

# Manifestation of Novel Social Challenges of the European Union in the Teaching Material of Medical Biotechnology Master's Programmes at the University of Pécs and at the University of Debrecen

Identification number: TÁMOP-4.1.2-08/1/A-2009-0011



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Transdifferentiation and regenerative medicine – Lecture 14

# ETHICAL BACKGROUND OF STEM CELL RESEARCH AND THERAPY



# Societal impact of stem cell research

- Scientific research and education
- Business: application, commercialization
- Media: communicating legal and moral responsibility towards the public
- Opinions are usually motivated more by non-scientific views (religion, political ideas) in a bi-directional manner.

# Main fields of ethical issues in stem cell research

- Experimental issues: animal rights, source of stem cells
- Human application: Purpose of the study - therapeutic or reproductive use of stem cells
- Source of stem cell, and the moral standing of the human embryo
- Patient selection criteria

# Pro-life view on the use of embryos in human stem cell research

- The moral standing of a preimplantation embryo is equal to a living person
- All preimplantation embryos have the chance to become viable progeny
- Destroying (even unwanted/unused) embryos is equal to murder
- Non-embryonic sources for stem cells are mostly approved

# View of dominant religious faiths concerning the moral standing of embryos

- Western Christian, Jewish, Islamic or polytheistic Hindu, and Buddhist traditions: the moral standing of human beings arrives later than the preimplantation period in the gestation process
- Other religious views consider the fetus of full standing if it is capable of viability outside the womb

# Biologically relevant aspects pertaining to the standing of human embryos

- None of the medical definitions applied to considering a person alive or dead is applicable to preimplantation embryos.
- There are practical differences between the quality of IVF embryos – they are unequal.
- Approximately 70-80% probability of loss of embryos generated during intercourse.

# Ethical aspects of stem cell application

- In 2009, the International Society for Stem Cell Research released a set of international guidelines to effective clinical applications for patients.
- Other issues to be articulated :
  - Uniform standards for cell processing and manufacture must be agreed upon by researchers, also stem cell banks, and regulators.
  - Standards for preclinical testing using animal models must be clarified before first-in-human clinical trials can begin
  - Fair procedures for enrolling human subjects in early stem cell–based clinical trials.



# Ethical aspects of patient selection for enrollment to stem cell therapy

- Informed consent – including risks and adverse effects
- Consequences of inclusion/refusal
- Necessity for long-term monitoring

# Summary

Phase of research	Ethical issues
Collection of biological materials	Informed and voluntary consent
Research with hESCs	<ul style="list-style-type: none"> <li>• Destruction of embryos</li> <li>• Creation of embryos specifically for research purposes:               <ul style="list-style-type: none"> <li>– Payment to oocyte donors</li> <li>– Medical risks of oocyte retrieval</li> <li>– Protecting reproductive interests of women in infertility treatment</li> </ul> </li> </ul>
Use of stem cell lines derived at another institution	<ul style="list-style-type: none"> <li>• Conflicting legal and ethical standards</li> </ul>
Stem cell clinical trials	<ul style="list-style-type: none"> <li>• Risks and benefits of experimental intervention</li> <li>• Informed consent</li> </ul>