeguard the interests of patients, children, the general public, doctors, service providers, the scientific community, and also future generations.

The purposes for which embryos can be used in research are listed in Schedule 2 of the Human Fertilisation and Embryology Act 1990 and in the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. These purposes are:

- Promoting advances in the treatment of infertility.
- Increasing knowledge about the causes of congenital disease.
- Increasing knowledge about the causes of miscarriages.
- Developing more effective techniques of contraception.
- Developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

- Increasing knowledge about the development of embryos.
- Increasing knowledge of serious disease.
- Enabling any such knowledge to be applied in the development of treatments for serious disease.

The HFEA has 18 members including its current chair Ms. Suzi Leather. All members are appointed by the UK Health Minister under rigorous standards laid down for public bodies in the UK. The members determine HFEA policies, review treatments, and research license applications. Under the Human Fertilisation and Embryology Act, more than half of the members must come from disciplines other than medicine and human embryo research. The HFEA reports to the Secretary of State, and publishes its report annually.

The HFEA is the official organization which grants licenses allowing researchers to create human embryonic stem cells through somatic cell nuclear transfer. In August of 2004, the HFEA granted its first license (valid for one year) to Newcastle Centre for Life and Dr. Alison Murdoch. Stem cells created under this license will be used for research purposes only. Research must be completed before the embryo is 14 days old. Research using human/animal chimeras is currently not permitted. Each proposal to the HFEA is fully peer reviewed.

Medical Research Council

The UK MRC is an independent, national organization established in 1913 and funded by the public. The MRC promotes research in all areas of medical and related science with the aim of improving human health and quality of life (similar to the NIH in the United States, yet not part of the government). The MRC reports to the Office of Science and Technology, which is part of the Department of Trade and Industry. The MRC governing body is a council of 15 members, which meets six times a year. The council is responsible for overseeing the MRC policy, research direction, management oversight, and other related issues.

The mission of the MRC is to encourage and support high-quality research with the aim of improving human health, producing skilled researchers, advancing and disseminating knowledge and technology; and promoting dialogue with the public about medical research. The MRC works through its council, scientific boards, and committees to determine which research to support. Since the MRC is not a government department, it is independent in determining how to spend money allocated. Although it is an independent organization, it works closely with the government health departments, other research councils, industry leaders, and others to identify and respond to current and future health needs. The council also advises the government on matters relating to biomedical research and health-related questions.

The MRC budget is around \$800 million (£430 million). Spending is split between grants to universities and the National Health Service (NHS), and funding MRC research centers. The MRC has over 50 research centers, employing over 3000. One of these centers is the UK Stem Cell Bank.

UK Stem Cell Bank

Sponsored by the MRC and the Biotechnology and Biological Sciences Research Council (BBSRC), the UK Stem Cell Bank provides an independent and competent

facility to produce, test, and release existing stem cell lines and new stem cell lines derived from adult, fetal and embryonic human tissues. Part of their mission requires **characterizing** stem cell lines for use in the UK and abroad. The bank presents information to the public on the cell lines and the technology used in their preparation and characterization. They will also be responsible for maintaining stem cell lines that are prepared under Good Manufacturing Practice (GMP) conditions. Under UK law, only materials derived under GMP can be used as therapeutics in humans. The UK Stem Cell Bank is managed by a steering committee chaired by Lord Naren Patel.

Materials were prepared by Kirstin Matthews, Ph.D.

Further Suggested Readings

UK Stem Cell Policy

- (1) The Department of Health
<http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/StemCell/fs/en>
- (2) The Wellcome Trust:
<http://www.wellcome.ac.uk/en/genome/geneticsandsociety/hg15b001.html>
- (3) HFEA: <http://www.hfea.uk.gov>
- (4) MRC: <http://www.mrc.ac.uk>
- (5) UK Stem Cell Bank: <http://www.nibsc.ac.uk/divisions/cbi/stemcell.html>