# Ethical issues in oocyte banking for nonautologous use: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

Ethical considerations for the banking of oocytes for nonautologous use are discussed. (Fertil Steril® 2021;116:644-50. ©2021 by American Society for Reproductive Medicine.)

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### **ESSENTIAL POINTS**

- At a minimum, all medical guidelines applicable to women donating fresh (non-cryopreserved) oocytes should also apply to women donating oocytes to an oocyte (egg) bank. These include informed consent as well as the medical, psychological, and genetic screening of oocyte (egg) donors.
- Care must be taken to safeguard the interests, health, and well-being of oocyte donors, regardless of whether the donation is directed or being made to an oocyte bank.
- Women donating to oocyte banks should be counseled that oocytes may remain banked for an extended length of time. They must provide explicit consent for each specific disposition and use of their oocytes, including: reproduction, basic science research, and research with reproductive intent. They should be aware that their donated oocytes might never be thawed or utilized for any purpose.
- Donation to oocyte banks for research purposes is acceptable with express written consent from the oocyte donors and institutional review board (IRB) or ethics committee for human study approval at the time of the donation. If such research has reproductive intent, explicit consent needs to be obtained for this indication and included in the IRB review.
- Physicians who facilitate third party reproduction with oocytes from an oocyte bank and the oocyte banks themselves should both provide information to intended parents regarding expected success rates and outcomes (1-7). Such counseling should discuss that the number of supernumerary embryos available for later use may be lower than with traditional oocyte donation cycles given that only a limited number of oocytes from a retrieval are allotted to the intended parent(s).
- Oocyte banks should inform the oocyte donor, recipients of their oocytes, and fertility centers who receive the oocytes if a child is born from one of their oocyte batches with an inherited condition and should inform the recipients and fertility centers who receive the oocytes if the oocyte donor is found to have a heritable condition, and this should be addressed in the written consent. Oocyte banks should make every reasonable effort to collect outcomes data, including oocyte survival and fertilization rates and the number of embryos resulting in live births, and to provide this information to intended parents and their reproductive endocrinologists as well as to the oocyte donors.
- Standards for oocyte banking may vary among countries, and care should be taken that oocytes acquired from a foreign oocyte bank meet the same standards as those acquired domestically. These includes appropriate infectious disease testing of the oocyte donor in accordance with United States (U.S.) Food & Drug Administration (FDA) regulations, and adherence to ethical standards in stimulation and care of the oocyte donor. Additionally, oocyte banks should make reasonable attempts to ascertain that oocytes shipped to foreign countries will be used for their specified purpose. Oocyte donors should provide specific consent for international distribution of their oocytes.
- Given the complex issues faced by potential donors, oocyte banks should ensure that all potential oocyte donors received psychological counseling. This counseling should include an exploration of the woman's feelings surrounding the use of her oocytes for reproductive or research purposes, issues of regret, considerations surrounding anonymity or the lack thereof, the possibility that the donor may herself one day face infertility.

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Fertility and Sterility® Vol. 116, No. 3, September 2021 0015-0282/\$36.00 Copyright ©2021 American Society for Reproductive Medicine, Published by Elsevier Inc. https://doi.org/10.1016/j.fertnstert.2021.06.051 he first successful in vitro fertilization (IVF) using cryopreserved thawed oocytes was described in 1986 and resulted in a twin gestation (1). Over the next two decades, techniques for freezing and thawing oocytes were further developed and optimized with the introduction of vitrification and improved embryology laboratory protocols. These paved the road for the development of oocyte cryopreservation for fertility preservation and planned oocyte cryopreservation by women for their future use. By 2007, oocyte banking was described as a method for storing anonymous donor oocytes for noncontemporaneous use by intended parents (2). This created an opportunity for the use of anonymous oocyte donation without the need to synchronize the cycles of the oocyte donor and recipient or even to designate a recipient at the time of the donation.

### TERMINOLOGY: OOCYTE BANKING VERSUS "TRADITIONAL" OOCYTE DONATION

Historically, the process of anonymous oocyte donation required menstrual cycle synchronization between the donor and recipient. Technology evolved to allow the retrieved oocytes to be fertilized with sperm from a donor or the intended parent and cryopreserved for future use. In both cases, the oocyte donor was generally required to travel to the fertility center where the intended parents or gestational carrier were located, and oocyte procurement and fertilization were temporally linked. The development of oocyte banking allows for oocytes to be frozen close to where the donor lives and then shipped essentially anywhere in the United States or the world once a recipient is identified. Cycles need not be synchronized, and oocytes may be stored for an extended period before being used.

The ability to cryopreserve oocytes allows intended parents quick access to a pool of available oocytes. These oocytes can be quarantined, following which infectious disease screening can be performed (3). Additionally, oocyte banking may be preferred by a subset of intended parents desiring a single child and who wish to limit the number of oocytes they receive. Although this type of indirect "cost sharing" may be attractive in some circumstances, the limited number of oocytes distributed by oocyte banks is usually lower than those obtained from a complete cohort of noncryopreserved oocytes from a fresh donation cycle, often resulting in few if any supernumerary embryos.

The Society for Assisted Reproductive Technology reported 1,723 completed cycles of donor oocyte banking in its 2018 preliminary report, up from 1,348 cycles the year prior (4). This upward trend is expected to increase as the demand for anonymous donor oocytes grows. Myriad reasons for this growth include the following: increased awareness and acceptance of this reproductive modality; demographic and social changes leading to delayed age of pregnancy (5); growth and acceptance of third-party reproduction by same-sex intended parents; faster time to pregnancy as cycles do not require synchronization; desire by a subset of those requiring oocyte donation for fewer supernumerary embryos; and improved survival and fertilization of cryopreserved oocytes. One key difference between third-party reproduction and traditional oocyte donation and oocytes from an oocyte bank is the further distancing between the oocyte donor and recipient. In a traditional oocyte banking cycle, the intended parents' physician either recruits the oocyte donor or at the very least meets her and screens her before managing her ovarian stimulation. Physicians who have reservations about the donor for any reason can share these concerns with the intended parents and determine whether to proceed with a cycle using that specific donor. There is generally less transparency when using banked oocytes, as the intended parents' physician and the oocyte donor in most cases have no direct interaction.

# CONSENT AND COUNSELING OF OOCYTE DONORS

Women donating oocytes to an oocyte bank need to be fully informed of the risks of undergoing oocyte retrieval (5). These include surgical risks such as bleeding and infection and ovarian hyperstimulation syndrome. Beyond the medical issues inherent to the donation process, women should be counseled that the oocytes will likely be divided among multiple intended parents. They should understand that their donated oocytes may or may not be used for an extended period of time. They must consent to specific destinies and uses of their oocytes, including for reproductive purposes, basic science research, and research with reproductive intent. If the intended use of oocytes is for research, this should be approved by the appropriate institutional review board. When the research has reproductive intent, an additional layer of explicit consent is required. Oocyte donors must also be made aware that the oocytes that they provide may never be thawed or may be thawed and discarded without being used.

Specific consent should be obtained that describes the potential uses of the donated oocytes. In some cases, the intended use is solely for reproductive purposes. Donors should either provide broad consent or be given the opportunity to identify specific uses. For example, donors may desire the distribution of their oocytes to a limited number of recipients, limit the number of offspring born from their oocytes, or donate only to those of a specific marital status or to those within a specific age range. Although oocyte donors have the freedom to decide how their oocytes will ultimately be used, oocyte banks can decline to accept donors if their allocation intentions differ. This discussion is a critical part of the informed consent process, and both the oocyte donor and oocyte bank need to be aligned regarding the possible dispositions of the resulting oocytes.

Additional consent should be obtained if the oocytes are (or may be) intended for research, and any research studies should be approved by an institutional review board. Explicit consent should be in place if the oocytes are to be used for research with reproductive intent, such as gene editing or any experimental manipulation of the oocyte or embryo with the goal of uterine transfer to achieve pregnancy (6).

In some cases, oocytes may be shipped outside of the United States, and donors should be informed of and provide

consent for this option if the possibility of international distribution exists.

### CONSENT AND COUNSELING OF RECIPIENTS

Oocyte banks have a responsibility to fully counsel intended recipients regarding the expected success rate when using frozen-thawed oocytes. They should provide their own internal data, including their level of experience with cryopreserved oocytes, and not national data or results of published studies that may not reflect their own experience.

Some studies have suggested that the pregnancy and live birth rates with cryopreserved oocyte cycles are lower than those achieved with "traditional" oocyte donation when fresh oocytes are fertilized, whereas other studies have suggested equivalent outcomes. This information should be disclosed to the intended parents (7–13). Intended parents should be fully informed of all of the financial pros and cons of using oocytes from a bank versus from a directed donor.

The number of oocytes that the intended parent(s) is to receive should be specified. Oocyte banks should clearly delineate what is being guaranteed, if anything, whether this be the distribution of a certain number of oocytes, a specific fertilization or blastocyst development rate, or the expectation that one batch of oocytes will lead to pregnancy and live birth. In general, the number of oocytes that an intended parent receives from an oocyte bank is lower than that received from women donating fresh (noncryopreserved) oocytes, whereby all the oocytes retrieved from one stimulation cycle fall under the dispositional control of the recipient. Acquiring oocytes from an oocyte bank may increase the risk that fewer or no embryos are available for transfer or cryopreservation. This may limit both the ability of the intended parent(s) to attempt more than one transfer should the initial cycle not result in a pregnancy and the possibility of cryopreserving embryos for use in conceiving genetically related siblings in the future.

Oocyte banks should keep track of where their oocytes have been shipped and make every possible effort to obtain outcome data regarding them. These data should be provided to intended parents as they make reproductive decisions. If oocyte banks are in possession of batches of oocytes that are known to have resulted in poor reproductive outcomes or that have not resulted in the development of viable embryos, this information should be fully disclosed to the intended parents. Ideally, such batches of oocytes should not be offered to intended parents for reproductive use.

#### "ANONYMOUS" VERSUS DEIDENTIFIED OOCYTE DONORS

Although most oocyte donations occur with the intention of anonymity between the donor and the eventual recipient(s), the ability to assure anonymity can no longer be guaranteed. As such, a more accurate term to describe oocyte donors is "deidentified" in contrast to "anonymous." With the increasing use of direct-to-consumer deoxyribonucleic acid tests, future children, oocyte donors, and their genetic relatives may be able to identify one another. This potential unveiling of anonymity occurs beyond the control of oocyte banks, intended parents, and the oocyte donors themselves. Intended parents and oocyte donors should be counseled that future anonymity cannot be guaranteed and the resultant children, oocyte donors, and their relatives could potentially be able to identify one another in the future. Recipients should also be counseled that the fact that they used a donor oocyte may become knowable to the offspring, who may not have been told of the circumstances of their conception, if they choose to compare their deoxyribonucleic acid to that of their presumed genetically related relatives.

# POTENTIAL ECONOMIC INCENTIVES AND ETHICS

In traditional oocyte donation, a donor is reimbursed for her time, inconvenience, and the risks of ovarian stimulation. Payment should not be dependent on the number or quality of oocytes she produces (14). Donation to oocyte banks should follow the same guidelines. Despite these recommendations, a number of oocyte banks charge a premium for oocytes from donors of certain ethnicities.

Furthermore, oocyte banks sell "batches" with a predetermined number of oocytes and, therefore, essentially charge on a per-oocyte basis. Hence, the cost structure of donated oocytes differs between traditional oocyte donation and oocytes obtained through oocyte banks, such that an oocyte bank earns more per donation if the oocytes can be distributed among a larger number of recipients. Alternatively, when using an oocyte bank, recipients may have some degree of reassurance as to the minimum number of oocytes guaranteed by the oocyte bank. This contrasts with recipients using traditional oocyte donation models using fresh (noncryopreserved) oocytes, where the oocyte yield is variable.

Because oocyte banks are usually paid on a per-oocyte basis rather than a per-cycle basis (as in traditional oocyte donation), incentives may differ. For example, oocyte banks may benefit from selecting oocyte donors who they anticipate will produce a high number of oocytes, encouraging such women to make additional donations. Moreover, physicians coordinating cycles of donors for oocyte banks may be more likely to stimulate women with higher doses of gonadotropins with the goal of producing more oocytes, which may place donors at higher risk of ovarian hyperstimulation syndrome. The donors, who take on all of the medical risks, may not necessarily benefit from, or even be aware of, these potential economic incentives, with the exception that high yield donors are more likely to be asked to make additional donations. Donors, whether their oocytes are intended for use by single or multiple recipients, should be stimulated in the safest possible manner. Consequently, and as the goals of the oocyte banks and the donors are not necessarily aligned, checks and balances must be put in place to ensure the safety of the donors. Donors must be protected against unethical treatment and overly aggressive stimulations.

In addition to recruiting women specifically to undergo ovarian stimulation for the purpose of donating to an oocyte bank, some programs may start to build their oocyte banks by cryopreserving a portion of oocytes retrieved from traditional oocyte donors, particularly from women who produce a large number of oocytes. In this setting, oocyte banks may incentivize the intended parents by discounting their oocyte donor cycle if they allow a certain number of their donated oocytes to be stored for oocyte donation by the oocyte bank. If such an arrangement is undertaken, there must be full transparency to both the donor and the intended parents regarding the potential consequences of such an arrangement.

Similarly, another way for an oocyte bank to obtain oocytes for donation is by apportioning some of the oocytes retrieved from a woman undergoing IVF to an oocyte bank in exchange for a lower payment for services rendered. When this approach is taken, the woman and her reproductive partner (if present) should be counseled that this may decrease success rates as well as limit the number of supernumerary embryos that may be available for a subsequent attempt if the first fails or for additional siblings at a later date.

One possible mechanism for minimizing the potential decrease in success rate associated with the aforementioned incentives is for the oocyte bank to maintain the additional oocytes tentatively allocated for oocyte banking in storage until the patients have completed their reproductive plan. In this way, individuals and couples who do not achieve their goals without the withheld oocytes would have continued access to the initial "batch" of oocytes until they are confident that they have reached their reproductive goals.

When oocyte banks offer oocytes that were procured from women undergoing fertility treatment, the recipients of these oocytes should be aware that the source of the oocytes was a woman who was herself undergoing fertility treatment because this may affect the ultimate chance of a successful pregnancy.

### LIMITING THE NUMBER OF COUPLES TO WHOM OOCYTES ARE DISTRIBUTED

According to the American Society for Reproductive Medicine guidance (15), it is reasonable and prudent that a donor donating fresh oocytes should donate no more than six times because of the potential cumulative health risks associated with ovarian stimulation and oocyte retrieval procedures. As such, following clinical guidelines can result in a limit on the number of families formed with the donor oocytes. Nevertheless, if provided by an oocyte bank, oocytes from one donor stimulation cycle may be distributed to a number of recipients. This could lead to several more intended parents receiving oocytes from a single donor than would be the case when a single donor donates one or more times to a specific intended parent or couple. Although there may be reasons for desiring to limit the number of recipients to whom one donor may donate, ensuring that this is difficult as a given donor can donate via multiple oocyte banks, oocyte donor agencies, and fertility centers. This difficulty of oversight is somewhat analogous to that of sperm donation, in which a given sperm donor may have donated to multiple cryobanks. In both cases, gametes may be shipped across the country or the world, such that the risk of consanguinity is significantly reduced. In the consent process, intended parents should be made aware of the difficulty inherent in seeking to limit the number of recipients from a given oocyte donor.

### DISPOSITION OF EXCESS OOCYTES INITIALLY STORED FOR AUTOLOGOUS USE

Autologous oocyte cryopreservation is increasing for a number of indications. These include fertility preservation by women facing the prospect of treatment with gonadotoxic therapies for the treatment of malignancies or other diseases. The designation of oocyte cryopreservation for this indication as no longer experimental (16, 17) has bolstered its use in recent years. Planned oocyte cryopreservation was in some ways a natural evolution of this technology, used by women who are not contemporaneously ready to start a family but who would like to preserve the possibility of this option in the future (18). Oocyte cryopreservation may also be chosen when an IVF cycle undertaken for infertility yields more oocytes than will likely be needed to satisfy current reproductive goals, and a decision is made to limit the number of oocytes that are initially fertilized in an effort to avoid supernumerary embryos.

All of these scenarios raise the possibility that oocytes will be cryopreserved but ultimately not needed by the woman who initially created them (19). These oocytes have the potential to be donated to oocyte banks for later distribution for reproductive or research purposes. Women who initially cryopreserved oocytes for their own use may later request reimbursement for donating these oocytes to an oocyte bank, seeing this as a potential income source. This may be an option if the Food and Drug Administration (FDA) donor eligibility guidelines have been followed. However, several ethical issues are raised in such situations. These include the possibility that women will be coerced into donating or selling their oocytes when they may wish to continue storing them for autologous use. In addition, if women know that their oocytes may ultimately be commoditized, they may pressure their providers to undertake more robust stimulations to obtain a higher oocyte yield. They may also choose to only initially fertilize a portion of the oocytes obtained, such that they have more options regarding their future disposition. Finally, a scenario could be envisioned in which women set out to donate a percentage of their fresh oocytes to a donor bank when undergoing a cycle for infertility to defray the costs of their treatment (20). This may be a viable option for women who are young and infertile due to male or tubal factors, as their oocytes may be as likely to lead to a pregnancy as those of anonymous oocyte donors. In such cases, counseling should be offered to these women to ensure that they are comfortable with identity nondisclosed (previously referred to as "anonymous") oocyte donation.

### MEDICAL TOURISM AND CROSS-BORDER CONCERNS

Increasingly, assisted reproduction occurs on an international stage. This is seen when patients travel abroad to receive care that may not be available or affordable in their country of origin (21). The ability to cryopreserve and transfer gametes from one country to another raises ethical concerns that should be considered when importing or exporting oocytes. In some countries, it is not permissible to financially reimburse women for oocyte donation. Shipping oocytes to such countries may bypass these country-specific regulations (22) but may raise both ethical and legal issues. Furthermore, donors may receive lower compensation in some countries, therefore making it desirable to establish oocyte banks in those countries and ship oocytes to countries where the intended parents can and are willing to pay a higher premium for them. When oocytes are created and stored in one country and sent to intended parents in another, oversight of this process may be limited. Ideally, the same standards of care established for domestic donors should be upheld. Additionally, oocvtes from other countries should only be accepted in the treatment of US patients if the FDA donor eligibility guidelines have been followed (23). Consequently, unique ethical issues may arise when procuring oocytes from abroad, as it may not be possible to verify the screening, counseling, and care of the donors, but the FDA guidance states that oocytes donated and stored in another country should only be accepted if appropriate FDA current good tissue practices, including donor eligibility determination and quarantine requirements, have been followed (24). Intended parents should be made aware of these potential deficiencies and the associated risks.

### **RESPONSIBILITIES OF OOCYTE BANKS**

Oocyte banks may be run by persons other than physicians or by entities that may not be owned or controlled by physicians. Despite this, the medical care and the consent requirements of the oocyte donors should be the same as for women donating fresh (noncryopreserved) oocytes. Additionally, embryology practices for oocyte banks should follow the same practices as IVF laboratories and be bound by the same regulatory guidelines. These include record keeping, quality control and assurance, and equipment maintenance. Physicians performing ovarian stimulation of oocyte donors who are donating to an oocyte bank should use the same best practices to minimize the risk of ovarian hyperstimulation as they would for any patient, regardless of the destination of the oocytes.

Oocyte banks should be able to uniquely identify donors so that intended parents can locate additional oocytes from a given donor in the future should they wish to do so. If an oocyte bank closes, is sold to another entity, or experiences any change in control, a mechanism should be put in place for continuity in the identification of donors.

Oocyte banks should obtain outcome information from the IVF centers and intended parents who use their oocytes. Such information should be shared with prospective intended parents as part of the oocyte selection process. Batches of oocytes that have not fertilized or not resulted in viable embryos or pregnancies should be labeled as such. Similarly, oocytes that result in recurrently aneuploid embryos may indicate issues with the oocytes, and this information should be made available to the donors and shared with those seeking to procure oocytes. If a child is born with an inherited disease following the use of donor oocytes, both the woman who initially donated the oocytes and all recipients of these oocytes should be informed. Batches of oocytes that result in lower-than-expected outcomes should be withdrawn, or full transparency regarding this limitation should be shared with future recipients. The oocyte donors should also be informed of potential issues with their own oocyte quality.

Ideally, oocyte banks—like fertility centers—should track and be able to report their outcomes. There will likely be variability of outcomes among oocyte banks, and intended parents should have access to this information. When oocyte banks also provide fresh (noncryopreserved) oocytes, the different outcomes between these two modalities should be reported separately. In some cases, fresh (noncryopreserved) oocytes may be more successful, and this information is significant to intended parents.

Oocyte banks may have "shared risk" contracts, by which additional oocytes will be distributed in certain situations. When such a contract exists, oocyte banks must clearly explain what is being guaranteed, whether this be fertilization, embryo development, or a live birth. They should also delineate the remedy for suboptimal oocytes, be this a refund or the ability to obtain additional oocytes without additional charge or for a reduced fee.

When oocyte donors are screened for genetic carrier status of inherited diseases, these results should be shared with the donor. Other test results, including ovarian reserve and ultrasound findings, should also become part of the donor's medical record, to which she should have access.

Unlike fresh (noncryopreserved) oocytes, those from a donor bank are distributed asynchronously from their cryopreservation, at a time when contact with the oocyte donor may have been lost. As donations may have occurred several years or even decades before oocyte use, there may be limited ability to go back and contact the initial donor if a problem with the oocytes is identified.

In fresh (noncryopreserved) oocyte donation, lawyerfacilitated contracts between oocyte donor and recipient can occur, allowing for the delineation of a host of potential concerns that may arise from the oocyte donation. Such contracts are likely not possible when banked oocytes are used for reproductive purposes. Intended parents should be aware of this limitation inherent to obtaining oocytes from a donor oocyte bank. This temporal disconnect is more akin to historical practices with anonymous sperm donation.

Given the complex issues faced by potential donors, oocyte banks should ensure that all potential oocyte donors have received psychological counseling. This counseling should include an exploration of the woman's feelings surrounding the use of her oocytes for reproductive or research purposes, issues of regret, considerations surrounding anonymity or the lack thereof, the possibility that the donor may herself one day face infertility, and the fact that once donated to an egg bank, she loses dispositional control over her oocytes.

In conclusion, the ability to successfully cryopreserve oocytes for later use has opened the door to the development and proliferation of commercial oocyte banks. The acquisition of oocytes from such oocyte banks has been growing as an option for both third-party reproduction and research. With this new technology come a number of ethical concerns that should be addressed by all oocyte banks before their formation. Oocyte banks have a responsibility to fully inform oocyte donors of the potential risks of ovarian stimulation, issues of anonymity, limits of donors' dispositional control over these embryos, and potential uses of the oocytes that they provide, among other issues. Oocyte banks should similarly ensure that intended parents are aware of the limits of anonymity, chance of success with cryopreserved oocytes, and pros and cons of acquiring oocytes from an oocyte bank versus from an oocyte donor providing fresh (noncryopreserved) oocytes. Finally, and most importantly, oocyte banks should prioritize the health and safety of the oocyte donors.

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Cuestiones éticas en el banco de ovocitos para uso no autólogo: una opinión de Comité Ético. Se discuten consideraciones éticas para el banco de ovocitos para uso no autólogo.