

Disposition of unclaimed embryos: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

Programs should create and enforce written policies addressing the designation, retention, and disposal of unclaimed embryos. In the absence of program-specific policies, it is ethically permissible for a program or facility to consider embryos to have been unclaimed if a reasonable period of time has passed since contact with an individual or couple; efforts as outlined in the consent form have been made to contact the individual or couple; and no written instructions from the individual or couple with dispositional control exist concerning disposition. In such cases, programs or facilities may dispose of unclaimed embryos by removing them from storage and thawing without transfer. In the absence of specific written instructions, unclaimed embryos may not be donated to others for reproductive use or be used in research. This statement replaces the American Society for Reproductive Medicine Ethics Committee document "Disposition of Abandoned Embryos" published in 2013. (*Fertil Steril*® 2021;116:48–53. ©2021 by American Society for Reproductive Medicine.)

El resumen está disponible en Español al final del artículo.

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KEY POINTS

- Programs and facilities must create, enforce, and make known to their patients written policies addressing the designation, retention, use, and disposal of unclaimed embryos. Programs should seek legal advice about developing and communicating these policies, taking into account any relevant state laws governing embryo disposition.
- In the absence of program-specific policies, cryopreserved embryos may be considered unclaimed when an individual or couple with dispositional control cannot be contacted for a reasonable period of time after reasonable efforts by the program.
- Embryos may also be considered unclaimed when the individual or couple with dispositional control clearly states to the program in the manner described in the program's policy that they do not wish to have further dispositional control of the embryos.
- Facilities may dispose of unclaimed embryos by removing them from storage and thawing without transfer.
- Embryos may be used for research only if previous written informed consent for research has been obtained, even when the individual with dispositional control cannot be contacted.
- Absent specific written instructions, unclaimed embryos may not be donated to others for reproductive use or be used in research.

Clinics should require all patients who cryopreserve embryos after undergoing in vitro fertilization to state in writing their wishes regarding the future disposition of cryopreserved embryos. Also, programs or facilities should create, enforce, and make known to their patients the written policies addressing the designation, retention, and disposal of unclaimed

embryos. In some cases, however, clinics have already stored embryos from couples or individuals who have not stated their wishes and cannot be contacted to make their wishes known. This situation may pose a problem for an assisted reproduction program ("program") or storage facility ("facility") faced with continued storage of these embryos. In the absence of such

policies, cryopreserved embryos may be considered unclaimed when an individual or couple with dispositional control cannot be contacted for a reasonable period of time after reasonable efforts to do so. A "reasonable period of time" and "reasonable efforts" should be defined by the program or facility in writing and made available to all patients when drafted if not previously written. In addition, individuals or couples with dispositional control over stored embryos may indicate clearly to the program or facility in the manner stated by the facility's policy that they do not wish to be

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responsible for their embryos, thereby effectively delegating dispositional control to the program or facility. Embryos are not considered unclaimed, however, if the storage fees are paid because this constitutes contact with the person who retains dispositional control.

ETHICAL ANALYSIS

Unclaimed embryos raise ethical concerns both for patients and for programs and facilities. Patient choice is a core value of reproductive ethics and patient choices about disposition should be respected if practical and within legal limits. However, indefinite storage of cryopreserved embryos is expensive and often logistically impractical; therefore, programs and facilities cannot reasonably be expected to continue to provide such services when patients cannot be contacted and do not continue to pay storage fees.

Clinical Scenarios

The following scenarios present guidance regarding different ethical challenges.

No contact with clear written disposition. Unclaimed embryos may present a considerable burden for assisted reproduction programs and facilities. Accurate current numbers are difficult to ascertain, but estimates suggest that a large number of unclaimed embryos remain cryopreserved. There may be many reasons on the patient and facility side leading to so many unclaimed embryos remaining in storage, even when clear written instructions for disposition exist. Loss of contact may result when patients do not notify programs or facilities of their whereabouts and contact information (i.e., phone number, address, email) may have changed over time. Partners initially involved in the creation of the embryo(s) may no longer be in a relationship together, one partner may have died or become incapacitated, and the remaining partner may have moved away without updating the facility about contact information and be unaware of efforts the facility has made to contact them.

As patients undertake certain obligations when cryopreserving embryos, programs must develop policies that require each individual or couple contemplating embryo storage to give written directives about the disposition of these embryos with regard to possible scenarios that may arise in the future. These scenarios may include the death of one or both participants, divorce/separation, the failure to pay storage fees, inability to agree on the disposition of embryos in the future, or prolonged lack of contact with the program (1, 2). Such written instructions may involve a witnessed or notarized signed consent form and should be obtained before the first treatment cycle (3), at the time of cryopreservation, or both (4). The written instructions for cryopreserved embryos should state specifically whether the program may dispose of embryos if no contact with the program has occurred for a specified period of time despite reasonable attempts by the program to make contact, and the individual or couple with decisional authority has not kept the program informed of their current contact information. A definition of what constitutes a “reasonable attempt” at contact should also be

defined in the program or facility’s policy. As these decisions may be very difficult for individuals or couples to agree on, formal discussion of the potential scenarios by a member of the staff and adequate time for reflection by the intended parent(s) is recommended.

Respect for individual choices also requires that individuals should be able to change their minds about the disposition of cryopreserved embryos. Decisions about disposition may be highly difficult for patients and may change depending on the stage of treatment. Commentators, therefore, recommend that informed consent about the disposition of embryos should be revisited periodically and especially after participants believe they have completed childbearing efforts (5). An individual or a couple with dispositional control must be permitted at any time to alter instructions for the disposition of embryos by submission of a new set of written instructions. Clinics should provide their patients with clear information about how to alter their directions for the disposition of stored embryos. Also, this information should include how couples or individuals may indicate to the facility that they no longer wish to have dispositional control of the embryos that have been stored for them. While this statement of the directive regarding the disposition of embryos may be verbal, it is always recommended that a written formal directive be produced.

It is recommended that clinics obtain written instructions for disposition before the cryopreservation of embryos. If written disposition is available, it is ethically permissible to follow the written instructions even when there has not been contact for an extended period of time as defined by the clinic policy. When written instructions have been provided clearly, recontact is not ethically required. This includes donating embryos for research without obtaining additional contemporaneous consent provided the written disposition indicates a desire to donate for research.

No contact without written or verbal disposition. The best way to ensure that patients’ choice is respected regarding the disposition of cryopreserved embryos is to ask patients to state their intentions in writing before cryopreservation. When embryos are cryopreserved without instructions and patients cannot be contacted for decisions regarding the embryo disposition, it is unclear what should be done with the cryopreserved embryos as the patients’ choice cannot be known or respected. Deciding what to do with excess embryos is difficult for many patients. Although patients may have completed their families or have decided to discontinue infertility treatment, they may continue to regard the existence of the cryopreserved embryos as a kind of insurance against misfortune (6). They may have complex attitudes about the status of the embryo (6). They may be unwilling to donate their embryos for research or use by others for reproduction (7) for various personal or unidentified reasons. Additionally, patients and partners may have differing beliefs and expectations about storage terms and limits (8) or patients may be unable to decide what to do about cryopreserved embryos and be reluctant to communicate about disposition as a result (5). They may be ambivalent about what to do with their remaining embryos or find the decision emotionally troubling (9).

Because these factors may prevent individuals and couples from coming to a determination about embryo disposition, it is recommended that a dispositional decision is made before undergoing the creation of embryos.

Facilities may currently be providing storage for cryopreserved embryos when instructions have not yet been provided but contact with participants can still be achieved. If facilities become aware that they are currently storing cryopreserved embryos for which no instructions have been given, they should notify participants about the importance of instructions and encourage their creation. In addition, it is recommended to develop policies to identify those situations to obtain directives from all parties with dispositional authority before contact is lost.

Programs or facilities may be reluctant to discard unclaimed embryos when no written disposition exists out of concern that, even when patients have been lost to follow-up for many years, they may return and be distressed by the disposition of the embryos (10), as the decision to discard embryos by the program or facility is not reversible. In addition, clinics may be concerned about legal liability if embryos are discarded without clear instructions from the patients (11). The financial cost of continued storage may be significant, although it may vary depending on the size of the facility and the number of unclaimed embryos stored (12). For example, a smaller storage facility may have significantly larger annual storage costs per embryo than a larger facility. Therefore, the financial burden of continued storage may vary by facility.

In cases where written directions for the disposition of embryos do not exist, and the relevant individual or couple cannot be located, a program or facility will be faced with the possibility of continued indefinite storage, along with its costs, or disposal of the embryos. At present, United States law does not give clear guidance on when it is lawful to dispose of unclaimed embryos (2, 13, 14), although it is reasonable to consider that the law will treat the embryos, after a certain passage of time, as unclaimed. As an example, the American Bar Association Model Act on Assisted Reproductive Technology § 504 (8) states that storage facilities may deem embryos to have been unclaimed if at least five years have passed since the creation of the embryo, diligent efforts have been made to contact participants without success, and participants have acknowledged in a previously executed written record that they have been informed about the possibility that embryos may be deemed unclaimed in this way (15). When faced with legal uncertainty, some programs or facilities might prefer to continue the storage of unclaimed embryos indefinitely. Others will find the risk of liability to be acceptable and dispose of embryos after a lengthy passage of time and unsuccessful efforts to contact those with dispositional control. In such circumstances, programs and facilities should make reasonable efforts to contact individuals or couples with decisional control over the embryos before determining that the embryos have been unclaimed. These attempts should be documented clearly.

As an ethical matter, it is permissible for programs or facilities to dispose of embryos after a passage of time and unavailability of a responsible individual or couple that

reasonably indicates the couple is no longer seeking to exercise decisional control over the embryos. A program's willingness to store embryos does not imply an ethical obligation to store them indefinitely. An individual who, or couple that, has not given written instructions for disposition, has not been in contact with the program for a substantial period of time, has not provided current contact information, has not paid storage fees, and cannot be reached after reasonable attempts by the program or facility cannot reasonably claim an ethical violation if a program or facility treats the embryos as unclaimed and disposes of them. This statement notwithstanding, the Committee recognizes the legal uncertainty surrounding a determination of unclaimed status and does not provide legal advice in this regard for the program or facility. Instead, the Committee recommends that programs seek legal advice in developing their policies concerning unclaimed embryos.

The Committee also recognizes that some commentators have argued for permitting the use of the embryos in research; that absent directions to the contrary, such beneficial use is permissible (12, 16). However, the Committee rejects this argument because of concerns about whether it appropriately respects what patient choices might have been. Data from a large multicenter study indicate that only 20% of patients would be very likely to donate their embryos for research (17). A separate American Society for Reproductive Medicine (ASRM) Ethics Committee opinion (18) addresses informed consent for the use of embryos in research and two additional ASRM Ethics Committee opinions (19, 20) address the use of embryos for research. Without any information about the couple's preferences despite reasonable efforts and given data that a significant majority of people would not be likely to choose for unclaimed embryos to be used in this way, the ASRM Ethics Committee believes that it is preferable not to assume that this or other alternatives to disposition would be preferred. Finally, the donation to research in the absence of express written consent by the gamete providers may be prohibited by the terms of a research protocol or by laws or rules governing research with human subjects (18).

No contact and written disposition states do not discard. This scenario can be the most challenging for clinics. A patient or couple's decision for indefinite storage of embryos may result from the same scenarios that prevent others from making a decision regarding disposition. These include insurance against future infertility; complex views regarding the status of the embryos; inability to come to consensus with a partner about disposition, or ambivalence. Some patients indicate that they do not want to discard excess embryos as a means to postpone the need for a decision or consensus. Clinics are more frequently requiring written dispositional consent as a prerequisite for undergoing embryo creation to avoid the scenario (2) stated above. This may lead to more programs and facilities facing the decision of what to do with unclaimed embryos where "do not discard" dispositions have been stated. One solution is to remove this option from the list given to patients and instead give the option to store embryos for a fixed number of years unless additional consent for continued storage is signed. This approach requires

the individual or couple who desires perpetual storage to stay in contact with the program or facility or otherwise waive their original “do not discard” directive.

As previously stated, a program’s willingness to store embryos does not imply an obligation to store them indefinitely. When written instructions state clearly that the desire is to not discard the embryos, this may raise concerns by the program or facility about the legal implications of acting in opposition to the desires of its patient. While seeking legal counsel is paramount in this scenario, the ethical position should be viewed the same as with other examples of unclaimed embryos. If a program or facility has written policies regarding what constitutes “unclaimed embryos” (i.e., the amount of time and a reasonable attempt to contact the person or persons with dispositional control) and these policies have been explained to the couple or individual before the cryopreservation of embryos with documented acknowledgment of the policy, it is ethically permissible to discard the embryos. If the consent for the disposition of the embryos was signed before the creation of a policy regarding unclaimed embryos and the program or facility has made a reasonable attempt to contact the couple or individual with dispositional authority, as outlined in a written policy, without success, it is ethically permissible to discard the embryos. In no situation, however, should unclaimed embryos be used for research or reproductive purposes unless prior consent for that disposition has been documented.

CONCLUSION

Programs and facilities should create and enforce written policies addressing the designation, retention, use, and disposal of unclaimed embryos. In the absence of program-specific policies, it is ethically acceptable for a program or facility to consider embryos unclaimed if a reasonable period of time has passed since contact with an individual or couple and reasonable efforts have been made to contact the individual or couple. What constitutes a “reasonable” effort and period of time should be defined by written policies.

If a program reasonably determines under this standard that embryos have been unclaimed, the Ethics Committee concludes that the program may dispose of the embryos by removal from storage and thawing without transfer if no disposition directive is documented or the disposition documented states permanent storage. In no case should embryos deemed unclaimed be donated to other couples or individuals for reproductive use or donated to research unless previously indicated in the written disposition plan.

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Committee and the Board of Directors of the ASRM have approved this report.

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Disposición de embriones no reclamados: una opinión del Comité de Ética.

Los centros deben crear y hacer cumplir políticas escritas que aborden la designación, retención y eliminación de embriones no reclamados. En la ausencia de políticas específicas de los centros, es éticamente permisible que un centro o instalación considere que los embriones no han sido reclamados si ha transcurrido un período de tiempo razonable desde el contacto con un individuo o una pareja; se han realizado los esfuerzos descritos en el formulario de consentimiento para ponerse en contacto con el individuo o la pareja; y no existen instrucciones escritas del individuo o la pareja con control de disposición con respecto a la disposición. En tales casos, los centros o instalaciones pueden deshacerse de los embriones no reclamados sacándolos del almacenamiento y descongelándolos sin transferencia. En ausencia de instrucciones escritas específicas, los embriones no reclamados no pueden ser donados a otros para reproducción ni ser usados en investigación.

Esta declaración reemplaza el documento 77 del Comité de Ética de la Sociedad Estadounidense de Medicina Reproductiva "Disposición de embriones abandonados", publicado en 2013.