Embryo Research

Françoise Baylis

In humans, the term "embryo" technically applies after implantation of the organism is complete (approximately 14 days after fertilization) until eight weeks of development, at which time the developing organism is referred to as a fetus. Prior to implantation, the scientific terms for the product of conception at different developmental stages are zygote, morula, and blastocyst. In common usage, however, the term "human embryo" refers to the human organism from the time of conception through to eight weeks' gestational age, and that is how the term is used below.

Most human embryo research involves *ex utero* embryos created by *in vitro* fertilization (*see* REPRODUCTIVE TECHNOLOGY). Most of this research also involves the destruction of human embryos either as part of the research process or as a result of rules prohibiting embryo transfer. For this reason alone, many object to human embryo research. Others, however, promote the scientific and therapeutic benefits of human embryo research as reason enough to proceed. There is, for example, basic research to increase knowledge about human development, the development of cancer cells, the causes of congenital diseases, and the causes of miscarriages. As well, there is applied medical research to develop new and improved contraceptive techniques, abortifacients, pre-implantation genetic diagnostic tests, infertility treatments, gene therapies, and cell-based treatments of serious disease.

Countries that explicitly permit human embryo research generally limit the research to 14 days after fertilization. The 14-day limit was recommended by the Ethics Advisory Board of the United States Department of Health, Education, and Welfare in its 1979 Report: "No embryos will be sustained *in vitro* beyond the stage normally associated with the completion of implantation (14 days after fertilization)" (Ethics Advisory Board 1979: 107). The proponents of this limit on human embryo research argued that individuality was a determinant of moral status, and that individuality could only be established once implantation was complete and neither twinning nor recombination was possible. Up to 14 days post-fertilization, two genetically identical individuals (i.e., monozygotic twins) could be created by a process of twinning and two different embryos could recombine to create a human chimera.

In 1984 the Warnock Committee in the United Kingdom also recommended a 14-day limit on human embryo research. For the Warnock Committee, the human embryo acquired moral standing sufficient to warrant its protection from invasive and destructive research with the appearance of the primitive streak (15 days after fertilization). The primitive streak eventually develops into the embryonic neural system. For reasons of caution, the Warnock Committee advocated a 14-day limit on human embryo research.

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In the recent past, human embryo research has resulted in important scientific and clinical breakthroughs. In turn, these breakthroughs have ignited (or fueled) significant public debate about the ethics of research involving human embryos. In 1978 there was the birth of the world's first "test tube" baby following *in vitro* fertilization (IVF) and embryo transfer (Edwards 1986). In 1990 there was the introduction of pre-implantation genetic diagnosis (PGD), a technique involving embryo biopsy of one or two cells at the eight-cell stage to diagnose a range of chromosomal and single-gene defects (Handyside et al. 1990). In 1998 there was the first successful derivation of human embryonic stem cells (HESC) (Thomson et al. 1998). And in 2011 scientists succeeded in using a cloning technique known as somatic cell nuclear transfer (SCNT) to reprogram human somatic cells, from which they were then able to derive stem cell lines (Noggle et al. 2011).

The first of these areas of research (i.e., IVF) spurred lively public debate about the ethics of research involving human embryos with a particular focus on the moral status of the developing human. This debate mirrored the ethics debate on abortion where it was assumed that the human embryo (and later fetus) must qualify as a "human" or "person" to warrant protection from invasive and destructive research (*see* ABORTION; FETUSES; MORAL STATUS; PERSONHOOD, CRITERIA OF; POTENTIAL PERSONS). The second area of research (i.e., PGD) galvanized disability rights activists who were interested in placing disability within a social context that highlighted the ethical consequences of disability-preventing strategies (*see* DISABILITIES, PEOPLE WITH). The introduction of this technology heightened the ethics debate about genetic discrimination, slippery slopes, and designer babies. Many anticipated that PGD would be used not only to identify embryos with serious disabling traits, but also to "select against" embryos with minor unwanted traits and to "select for" embryos with desired traits (including sex). The third and fourth areas of research (i.e., HESC and SCNT) reinvigorated the moral status debate and also expanded the debate about the ethical requirements for human embryo research (*see* STEM CELL RESEARCH). HESC research also sparked international debate about the ethics of cloning for biomedical research, as contrasted with cloning to produce children. In particular, the proponents of personalized medicine insisted that while it might be appropriate to ban cloning to reproduce, it was wrong to prohibit the creation of cloned embryos from which to derive patient-specific stem cell lines for drug screening or for autologous transplantation (*see* CLONING).

To this day, many opponents and proponents of human embryo research focus the ethics debate on the moral status of the intended research subject. "Is the human embryo truly human?" ask some authors. "Is it a person?" question others. "Does it have a right to life, or is it merely due respect?" "Can it be destroyed with impunity, or is its destruction intrinsically wrong?" In response to these sorts of questions, commentators on the ethical acceptability of human embryo research commonly pursue a similar course. They outline their understanding of the relevant moral concept(s), answer the corresponding status question, and then detail the implications of their view for human embryo research. According to some, the human embryo has full moral status at conception when it receives its genetic code (Noonan

1970). At this stage, the human embryo is fully protectable human life and should not be used for research that will inevitably result in its destruction. At the other end of the spectrum are those who maintain that the early human embryo has no intrinsic value (and no right to life), and can be used for research – provided the persons whose gametes were used to create the embryo provide informed consent (Singer and Kuhse 1986). Between these extremes are those who insist that the developing embryo has limited moral status. In their view, the human embryo is to be treated as an entity of intrinsic value that is "entitled to profound respect, but this respect does not necessarily encompass the full legal and moral rights attributed to persons" (Ethics Advisory Board 1979: 101). From this perspective, research involving the early human embryo may be ethically permissible when the research is in pursuit of important therapeutic goals, when these goals cannot be achieved by less ethically controversial means, and when there is informed consent from the gamete providers (*see* INFORMED CONSENT).

Within this broad framework, there are several distinct strategies for determining which, if any, moral rights should be attributed to the human embryo, three of which are described below. The first strategy involves analogical reasoning. Moral status is determined by comparing the human embryo to an entity that resembles it. If the two are sufficiently similar, in most if not all morally relevant respects, then it is presumed that whatever status is usually attributed to the entity in question should also be attributed to the human embryo. Those who rely upon arguments from analogy to claim full protection for the human embryo usually compare the embryo to the full-fledged adult human (the paradigm example of a being with full moral status). Those who do not believe that the human embryo is similar to the adult human (and so does not merit similar treatment), have compared the human embryo to a lettuce, a cluster of cells, or a human corpse.

With the second strategy, the focus is on identifying one or more characteristics essential for personhood or humanhood. The human embryo's moral status is then determined by measuring the embryo against proposed definitions of either concept to see whether it qualifies as a being with a serious moral right to life. For example, if the definitive criterion of moral standing is developmental individuality (i.e., being the source of one individual) (McCormick 1991), the relevant moral demarcation line would be the appearance of the primitive streak after which time twinning and recombination are no longer possible. Beings of unknown or uncertain moral status can then be evaluated in relation to this demarcation line to determine what value, rights, and protection they are due. The underlying assumption is that entities on one side of the moral dividing line are, by definition, members of the moral community (whether labeled persons or humans), whereas those on the opposite side fail to qualify.

A serious problem with this strategy is the existence of multiple, conflicting definitions of personhood or humanhood, each of which lists different morally relevant features, and the absence of any mechanism for adjudicating between these definitions. It follows that no authoritative decision regarding the ethical acceptability of a proposed course of action can ever be reached. At one end of the

continuum are definitions of personhood or humanhood that exclude not only the human embryo or fetus, but also the young infant during the first months of life (Warren 1973; Tooley 1972). At the other extreme are arguments for attributing full moral status to the human embryo from the time of conception, or some slightly later time, onward (Ramsey 1975; Noonan 1970). In between these two extremes are the many arguments for attributing full moral status to the human organism at different developmental stages, including appearance of the primitive streak, gastrulation, organogenesis, sentience or the ability to feel pain and pleasure, quickening, viability, and birth.

A third strategy for determining moral status examines the moral relevance of potentiality. In this case, the potential of the human embryo is explored to determine if it is a being capable of achieving personhood or humanhood. On the basis of this potentiality, or lack thereof, moral rights are attributed or denied. Arguments based on the doctrine of strict potentiality hold that potential entities should be treated as if they were that which they could become. Accordingly, all human embryos should be attributed the same moral status as adult humans (paradigmatic persons) by virtue of their inherent capacity (i.e., potentiality) for becoming adult members of the species. One difficulty with the strict potentiality criterion is that it involves a logical error – that of deducing "actual rights from merely potential (but not yet actual) qualification for those rights" (Feinberg 1984: 145). The charge, in this instance, is that the potential for full moral standing does not logically ensure full moral status. As Singer and Kuhse suggest, "there is no general rule that a potential X has the rights of an X. To destroy an acorn is not the same as sawing down a fine old oak" (1986: 135).

As this brief survey of the relevant ethics literature suggests, the debate regarding the moral status of the human embryo remains unresolved. In an attempt to sidestep this interminable debate, some have argued from a utilitarian perspective that human embryo research should be permitted to realize the scientific benefits of increased knowledge, and to secure the therapeutic benefits of reproductive, genetic, and regenerative medicine. Following this reasoning, a number of jurisdictions have formally sanctioned human embryo research during the 20 years separating the introduction of IVF (1978) and the derivation of HESC (1998). This overt shift in policy has served to broaden the ethics debate to consider a range of additional issues including the nature and scope of embryo research, the acquisition of embryos for research, and the oversight of embryo research (*see* RESEARCH ETHICS). Also important are issues concerning the commodification of human life, human reproduction, and human reproductive tissues (*see* FEMINIST BIOETHICS); free and informed choice; species integrity (e.g., the creation of human–nonhuman chimeras and hybrids); university–industry R&D partnerships; commercialization and patenting; resource allocation; distributive, social, and global justice (e.g., equitable access to the benefits of research); genetic enhancement (*see* ENHANCEMENT, BIOMEDICAL); and new forms of eugenics (*see* EUGENICS).

Of particular importance among these ethical issues is the acquisition of human embryos for research. This includes issues concerning (1) the use of so-called "spare"

(or "excess," "surplus," or "supernumerary") embryos versus research embryos; (2) the use of fresh "spare" embryos versus frozen-thawed "spare" embryos; and (3) the use of donated embryos and gametes versus purchased embryos and gametes.

In the first instance, a moral distinction is drawn between "spare" embryos (i.e., embryos remaining after infertility treatment) and research embryos (i.e., embryos created solely for research use without there ever having been any intention of allowing embryonic development). Some defend the research use of "spare" embryos on the grounds that such embryos are in excess of clinical need, and are already fated to die when the woman for whom these embryos originally were created does not consent to embryo transfer or to embryo donation. These embryos "will die in any case" and so "no harm is done" in using them for research. In this view, "spare" embryos are a precious resource that should not be wasted if some benefit might come from their inevitable demise (Outka 2002). Others insist that "spare" and research embryos have the same moral status and that attempts to distinguish between them are both unnecessary and unjustified (Singer and Kuhse 1986). In practice, several jurisdictions currently permit research involving "spare" embryos, but expressly prohibit the creation of research embryos.

In jurisdictions that permit the research use of "spare" embryos but prohibit the creation of research embryos, there is controversy concerning the use of fresh versus frozen-thawed embryos. Some insist that the category "spare" embryo only includes fresh, poor-quality embryos that are not suitable for embryo transfer or freezing, and frozen (presumed "healthy") embryos no longer wanted for their original reproductive purpose. In this view, fresh embryos suitable for transfer that are not used in the initial IVF cycle should be frozen for potential future reproductive use, until such time as the woman's infertility needs are met or a decision is made to discontinue treatment. This option best satisfies patients' self-interests. It also minimizes the twin risks of exploitation and coercion (McLeod and Baylis 2007). As well, restricting embryo research to frozen-thawed "spare" embryos stops the creation of research embryos under the guise of creating embryos for reproductive purposes. Others insist that women should be free to decide which embryos are spare, irrespective of whether these embryos are fresh or frozen, or whether their reproductive project is complete.

Next, there is the issue of payment (including exchange for property or services) for both gametes (to create research embryos) and embryos. In those jurisdictions where the sale or trade of gametes and embryos is permitted, scientists target fertility patients who could not afford IVF treatment without exchanging their eggs or embryos for discounted treatment, fertility patients who have discontinued treatment and have "spare" frozen embryos, and healthy volunteers who are willing to undergo ovarian hyperstimulation and egg retrieval to provide eggs to create research embryos. Arguments against these practices typically focus on the commodification of reproductive labor or tissues, and the voluntariness of those who sell or trade their gametes or embryos. Of particular concern are the potential harms of undue inducement and exploitation of economically disadvantaged women who are asked to provide their eggs or embryos for research (Baylis and McLeod 2007). Others, including the International Society for Stem Cell Research, insist that women should

be paid a fair wage for their reproductive labor or tissues and that, as concerns payment for eggs, it would be exploitative of women to expect them to accept the harms of ovarian hyperstimulation and egg retrieval without fair compensation.

Another issue of particular importance is the oversight of human embryo research. Among the proponents of this research are many who advocate clear research limits (entrenched in guidelines, regulations, or laws) to prevent any kind of slide down the slippery slope of exploitation and abuse. At minimum, there should be proper research ethics review of human embryo research, as with all research involving human subjects. As well, for some embryo research, specifically HESC research, additional regional or national research ethics review may be required. The ethics review should scrutinize the research objectives (with particular attention to limits on the type of research that may be pursued), the source of the embryos (with particular attention to any limits on the creation of research embryos), and the quality of the informed consent (with particular attention to voluntariness).

As this brief sampling of ethical issues suggests, the ethics of human embryo research is highly complex. Many believe that notwithstanding the potential scientific and therapeutic benefits of embryo research, such research is ethically objectionable and should be prohibited. In a global context, however, such research is moving forward at an incredibly fast pace in dogged pursuit of what some might disparagingly describe as the elixir of life. The current high demand for human embryos for research is undeniably driven by the promise of effective cell-based therapies to cure disease and disability. This demand may lessen with further research on induced pluripotent stem cells and SCNT, but for now the ethics of embryo research remains one of the more contentious contemporary issues in applied ethics.

***See also*:** ABORTION; CLONING; DISABILITIES, PEOPLE WITH; ENHANCEMENT, BIOMEDICAL; EUGENICS; FEMINIST BIOETHICS; FETUSES; INFORMED CONSENT; MORAL STATUS; PERSONHOOD, CRITERIA OF; POTENTIAL PERSONS; REPRODUCTIVE TECHNOLOGY; RESEARCH ETHICS; STEM CELL RESEARCH

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