

#### ***4.2.5 Storage & Use of Human Embryos***

Embryos created during cycles of in vitro fertilization (IVF) that are not intended for immediate transfer are often frozen for future use. The primary goal is to minimize risk and burden by minimizing the number of cycles of ovarian stimulation and egg retrieval that an IVF patient undergoes.

While embryos are usually frozen with the expectation that they will be used for reproductive purposes by the prospective parent(s) for whom they were created, frozen embryos may also offer hope to other prospective parent(s) who would otherwise not be able to have a child. Frozen embryos also offer the prospect of advancing scientific knowledge when made available for research purposes. In all of these possible scenarios, ethical concerns arise regarding who has authority to make decisions about stored embryos and what kinds of choices they may ethically make. Decision-making authority with respect to stored embryos varies depending on the relationships between the prospective rearing parent(s) and any individual(s) who may provide gametes. At stake are individuals' interests in procreating.

When gametes are provided by the prospective rearing parent(s) or a known donor, physicians who provide clinical services that include creation and storage of embryos have an ethical responsibility to proactively discuss with the parties whether, when, and under what circumstances stored embryos may be:

- (a) Used by a surviving party for purposes of reproduction in the event of the death of a partner or gamete donor.
- (b) Made available to other patients for purposes of reproduction.
- (c) Made available to investigators for research purposes, in keeping with ethics guidance and on the understanding that embryo(s) used for research will not subsequently be used for reproduction.
- (d) Allowed to thaw and deteriorate.
- (e) Otherwise disposed of.

Under no circumstances should physicians participate in the sale of stored embryos.

***AMA Principles of Medical Ethics: I,III,IV,V***

*Background report(s):*

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

Board of Trustees Report 00-I-89 Frozen pre-embryos

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*When gametes are provided by the prospective rearing parent(s) or a known donor, physicians who provide clinical services that include creation and storage of embryos have an ethical responsibility to proactively discuss with the parties whether, when, and under what circumstances stored embryos may be: [new guidance clarifies context of guidance]*

- (a) Used by a surviving party for purposes of reproduction in the event of the death of a partner or gamete donor.
- (b) Made available to other patients for purposes of reproduction.
- (c) Made available to investigators for research purposes, in keeping with ethics guidance and on the understanding that embryo(s) used for research will not subsequently be used for reproduction.
- (d) Allowed to thaw and deteriorate.
- (e) *Otherwise disposed of. [extends scope of guidance to address possible future situations]*

Under no circumstances should physicians participate in the sale of stored embryos.

***AMA Principles of Medical Ethics: I,III,IV,V***

## Frozen Pre-embryos

WHILE in vitro fertilization (IVF) has enabled many previously infertile couples to have children, it has also posed troubling legal and ethical dilemmas. This report, which was prepared by the Committee on Medicolegal Problems and the Council on Ethical and Judicial Affairs, will discuss the legal and ethical issues created by the freezing of human pre-embryos and will indicate how rights, if any, should be allocated among the two gamete providers, the frozen pre-embryos, and third parties. (Because fertilized eggs are frozen before the embryonic stage of development, they are referred to as pre-embryos.)

Two recent court cases illustrate several of the dilemmas that have arisen as a result of human pre-embryo freezing. In the Davis case, a divorcing couple contested authority over pre-embryos that had been frozen for later use. The Davis case began in 1988, when Junior and Mary Sue Davis entered an IVF program and had nine pre-embryos created from the union of Mr Davis' sperm and Ms Davis' ova. Two of the pre-embryos were transferred to Ms Davis' uterus (no child resulted), and seven were frozen at the Fertility Clinic of East Tennessee in Knoxville for later use (*New York Times*, August 8, 1989:A11). Subsequently, however, the Davises filed for divorce, and they disagreed about the disposition of their frozen pre-embryos. Ms Davis wanted to become a mother and therefore asked the court for permission to try to become pregnant with the pre-embryos. Mr Davis preferred to remain childless and therefore sought to prevent his former wife from being able to use the pre-embryos. The court, then, was faced with the question of who has decision-making authority when there is a disagreement between the man and woman who provided the pre-embryos' gametes (the sperm and ova). The court found that human life begins at conception and that Ms Davis should be given custody of the pre-embryos to try to become a mother with them (*New York Times*, September 22, 1989:A13). Mr Davis plans to appeal.

In the York case, the court was asked

to decide who has decision-making authority when the couple who provided the gametes agrees on the use of the pre-embryos but a third party challenges the decision. The Yorks entered an IVF program in Virginia while living in New York. In 1988, they moved to California and asked to have their frozen pre-embryos moved to a Los Angeles fertility clinic where they could continue their efforts to become parents. The Virginia clinic refused their request on the ground that the pre-embryos should be transferred to Ms York's uterus only at the Virginia clinic (*Time*, July 24, 1989:63). Before trial, the case was settled, with the clinic agreeing to release the pre-embryos to the Yorks (*Roanoke Times & World-News*, September 19, 1989:B3).

For the reasons described in the remainder of this report, the Board of Trustees recommends as follows:

1. Primary authority for frozen pre-embryos rests with the two gamete providers, and they must agree to any disposition of the pre-embryos.

2. Agreements by the gamete providers for the future disposition of their pre-embryos should generally be enforceable. However, either gamete provider should be able to show that changed circumstances make enforcement of the agreement unreasonable. The gamete providers should not be required to enter into an agreement that will govern the future disposition of their pre-embryos.

3. Frozen pre-embryos may be used by the gamete providers, donated for use by other parties, or donated for research. The frozen pre-embryos also may be allowed to thaw and deteriorate.

### MEDICAL BACKGROUND

The freezing (or cryopreservation) of pre-embryos has occurred because of several developments in IVF. First, "superovulation" techniques are now used to ensure that multiple ova can be collected at any one time. When IVF was introduced, collection of ova from the woman occurred during the natural monthly cycle. As a result, only one ovum could be obtained per collection. Moreover, because of the variation of the time of ovulation from month to month, it was difficult to predict when ovulation would occur.<sup>1</sup> Consequently, women are now given drugs that stimulate ovulation in a way that produces multiple ova for retrieval and makes the

time of ovulation more predictable.<sup>1</sup>

One of the common results of superovulation is the creation of more pre-embryos than are desirable for use at any one time. If more than two or three pre-embryos are implanted into the woman, the chances of a pregnancy with three or more fetuses is present, and such a pregnancy poses substantial risks to the health of the woman and her fetus.<sup>2</sup> Accordingly, when more than two or three pre-embryos result from a retrieval of ova, the extra pre-embryos are often frozen and saved for use at a later time.<sup>3</sup> Estimates suggest that the freezing of extra pre-embryos for later use could increase the likelihood of pregnancy by 8% to 12% for every ovum retrieval procedure.<sup>1</sup> Moreover, it is less invasive for the woman and less costly to use the frozen pre-embryos than to collect more ova for subsequent attempts to become pregnant.<sup>1</sup>

Preservation of pre-embryos for future use also occurs because, on occasion, the woman cannot receive the pre-embryos during the cycle in which they were collected but must wait at least another month for implantation.<sup>4</sup> In addition, women threatened with a loss of ovarian function from gynecologic dis-

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ease or the use of chemotherapy to treat a nongynecologic cancer may want to have ova collected and fertilized for future use.<sup>5</sup> A fertilized ovum survives freezing much better than does an unfertilized ovum.

## LEGAL CONSIDERATIONS

The central legal questions raised by cryopreservation of pre-embryos are as follows: (1) Who should exercise primary control over the pre-embryos? (2) What may be done with the pre-embryos?

### Decision-Making Authority

Whether frozen pre-embryos are considered to be persons, body parts, or something in between, this country's cultural and legal traditions indicate that the logical persons to exercise control over a frozen pre-embryo are the man and woman who provided the sperm and ovum.

First, the gamete providers have a fundamental interest at stake, their potential for procreation.<sup>6</sup> Indeed, the federal constitution, many state constitutions, and society in general recognize that individuals must be allowed to control the exercise of their reproductive capacities.<sup>7</sup> Consequently, individuals should be able to protect that interest in the absence of compelling reasons to override their choice. Even though the government may limit the individual's freedom of reproductive choice,<sup>8</sup> the government does not grant decision-making authority to private third parties but rather restricts the individual's ability to choose among potential courses of action.

From the perspective of the pre-embryo's interests, the gamete providers are also the logical decision makers. By way of analogy, parents have long been recognized as the proper decision makers for their children. It is they who are most concerned with their children's welfare and most willing to undergo sacrifices on behalf of their children. Accordingly, the law has deferred to parental choices on all aspects of their children's lives<sup>9</sup> as long as the child is not neglected or abused.<sup>10</sup> Similarly, the gamete providers are the persons who are most concerned with the interests of the pre-embryo and most likely to protect those interests.

The gamete providers are the logical decision makers also from the perspective of pre-embryos as body parts. Individuals have traditionally been accorded primary control over their body parts. While people may donate their organs, semen, or blood to others, they cannot be compelled to give them up.<sup>11</sup>

The conclusion that the providers of

the sperm and ovum should exercise primary control over a frozen pre-embryo means that couples like the Yorks have priority over the physicians who perform the IVF. Hence, the gamete providers would have the authority to decide when a frozen pre-embryo should be thawed for transfer and which woman would receive the pre-embryo. In addition, they would be able to change physicians and move their pre-embryos to other facilities for implantation.

On showing a sufficiently compelling interest, governments might impose certain limitations on the ability of individuals to move their pre-embryos from one facility to another. For example, the state may regulate the procedures for IVF and pre-embryo transfer. The state may require, if a frozen pre-embryo is to be thawed for transfer to the woman, that the thawing and transfer be performed by a licensed facility. Other potential limitations on the authority of the gamete providers will be discussed in below in the section "Extent of Decision-Making Authority."

In some cases, a couple may cede part of their control to their physician when they sign an agreement to undergo IVF. For example, they may decide that, if they become divorced, the physician should choose another couple to use their frozen pre-embryos. The advisability of such transfers of control and the extent to which they should be enforced are discussed in the section of this report on "Advance Agreements."

If one of the gamete providers dies while the pre-embryos are still frozen, the other provider should assume full decision-making authority. While the provider who has died may have wanted to designate a surrogate decision maker, no surrogate would have the same degree of interest as the surviving gamete provider. Family law provides a useful analogy here. When a parent dies, the surviving parent becomes the child's sole guardian.<sup>12</sup> In some cases, the surviving provider will die or both providers will die simultaneously. Just as parents may designate a guardian for their minor children in the event that both die,<sup>13</sup> gamete providers should be able to designate a recipient or guardian of their pre-embryos.

In the event that the gamete providers do not indicate their intent in advance, an appropriate presumption would be to assume that the couple would want the pre-embryos used by someone else. According to data at one clinic, more than 75% of gamete providers choose to have their pre-embryos donated to other couples in the event that the gamete providers cannot use them.<sup>2</sup> Consequently, the fertility clinic

should be able to make the pre-embryos available for use, with preference given to relatives of the couple, as long as the gamete providers are given notice of the policy by the clinic. With notice, the policy need not cause any unfairness to the gamete providers, since they could override the policy by an advance directive.

### Extent of Decision-Making Authority

The second important issue to be resolved with frozen pre-embryos is what decisions regarding their use are permissible. In addition to being used by the gamete providers or donated to others for use, the pre-embryos could be used for research or be allowed to thaw and deteriorate (in such a manner as to prevent their survival).

A consensus has developed that the gamete providers should be able to use the pre-embryos themselves or donate them to others. Some commentators question, however, whether the pre-embryos may be used by single people. Such a situation would arise, for example, if the gamete providers wished to donate their pre-embryos to a particular single woman or to make their pre-embryos available to an infertile woman, regardless of her marital status. Alternatively, the male gamete provider might die and the woman might still want to use the pre-embryos.

Some people have argued that it is not fair to the potential child to be raised by a single parent. There has been some evidence that children from single-parent households do not do as well academically as children from two-parent households.<sup>14,15</sup> However, this finding may reflect differences in income, education, and other socioeconomic factors between the single parents and the parental couples. Indeed, other studies do not find disparities in aptitude among children depending on the number of parents, and some research suggests that girls who have a single mother are more independent and more achievement oriented.<sup>14</sup>

Even if children generally benefit from being raised by two parents, it does not follow that single individuals should be denied parenthood. This country's constitutional tradition recognizes as fundamental the right to procreate and to raise children according to individual preferences.<sup>7,16-18</sup> This tradition rejects the view that government should try to produce "perfect" children by engaging in social engineering. In addition, a denial of parenthood to single individuals raises serious equal-protection concerns and would therefore not be appropriate.

Whether a couple may choose to allow

their frozen pre-embryos to thaw and deteriorate (in such a manner as to prevent their survival) is a question that turns on moral, religious, and philosophical views about personhood. This report takes no position on the question of when personhood status begins. Instead, the report will work within the existing body of law on abortion and will reach conclusions about the treatment of frozen pre-embryos based on that law.

If a woman may choose to abort her fetus, it arguably follows that she should be able to allow a frozen pre-embryo to thaw and deteriorate (in such a manner as to prevent its survival). The pre-embryo has a much smaller chance of becoming a child than a fetus. In addition, the "natural" course of a frozen pre-embryo is to deteriorate. Unlike a fetus, it will not become a child if left alone. On the other hand, a frozen pre-embryo does not intrude on the woman's bodily integrity.

As long as a woman can lawfully abort her fetus, however, it would be inconsistent and ineffectual to have a rule against the thawing and deterioration of a frozen pre-embryo. A couple that wanted to dispose of its pre-embryo could have it transferred to the woman's uterus. The woman could then immediately abort the pre-embryo.

In addition, it would be difficult to draft a rule aimed at preventing the deterioration of frozen pre-embryos. A couple intent on not having the pre-embryo develop into a child could donate the pre-embryo to a woman whom they knew to be incapable of becoming pregnant, or the couple could ask that the pre-embryo be transferred to the female partner's uterus during the time of her cycle when her uterus is not receptive to pregnancy.

It has been suggested that, if a couple does not use a frozen pre-embryo by a certain time, they be required to donate the pre-embryo to another couple. There are several problems with this proposal. Such a rule would treat couples who use IVF differently from couples who conceive naturally. The latter are not subject to the dictates of society in deciding when to have their children. In addition, an arbitrary time limit would prevent some couples from acting on a subsequent desire to use their pre-embryos to have a child. Finally, even if there would be no parental obligations after donation, the couple should have a right to decide not to have a genetically related child.

The Council on Ethical and Judicial Affairs has previously addressed the question of whether pre-embryos produced by IVF may be used for research.

The Council observed that research on pre-embryos in vitro plays an important role in providing society with a better understanding of how genetic defects arise and are transmitted and how they might be prevented or treated.<sup>19(p10)</sup> Consequently, the Council concluded that research on pre-embryos is permissible as long as the pre-embryos are not destined for transfer to a woman's uterus and as long as the research is conducted in accordance with the Council's guidelines on fetal research.<sup>19(p10)</sup>

### Disputes Between the Gamete Providers

In some cases, the providers of the gametes will be unable to agree on the use of their pre-embryos. For example, after a divorce, one may want to have a child with the pre-embryos while the other may want the pre-embryos thawed and discarded. Several considerations suggest that the man and woman should presumptively have an equal say in the use of their pre-embryos and that, therefore, the pre-embryos could not be used by either party without the consent of the other party. First, the man and woman both have contributed half of the pre-embryo's most important component, its genetic code. In addition, whether a person chooses to become a parent and assume all of the accompanying obligations is a particularly personal and fundamental decision. Even if the individual could be absolved of any parental responsibilities, he or she may feel strongly about not having offspring. The absence of a legal duty does not eliminate the moral duty many would feel toward any genetic offspring. Moreover, the far-reaching social implications of requiring individuals to have unwanted children counsels caution. In addition to concerns about the child's economic needs, psychological needs of these children are often left unsatisfied.

Accordingly, the choice not to have children should not be overridden by another person's desire to have offspring. A woman could not insist, for example, that she have access to the sperm of a man that had been frozen for his later use, without the man's permission. In addition, the gamete provider who wants to use the frozen pre-embryos can fulfill his or her desire to have children without frustrating the other gamete provider's desire not to have children. For example, the gamete provider could try IVF with a new partner or turn to adoption. While the gamete provider may not be willing to adopt one of the many children available for adoption (and the preference for genetically related children is understandable), the

desire for a genetically related child (or a particular kind of child) should not justify imposing parenthood on the other gamete provider. Under this analysis, then, the trial court in the Davis case inappropriately awarded custody of the pre-embryos to Ms Davis.

In some disputes, the issue will be whether the frozen pre-embryos should be donated to others, used for research, or allowed to thaw and deteriorate (in such a manner as to prevent their survival). In these cases as well, the pre-embryos should not be changed from their frozen state unless both gamete providers agree to the change.

Some commentators have suggested bases for giving one of the gamete providers priority in a dispute. It has been argued that the woman should have priority because she has undergone greater medical risks than the man during the IVF process. In effect, then, she has assumed certain burdens in reliance on the man's willingness to help her have a child. However, we generally do not force one person to waive his or her rights because of another person's reliance. A couple who relies on a pregnant woman's promise to let them adopt her child or a candidate who relies on a citizen's promise to vote for the candidate has no recourse if the promisor changes his or her mind.

Priority for the woman might be deduced by analogy to abortion law. Under current law, a woman's right to choose between abortion and childbirth cannot be overridden by the man who would be the child's father.<sup>20</sup> However, in that case the woman's bodily integrity is at stake, a concern not present when pre-embryos are stored in a freezer. Thus, it does not follow from principles of abortion law that the woman's desire to procreate with the pre-embryos should override the man's desire not to procreate.

There is a legitimate concern that neutral rules for the resolution of disputes between gamete providers would, as a practical matter, systematically disadvantage women. Since men have longer reproductive lives than women, for example, their ability to have genetically related offspring is not as likely to be stymied by a lack of access to their frozen pre-embryos. Legal and policy decision makers, therefore, must monitor the impact of the rules governing frozen pre-embryos and, where appropriate, modify the rules to prevent gender-based inequalities.

Another basis proposed for giving one of the gamete providers priority in a dispute is a theory of implied consent. It has been argued that, by virtue of their participation in IVF, the providers of

the sperm and ovum have consented to have a child. Consequently, if one wants to use a frozen pre-embryo to have a child and the other does not want to use the pre-embryo, the pre-embryo should be available to the person who wants the child. There are several problems with this theory of implied consent. First, it is not clear that the gamete providers consented to anything more than the creation of a pre-embryo that would become a child whose parenting they would share as a married couple. Specific consent to use the pre-embryo for any other purpose would therefore be required before such a use could be made of the pre-embryo. In addition, society has recognized that an individual's feelings about reproductive decisions may reasonably change with the passage of time. Thus, for example, under current law a woman cannot be bound by an agreement not to abort her fetus, nor can a surrogate mother be bound by her decision to turn her child over to the father of the child.<sup>21</sup> Similarly, a pregnant woman's agreement to give her child up for adoption can be revoked, at least until she actually delivers the child to the adoptive parents.<sup>22(pp92-93)</sup> Consequently, until the time for pre-embryo transfer, it would be inappropriate to assume that there is binding consent by either party to have the pre-embryo transferred to a woman's uterus.

### Advance Agreements

The inappropriateness of assuming binding consent suggests that disputes over the use of frozen pre-embryos cannot always be appropriately resolved by a prior general agreement, even a written one, between the gamete providers. The IVF guidelines of professional societies often recommend that the gamete providers specifically decide at the time of IVF about the disposition of their frozen pre-embryos in the event of divorce or other changes in circumstances.<sup>2</sup> The gamete providers might decide that, in the event of divorce, the woman should be able to use the pre-embryos or that the physician should choose another couple to use the pre-embryos. Advance agreements can help ensure that the gamete providers undergo IVF after a full contemplation of the consequences. In drafting their agreement, the gamete providers can be given careful and complete counseling regarding the implications of their endeavors, the potential uses of the pre-embryos, and the possibility that the passage of time will alter their circumstances and their feelings about their initial decision to become a parent through IVF. In general, therefore, these agreements should be enforced.

However, decisions about the disposition of pre-embryos can have such profound consequences that the law should include provisions for either gamete provider to be able to show that changed circumstances make enforcement of the agreement unreasonable. (A challenge to an agreement might arise in a dispute between the two gamete providers or between the gamete providers and the clinic.)

Although advance agreements can be useful, gamete providers should not be required to enter into advance agreements providing for the disposition of their future pre-embryos, because of the potential problems with advance agreements. Gamete providers may not be able to predict how they will feel about becoming parents at some later time. Advance agreements are also problematic because of the way they are usually developed. Ideally, advance agreements would be drafted by the gamete providers to reflect their particular concerns and preferences. However, the terms of advance agreements are generally decided by the operators of IVF programs on a standardized basis for all of their patients. Consequently, the agreements may reflect the values of the program operators rather than those of the gamete providers. The standard contract of a clinic in Cleveland, Ohio, for example, stipulates that, in the event of a divorce, the couple will permit the clinic either to destroy the pre-embryos or to donate the pre-embryos to an anonymous infertile couple (*Chicago Tribune*. September 28, 1989:1A25). Under the standard contract of a clinic in Detroit, Mich, on the other hand, the pre-embryos would go to the woman or, if she does not want them, to an infertile couple (*Chicago Tribune*. September 28, 1989:1A25). Couples undergoing IVF may try to revise their clinic's standard contract, but the clinic may have sufficient monopoly power that it can effectively offer its terms on a take-it-or-leave-it basis.<sup>23</sup> In addition, standard contracts are not designed to encourage individual approaches.

Advance agreements have been advocated on the ground that they would preclude the need for judicial intervention to resolve disputes that might arise regarding the use of frozen pre-embryos. However, a gamete provider who did not want to be bound by his or her prior agreement could challenge the agreement in court. Indeed, in a recent case, a woman asked the court to void her agreement to have her frozen pre-embryos destroyed in the event of divorce (*Chicago Tribune*. September 28, 1989:1A25). Similarly, written con-

tracts in surrogate mother arrangements have not prevented litigation, nor have they been upheld routinely by the courts.<sup>22(pp1-4)</sup>

There are ways to avoid costly and time-consuming lawsuits without requiring advance agreements. The Davis case arose not only because there was no advance agreement but also because the law governing frozen pre-embryos is uncertain. Consequently, the adoption of clear legal rules regarding the disposition of frozen pre-embryos in the event of a dispute is an alternative approach that would eliminate the need for courts to resolve disagreements between gamete providers or between clinics and gamete providers. For example, if courts or legislatures adopted the proposal in this report that frozen pre-embryos not be used, donated, or discarded unless both gamete providers agree to the same disposition, gamete providers would have to resolve their disputes by themselves.

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