

Position statement on the use of stem cells in research

The position of Great Ormond Street Hospital Children's Charity

Great Ormond Street Hospital Children's Charity supports the use of all stem cells in research where such research meets legal and ethical requirements. The charity sees considerable potential in using stem cells for expanding our knowledge about childhood conditions and providing new ways of treating such conditions. In addition, the charity recognises the importance of stem cell research in the work of Great Ormond Street Hospital and its academic research partner the UCL Institute of Child Health (ICH). As with all scientific research funded by the charity, all stem cell research is funded on merit and scientific excellence after rigorous peer review and in line with current legal and regulatory framework.

We recognise that there are important ethical issues concerning use of human embryonic stem cells and that some supporters of the charity will hold moral objections to the use of human embryonic stem cells in research. The wishes of these donors will be fully respected in relation to any donations they make.

Background

Stem cells have several powerful and unique features that distinguish them from other types of cells. They are 'master cells' that can self-renew and under certain conditions are capable of developing into a variety of different types of specialised cells, such as a neuron or heart cell. Their capacity to differentiate into specialised cells varies between different types of stem cells.

Research using stem cells is advancing our understanding of biological development, tissue repair and regeneration, and researchers are exploring the potential of stem cells in developing new treatments and therapies for many conditions.

Stem cells can be derived from a number of different sources.

- **adult stem cells** are isolated from specialised tissues and organs in humans or animals such as bone marrow.
- **human embryonic stem cells** are extracted from a very early stage human embryo when it is a collection of cells known as a blastocyst. These are usually sourced from early stage embryos no longer required for IVF which would otherwise be destroyed.
- **induced pluripotent stem cells (iPSCs)** are a type of stem cell that can be generated from adult cells. Researchers have discovered ways of turning adult cells, such as skin cells, back into "blank" stem cells. These newly programmed cells, called iPSCs, have the potential to be turned into any type of cell body and serve as an alternative source of stem cells.

Regulation and ethical guidance

The UK has a comprehensive and well-established regulatory framework for stem cell research. The regulation of stem cells in the UK is affected by two pieces of legislation: the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which fully implement the EU Tissues and Cells Directives (EUTCD).

The Human Tissue Act 2004 regulates the removal, storage and use of human bodies, organs, tissue and cells for a number of purposes, including research. The EUTCD – which was brought fully into force in 2007 – creates a common framework that ensures high standards in the procurement, testing, processing, storage, distribution and import/export of tissues and cells across the EU. The primary aim of the directive is to ensure the quality, safety and traceability of tissue and cells used for human application. It also aims to support the exchange of tissues and cells between member states.

The Human Fertilisation and Embryology Act (1990) laid the foundation for regulating embryonic stem cell research. The Act established The Human Fertilisation and Embryology Authority (HEFA), which is empowered to approve all embryo research conducted in the UK

Embryonic stem cell research is illegal unless it carried out under a license granted by the HEFA. In order to gain a license the researcher must demonstrate that embryo research is necessary and that the proposed research is being done for one of the five purposes specified in the Act. Licensed research can only take place on embryos created *in vitro*: embryos that have developed from eggs fertilized outside the body. Most embryos used in UK stem cell research are embryos initially created for use in fertility treatment, but not used. These IVF embryos, if donated with the full consent of the parents, can be used for research. Licensed research can only take place on embryos up to 14 days. Stem cells are isolated from the blastocyst much sooner than this – at 5 to 6 days.

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