

International Trends in Bioethics for Embryonic Stem Cell Research

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Embryonic stem cell (ESC) has been recognized as one of the most promising therapeutic tools for the next decade. However, there are many controversial issues in bioethics for this challenging research area. Each country has its own distinct regulations and policies for ESC research due to their differences in cultural background, religious belief and political influence. These differences will eventually play an important role on international ESC research collaboration. The present article will provide a concise summary of the different policies and regulations regarding bioethical points for ESC research worldwide and show current progress towards establishing standard bioethical guidelines for ESC research on the international level.

Keywords: Bioethics, Ethics, Stem cell, International, Guideline

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Embryonic stem cell (ESC) has obtained great attention for its unlimited self-renewal potential and its ability to remain in an undifferentiated state until required and then to differentiate into any type of cell. With these exceptional characteristics, ESC has been proposed as a key element for cell and tissue therapy known as "Regenerative Medicine"⁽¹⁻³⁾. However, there are a lot of ethical controversies for ESC research. Currently, the standard ESC line derivation protocol is to retrieve cells from an inner cell mass of blastocyst. Therefore, to establish new ESC line, blastocysts may have to be destroyed⁽⁴⁾. So, there is a challenging question on when life begins. There are different answers from one country to another based on differences in religious beliefs and cultural background. Furthermore, politics also has an important effect on ESC research policies and regulations in each country⁽⁵⁻⁷⁾.

Current trends in bioethical policies and regulations for embryonic stem cell research

There are different policies and regulations

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for ESC research worldwide. Nevertheless, these can be grouped into three categories^(5,6,8):

1. All types of research in ESC are prohibited: Austria, Cyprus, Costa Rica, Italy, Ireland, Lithuania, Norway and Poland.
2. The creation of embryos for the purpose of ESC research is permitted. However, it has to be demonstrated that the research cannot be accomplished with other types of stem cells (ESCs from surplus in vitro fertilization (IVF) embryos or adult stem cells): Belgium, Japan, Singapore, South Korea, Sweden, the United Kingdom, and several states in the United States (e.g. Massachusetts, California and New Jersey).
3. In most countries, ESC research is allowed only in surplus embryos from IVF services or imported ESC lines.

Common principles and procedures in embryonic stem cell research worldwide

Currently there are common accepted and adopted principles for ESC research in most countries worldwide. These fundamental principles are^(5,6,8,9).

1. Respect for human dignity
2. Respect for life (limiting growth of blastocyst to 14 days when a primitive streak is formed)

3. Autonomy (informed consent from embryo donors)
4. Donor and recipient (patient) privacy and confidentiality
5. Non-commercialization (prohibiting both buying and selling human embryos for both research and clinical purposes)
6. Limitation to research for therapeutic purposes (no reproductive cloning that aims at creating new human beings)
7. Ethics review before commencement of the research (ethical approval from the ethic committee or the Institutional Review Board (IRB))
8. Traceability of cell lines used in both research and clinical practice for safety and quality assurance.

In some countries, there are additional regulations on ESC research to enhance safety, effectiveness and ethical standards. Licenses are required to ensure the competence of personnel. Importation or exportation of ESC lines is limited to the countries that have ethical standards, which fulfill the criteria required by the host country. For ESC line importation, allowance on performing research on imported cell lines is the most important requirement. Monitoring of ongoing stem cell lines research is also proposed for quality and safety of ESC lines distributed from the ESC bank⁽⁵⁻¹³⁾.

International bioethical guideline on embryonic stem cell research

The stem cell research fraud in South Korea has emphasized the importance of having international bioethical guidelines for ESC research⁽¹⁴⁾. It has been shown that both economic and political influences have great effects on the research society. Validation of study results should be carried out at an international level. An informed consent should be made clear and understandable. A system to evaluate and monitor the transparency of all steps and procedures in ESC research has been proposed. This will provide great benefits to both researchers and donors^(9-13,15).

Currently, there are at least two international organizations that would like to promote an international collaboration in ESC research among countries and promote the establishment of international bioethical guidelines on ESC research^(5,16). The International Society for Stem Cell Research (ISSCR) will hold thorough discussions its fourth annual meeting in Toronto (June-July 2006) to find an initial conclusion

for international bioethical guidelines. The International Stem Cell Forum (ISCF) has an Ethics Working Party (EWP). The EWP was founded with 19 participants from 17 countries (Australia, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Italy, Israel, Japan, Netherlands, Singapore, Switzerland, Sweden, United States, and the United Kingdom). Their role is to clarify controversial ethical issues, harmonize ethical standards, promote sharing of stem cell lines, and make agreements on standards for the characterization and registration of ESC lines⁽⁵⁾.

Conclusion

Embryonic stem cell research is a very dynamic research area. It involves scientific, economic, political and cultural issues for the whole society. To obtain the most benefits with the least negative impacts from this invaluable, but controversial research area, standard, international bioethical guidelines should be established. Although it is quite difficult to establish perfect guidelines, at least the establishment of a standardization guidelines would be a positive step in the right direction, especially in promoting scientific progress.

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แนวโน้มชีวจริยธรรมการวิจัยเซลล์ต้นกำเนิดตัวอ่อนระดับนานาชาติ

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เซลล์ต้นกำเนิดตัวอ่อนได้รับความคาดหวังว่าจะเป็นเครื่องมือสำคัญในการรักษาโรคในทศวรรษหน้า อย่างไรก็ตามก็ยังคงมีประเด็นทางชีวจริยธรรมที่มีความกำกวมจำนวนมาก สำหรับการศึกษาวิจัยในสาขาที่มีศักยภาพสูง และท้าทายนี้ ทั้งนี้พบว่าแต่ละประเทศต่างมีกฎระเบียบ ข้อบังคับ และแนวนโยบายด้านเซลล์ต้นกำเนิดตัวอ่อนที่แตกต่างกันไป ตามพื้นฐานทางวัฒนธรรม ความเชื่อทางศาสนา และอิทธิพลของการเมืองการปกครอง ความแตกต่างดังกล่าวนี้จะส่งผลกระทบต่อความร่วมมือด้านการวิจัยเซลล์ต้นกำเนิดตัวอ่อนระหว่างประเทศทั้งในปัจจุบันและในอนาคต บทความนี้นำเสนอถึงบทสรุปโดยย่อของแนวทางและความแตกต่างทางชีวจริยธรรมของประเทศต่าง ๆ ทั่วโลก และกล่าวถึงความก้าวหน้าของการพัฒนาสร้างแนวทางมาตรฐานด้านชีวจริยธรรมในการวิจัยเซลล์ต้นกำเนิดตัวอ่อนในระดับนานาชาติ