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Research: Embryo

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Abstract

Embryo research generates therapies for reproductive and nonreproductive conditions. It often involves embryonic stem cells (ESCs) obtained through the destruction of embryos. Ethical and regulatory questions about the acceptability of destroying embryos center on whether and when embryos become morally significant. Many regulatory frameworks hold that human embryos have some level of moral significance but are not morally equivalent to persons and that it is preferable to use excess embryos for research than to discard them. These permit embryo research with restrictions, typically limiting it to using excess embryos that are no longer clinically needed. Ethical concerns also arise about using the word "discard" as a euphemism for "destroy"; the adequacy of disclosure during informed consent; societal influences that impede voluntariness; and possible commodification of ova, embryos, and women. This entry explores these issues for human embryo and ESC research and highlights the roles of governments, associations, institutions, and RECs in promoting research integrity and adherence to human subject protections, without which clinical advances in research would be impossible. It does not discuss the many ethical concerns regarding nonhuman embryo research or human manipulations to determine sex or enhance traits.

Keywords

Embryo research; Stem cells; Moral significance; Women; Policy; Research integrity; Responsible conduct of research; Human subject protections

Introduction

Research on human embryos and embryonic stem cells (ESCs) contributes to the development of clinical therapies for a range of medical conditions. Much of it involves manipulations of ESCs obtained from human embryos. Technically, an embryo can develop normally for several days after a single ESC is removed for research, but embryos are usually destroyed to obtain ESCs. Whether it is acceptable to destroy embryos in order to conduct such research raises ethical and regulatory questions centered on whether and when embryos have moral significance.

If human embryos have the same moral significance as a person from the time they are conceived, then their destruction at any time is unacceptable. If they are not morally equivalent to persons, then they may still have some level of moral significance and be worthy of respect and protection derived from their humanness or potential human life. This perspective suggests that embryo research may be acceptable under some conditions, and grounds many regulatory frameworks.

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Regulatory frameworks typically permit embryo research but restrict it to using excess embryos that were produced through assisted reproductive technology (ART), frozen and stored within 14 days of conception (before the rudimentary nervous system appears), and would otherwise be discarded. The justification is that it is preferable to use excess embryos for research aimed at generating therapeutic benefits for others than to discard embryos. The word "discard" is widely used in ART but masks the reality that embryos are destroyed. This sidelines controversy about their moral significance and ensuing rights, if any, and encourages their donation for research or clinical purposes.

Embryo research also raises other ethical questions. What responsibilities do parents, physicians, and researchers have regarding recently acquired capacities to determine sex, select against some genetically based conditions, or select for genes that may enhance the physical or mental abilities of embryos and the persons they become? How does women's status in different societies affect their vulnerability or influence their willingness to donate ova or embryos? Women's status, and the possible commodification of ova and embryos, raise unique concerns because they involve ART and the extraction of ova "in multiple and unnatural quantities, through laborious and risky procedures. . . . women labour to produce extracted ova, in the purposeful manner which characterises the sort of labour which grounds property rights" (Dickenson 2006, p. 8).

Additional ethical questions involve what information is disclosed to donors during informed consent, whether it is acceptable to pay donors for ova or embryos, whether standard practices in ART and embryo research adequately protect the interests of donors, and the justice implications of having different regulations for embryo research in different nations. This entry examines some of these issues with respect to human embryo research, inclusive of ESC research. It does not address equally complex questions regarding (a) nonhuman animals, embryos, ESCs, or xenographic research aimed at developing therapeutic benefits; (b) the recently developed capacity to replace diseased mitochondrial DNA in otherwise healthy ova with healthy mitochondrial DNA from donor ova (which raises questions about parenthood, and safety and efficacy studies in embryos); or (c) scientific opposition in 2015 to efforts to genetically manipulate human germ cells in ways that alter the DNA of an entire embryo.

Stem Cell and Embryo Research

Types of Stem Cells

Enthusiasm for embryo research is based on the capacity of ESCs to divide and differentiate into different types of cells and tissues such as nerve and cardiac muscle cells. Some types of adult cells can also be extracted, cultured, manipulated into stem cells, and further manipulated to differentiate into an adult cell type. In contrast to ESCs, adult stem cells are more difficult to culture and can differentiate into a smaller range of cell types, so they have less potential than ESCs in research. They are advantageous, however, in that they can be obtained without destroying embryos, and autologous adult stem cells are less likely to induce rejection after injection or transplantation.

Today, for example, adult stem cell research has enabled physicians to remove, culture, and manipulate bone marrow cells derived from patients who have had an acute myocardial infarction and inject them into that patient's own cardiac muscle to improve heart function (Clifford et al. 2012). Ethical concerns about adult stem cell research including that which made this therapy possible center on protecting human subjects. Those regarding embryo and ESC research are perhaps more complex because they include philosophical dilemmas regarding the moral significance of embryos, and controversial questions about women's status and reproductive rights.

While the ability to extract adult stem cells, and direct the cell types they differentiate into, has made possible new therapies for patients with cardiac, diabetes, and neurodegenerative conditions including

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Alzheimer's and multiple sclerosis, ESC research offers promise for a wider range of diseases. Alternatives to adult stem cells and ESCs have developed through biotechnological advances. These include somatic-cell nuclear transfer (SCNT) and induced pluripotent stem cells (iPSCs).

SCNT creates stem cells from ova by replacing the nucleus of ovum with a nucleus from an adult somatic cell and then artificially stimulating the ovum to divide. iPSCs are cultured from adult somatic cells, typically from the skin, and genetically manipulated to express stem cell markers common to ESCs. The first human iPSCs were reported in 2007, but iPSC research has made little progress since some subsequent iPSC studies were revealed as fraudulent (Jones 2014). Meanwhile, stem cell research of all types continues.

Types of Embryo Research

In addition to different sources and types of cells, different goals and types of embryo research bear on what ethical concerns they raise. Some embryo research is conducted for reproductive purposes such as understanding infertility and its epidemiology; improving safety and efficacy of ART; improving perinatal technology, surgery, and outcomes; and improving capabilities and safety of genetic and other screening and diagnostic tests conducted on embryos. Such research may involve the use of retrospective data, in vitro interventions, placebo or sham controls, invasive or noninvasive imaging procedures, and the testing of innovations by clinical practitioners. Potential harms involved in such studies only sometimes affect embryos, and may be balanced by the aim of improving reproductive and fetal medicine and perhaps benefiting patient participants. Embryo research becomes controversial when it seems less directly applicable to patient care or more directly linked to destruction of embryos.

Moral Significance

Twelve to fourteen hours after fertilization, the DNA from an ovum and sperm will have combined and duplicated. The fertilized ovum will then divide into two stem cells with identical DNA. These two stem cells each then replicate their DNA and divide, and so on. As the number of cells increases, the embryo grows. Each embryo is comprised entirely of identical stem cells until about 14 days after fertilization, when a rudimentary nervous system called the primitive streak appears.

These facts underlie a range of views about whether embryos are morally equivalent to persons; at what developmental stage they attain moral significance; whether and under what conditions it is acceptable to use them for research; and whether it is acceptable to create, store, discard, or destroy them. Dialogue about how societies should value embryos and the earliest stages of human life, however, centers on values rather than facts, and often appeals to the concept of personhood which is too ambiguous to be helpful (Warnock 1986). Nevertheless, religious and other dialogue about embryos often focuses on personhood and the similarly ambiguous concept of ensoulment (Warnock 1986; Gillon 2001).

A 2008 report from the Pew Research Center outlines the official views of 16 different faiths on stem cell research, including ESC research. Some have no official position, others oppose or support it, and still others are permissive with various restrictions. These theological differences are compounded by differing national and individual beliefs about the moral significance and possible rights of embryos and the reproductive rights of women. Intentional mischaracterizations of both conservative and liberal positions on embryo research, ART, women's reproductive rights, and abortion demonstrate the political significance of these issues (Macklin 2006).

Not only are the many conflicting positions unlikely to be resolved in today's pluralistic and often politically polarized world (Holm 2002; Gillon 2001; Warnock 1986), but they are confounded by another issue. If embryos derive moral significance from their humanness and capacity to develop into a person,

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then all cells with humanness and capacity to develop into a person may have the same moral significance as embryos. This could extend to ova and sperm, adult stem cells, ESCs, SCNT, iPSCs, and even adult somatic cells such as skin and muscle. This possibility is altering views on iPSCs in Japan, which has been a leader in research on developmental biology and embryology (Sawai 2014).

Informed Consent and Commodification

In addition to the moral significance of embryos are ethical concerns about their commercialization and the adequacy of donor consent. While tentatively resolved in many jurisdictions by related regulatory frameworks and guidance (below), these concerns remain the focus of ongoing public and policy dialogue around the world. Internationally accepted standards of informed consent suggest that information disclosed to donors ought to address

(i) Conflicts of interest that stem from the probability of immense financial gain associated with the development, marketing, and widespread use of commercialized embryo-derived products and services
(ii) Long- and short-term burdens and risks of the process of procuring ova (Lo and Parham 2009; Dickenson 2006)
(iii) Whether and how donors may access products or services developed through the research
(iv) Harms arising from medical and reproductive tourism predicated on misunderstanding or misrepresentation of the safety or efficacy of the therapies or cell types involved (Einsiedel and Adamson 2012)

Growing concern about the harms of unproven ESC therapies led the International Society for Stem Cell Research (ISSCR) to, in its 2008 Guidelines for the Clinical Translation of Stem Cells, caution scientists, clinicians, and institutions against therapeutic uses of ESCs or their derivatives unless documented to be safe and effective, or as part of a clinical trial.

Informed Consent

The complexities of designing and implementing an informed consent process are compounded in embryo research by the need to ensure donor understanding of often unfamiliar scientific and ethical concepts. Among other things, guidelines for human subject protections (below) require that the informed consent process disclose in layperson language the research aims; what participating entails; how donated cells will be obtained, used, and destroyed; the absence of medical benefit to donors and embryos; how donors' personal information will be used and confidentiality protected; conditions under which donors may be contacted regarding future use or incidental genetic findings; sources of research funding; commercial benefits that may derive from the research; and likely recipients of commercial benefits. Additionally, this information should be conveyed with sensitivity to coercive influences on women that arise from socioeconomic and other conditions. Such influences may hinder women's understanding of harms and benefits to themselves and others, and increase their willingness to donate.

The American Society for Reproductive Medicine (ASRM) recommends disclosing this and other information including that cells will be taken from the inner cell mass of an embryo at the blastocyst stage and that this destroys the embryo; ESCs created through the research may be stored and used for an indefinite time period; ESCs may have commercial value in which donors will not share; what provisions will protect donor privacy and confidentiality; that ova and sperm donors must agree on the disposition of excess embryos before they can donate; that recipients of donated ova and sperm have the right to

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determine the disposition of resultant embryos; and what the research entails so that donors may refuse if it conflicts with their moral commitments (ASRM 2013).

Providing all this information entails translating and explaining complex concepts from embryology and research ethics in layperson language. The extent to which such information is disclosed to and understood by donor participants varies with regulatory requirements, institutional ethos and culture, researcher's skills and values, and donor's preexisting knowledge. This has practical implications for all aspects of informed consent and bears on the adequacy of disclosure, understanding, and voluntariness in all embryo research (and therapeutic ART as well).

Another consent issue is that human subject protections require disclosure to donors that they may withdraw from a study at any time without penalty or harm. In contrast, ASRM recommends that donors be informed that they may withdraw consent "at any time until the experiment begins" (ASRM 2013, p. 937.). This clause makes it impossible to withdraw at any time despite the likelihood that donors' moral commitments will change over time, sometimes in ways that affect their decision. For example, few donors will anticipate scientific advances such as mitochondrial DNA techniques that might alter their decision, and few will fully comprehend the implications to themselves or others of donating ova or embryos. Such implications tend to become clear, and gain or lose significance, as one's priorities and values evolve with time, experience, and societal influences, but many donors are relatively young.

A related concern is that embryo research discounts donors' interests by failing to recognize ova and embryos as property produced by women's labor (Dickenson 2006, p. 17). The power imbalance between donors and biotechnology companies, stem cell banks, etc., warrants greater attention, particularly because those with greater power do not explore or design consent mechanisms to ensure at least some rights of later refusal (Dickenson 2006, p. 16). The potential scale of commercial gains to be obtained through embryo research and ART are such that mechanisms for later refusal would not impede investment or development in embryo research (Dickenson 2006).

The ability to withdraw at any time is a cornerstone of all human subject protections. This counters any possibility that later withdrawal might disrupt research, clinical progress, careers, or investments in embryo research. It is deceptive to suggest that donors may withdraw at any time if they may not withdraw once their ova, embryos, or ESCs are in use. Because ASRM guidelines derive from ART physicians and industry with greater societal and economic influence than donors, and ASRM guidelines conflict with human subject protections regarding later withdrawal, possibilities for later refusal ought to be fully examined. While aimed at protecting the interests of donors and patients, ASRM guidelines also protect ASRM's interest in promoting ART. Efforts to permit later refusal, and minimize societal influences underlying it its denial, are needed.

Commodification

Conflicts of commitment and interest exist in all walks of life. Minimizing their harmful impacts requires recognition and transparency about them. Investigators, institutions, and sponsors of embryo research have interests in protecting the health interests of donors; developing science, technologies, products, and services that show promising therapeutic potential; and pursuing collaborations, job or institutional security, financial gain, etc. Such interests sometimes conflict in ways that lead to inappropriate compromises of one for the other.

This underlies concerns that potential commercial and institutional gains derived through embryo research will lead to undue inducements, coercive or exploitative means of procuring embryos, and commodification of women and embryos. The potential for commodification and commercialization involves property rights, patent and trade issues, human rights and dignity, and women's rights and societal status.

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Substantiating these concerns is a report from the Nuffield Council on Bioethics on egg and sperm donation urging the World Health Organization (WHO) to develop guidance protecting against their exploitation. Moreover, despite evidence of illicit trade in ova, and of socioeconomic and other imbalances that affect this trade, the ethical debate continues to center on embryos rather than women (Dickenson 2006). Unlike sperm, the sale of ova can be as exploitative as selling kidneys because ova are finite in number and their extraction involves risks associated with hormonally shutting down the ovaries, hyperstimulating them, and surgically removing ova; and the long-term impacts of these interventions on fertility, menopause, bone density, etc. are not known (Dickenson 2006).

Socioeconomic Influences on Donor Consent

The procurement of embryos or ova requires donor consent, and donors biologically are women. Human subject protections have historically categorized women as vulnerable and needing special protections in research. While this is changing, women are still excluded from much medical research except that involving fertility, fetal medicine, or maternal and child health. Accordingly, countless medications and procedures are untested for safety and efficacy in women despite harms arising from gender differences in average body mass indices and physiological and hormonal processes (Guidry-Grimes and Victor 2012; Office of Research on Women's Health 2010).

The USA's National Institutes of Health (NIH) recently implemented policies to increase the inclusion of women in clinical research and increase research on health-related gender differences (ORWH 2010). Embryos, embryo research, and reproductive issues are largely absent from the strategic plan for 2020 of its Office of Research on Women's Health (ORWH); however, this has a related objective to "explore sex differences in the structure and function of male and female cells (including stem cells), tissues, organs, and physiological systems" (ORWH 2010, p. 18).

Women's status and rights are thus central to the ethics of embryo research, and are influenced by socioeconomic, cultural, religious, political, environmental, and other forces. There is widespread understanding that such forces impact women's health and that of their families and communities. There is disagreement, however, about related ethical and regulatory issues such as

(i) Whether women or embryos constitute vulnerable groups
(ii) What special protections, if any, are warranted for ova and embryo donors
(iii) Whether disclosure is adequate, and coercive influences minimized, when seeking informed consent from donors
(iv) What health, economic, or other measures during and after pregnancy ought to be provided, and by whom, to protect healthy fetal and early child development and maternal health for donors, and women in general
(v) Whether women are legally or ethically entitled to give consent on behalf of themselves or their embryos
(vi) What rights women have over their ova, embryos, and reproductive tissues, for example, rights to possess, use, manage, donate, bequest, sell, derive income from their use or capital value; security against theft; refrain from harming; or be liable for harms they bring to others (Dickenson 2006)

Human Subject Protections for Ova and Embyro Donors

Embryo research, like any research using donated cells or tissues, is subject to international, national, and institutional guidelines for the protection of human subjects. Such guidelines were first promulgated after the Nuremberg trials exposed Nazi atrocities conducted in the guise of medical research during World War II.

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Formulated in 1947, the Nuremberg Code is the backbone of a multinational effort to prevent such atrocities. It states that the voluntary informed consent of human subjects is absolutely essential. This underlies all human subject protections. As discussed above, ASRM guidelines for embryo research poses a challenge to this.

After Nuremberg, the World Medical Association (WMA) and Council for International Organizations of Medical Sciences (CIOMS) also produced guidelines. WMA's Declaration of Helsinki (DOH) was ratified in 1964 by over 100 member nations. CIOMS guidelines, produced in 1982 and finalized in 2002, include commentary clarifying their intent. Ongoing deliberation and revision of both guidelines is prompted by scientific developments and growing sensitivity to coercive influences in low- and middle-income host nations.

Most guidelines define women and children as vulnerable and needing special protection. Few address any specific type of research, like embryo research, but CIOMS specifies that pregnant women should be eligible to participate in research relevant to their health and the health of their fetuses. WHO guidelines address the structure and function of research ethics committees (RECs) which provide ethics review of research protocols involving human subjects. These are also known by similar names and as institutional review boards (IRBs).

Guidelines in the USA were produced in the 1970s, after mainstream news media reports about the now infamous Tuskegee study. Begun in the 1930s, it examined the natural history of syphilis in a population of socioeconomically disadvantaged African American men. It used deception to obtain consent for unnecessary spinal taps (which then carried high risks and burdens) and, after penicillin was discovered in the 1940s, systematically withheld it from participants even for conditions other than syphilis.

Exposure of the study prompted Congress to establish the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Charged, among other things, with developing guidelines to protect human subjects of research, its findings were released in 1979 as the Belmont Report, which became the basis of legal protections in the USA, and defined the now globally recognized principles of autonomy, utility, and justice.

Repeated violations of all such guidelines occur and are met with ongoing efforts to expand appreciation for, and compliance with, them. Underlying all such guidelines are seven ethical requirements. The research must (i) be able to produce potentially valuable outcomes for medicine or society; (ii) use methods capable of answering the research question of interest; (iii) be fair in its inclusion criteria, recruitment, and enrollment; (iv) adapt its design to minimize harm and maximize benefit to subjects; (v) receive REC review and approval before beginning; (vi) disclose relevant information about the study to prospective participants and obtain their informed consent before enrolling them; and (vii) uphold respect for individuals and populations being studied (Emanuel et al 2000).

Research integrity (RI) helps to meet these requirements and ensure that research is conducted and reported accurately. RI grounds the development of safe and effective therapies, public trust and funding, and ethical guidance from research bodies including the European Science Foundation, Canada's National Research Council, and the USA's National Academies, Office for Human Research Protections (OHRP), and Office of Research Integrity (ORI). The extent to which RI is nurtured and valued differs with institutions and bears on how thoroughly researchers and sponsors embrace human subject protections; their honesty in conducting and reporting research; and their transparency about potential conflicts of interest and commitment.

Embryo research is subject to this, and more specialist, guidance, such as that from the Nuffield Council on Bioethics, International Society for Stem Cell Research (ISSCR), Indian Council of Medical Research, American Congress of Obstetricians and Gynecologists, ASRM, and the Code of Practice for the Use of Human Stem Cell Lines from Britain's Medical Research Council. These bodies hold that embryos are worthy of special respect but not equivalent to persons. Most recommend that embryo research be

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conducted only under certain conditions: embryos should not be bought, sold, or allowed to develop longer than 14 days after fertilization, and only the smallest possible number of embryos should be used.

In addition to REC approval, some guidance requires review from an additional committee. The USA has local embryonic stem cell research oversight committees (ESCROCs) comprised of scientists, physicians, ethicists, legal experts, and community members. ESCROCs review issues ranging from reimbursements to consent. They suggest that disclosure should address the issues mentioned above and that ESCs may be genetically altered, combined with nonhuman cells, transplanted, stored, and used for decades and describe under what conditions donor identity may be ascertainable by others.

Regulatory Frameworks

Human subject protections are legally binding when officially adopted into regulatory documents and laws. Differences in whether and how nations adopt them reflect their different circumstances, values, and priorities. Many governmental, intergovernmental, and nongovernmental websites provide access to regulations and laws regarding embryo research. EuroStemCell, for example, aims to enhance public engagement about stem cell research within the European Union (EU). It offers links to regulatory policies for each of the EU's 25 member states. These nations take diverse stands. Some, including Germany and Italy, ban embryo research except with existing ESCs. Switzerland permits embryo research up to 7 days post fertilization, while Finland, Sweden, and the UK permit it until 14 days post fertilization.

Embryo research in the UK is regulated by its Human Fertilisation and Embryology Authority (HFEA), which provides a comprehensive Code of Practice and other information regarding embryo research and ART. Similarly, guidelines from Canada's Institutes of Health Research were incorporated into Canada's 2004 Assisted Human Reproduction Act, and are available from Health Canada. In the USA, the OHRP publishes information on regulatory frameworks for human subject protections around the world including those specific to embryo research. It provides links to related documents from the USA and over 107 nations on all continents. Japan, mentioned earlier, has more such documents than most nations (OHRP 2014).

Conclusion

Embryo research contributes significantly to advances in clinical medicine and science. These advances are contingent on the RI of investigators, institutions, and sponsors in designing, conducting, and reporting research. Governments, institutions, and RECs have important roles in promoting RI and adherence to human subject protections. Ova and embryo donors are protected by the guidelines above, and others. As women, however, their autonomy and reproductive rights vary with national and societal circumstances.

Ethical concerns about embryo research are tentatively resolved in some jurisdictions by regulatory frameworks, but violations and related deliberation continue. Concerns include the possible commodification of ESCs, embryos, and women; adequacy of informed consent with respect to what information is disclosed to donors, the extent to which donors assimilate disclosed information, and whether donors should have opportunity for later refusal; whether and when embryos attain moral significance; and whether it is acceptable to destroy embryos or conduct embryo research. Disagreements about these issues are likely to continue, as new technologies and understandings arise.

Cross-References

- ▶ Commodification
- ▶ Donation: Embryo
- ▶ Research: Human Subjects
- ▶ Stem Cells: Adult
- ▶ Stem Cells: Embryonic

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Further Readings

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