Misconduct in third-party assisted reproductive technology by participants and nonmedical professionals or entities: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Washington, DC

Physicians involved in third-party assisted reproductive technology arrangements who discover material misconduct or other undisclosed information by a party to the arrangement (such as a gamete or embryo donor, gestational carrier, or intended parent) or by a nonmedical professional participant or entity (such as a recruiting program, gamete or embryo bank, or lawyer) should encourage that party or professional participant to disclose such misconduct or information. In some instances, it is ethically permissible for the physician to either disclose material information to the affected party or to decline to provide or continue to provide care. In all cases involving the legal status or rights of the parties, physicians should recommend that patients seek independent legal professional advice. This document replaces the document "Misconduct in third-party assisted reproduction," last published in 2018. The use of a physician's own gametes for the purpose of reproduction without the informed consent of the recipient(s) is unethical and illegal, as well as never permissible. (Fertil Steril® 2023;120:802–9. ©2023 by American Society for Reproductive Medicine.)
El resumen está disponible en Español al final del artículo.

Key Words: Malfeasance, gestational carrier, egg donor, sperm donor, embryo donor

KEY POINTS

- Third-party assisted reproductive technology (ART) arrangements typically involve multiple participants, including parties to the arrangement, which may include intended parent(s), one or more gamete or embryo donors, and/or a gestational carrier (GC), as well as professional participants such as a recruiting program, gamete bank, attorney, and/or other nonmedical individuals of entities who assist them.
- The parties to the arrangement, including the intended parent(s), GC, and any gamete or embryo donors, may or may not all be patients of the physician; for example, donors may not be the physician's patients when frozen gametes or embryos are provided from a bank or donor recruiting program.
- Third-party ART arrangements can be complicated by material misconduct or undisclosed information on the part of one or more of the parties to the arrangement or the professional participants who assist them.
- Physicians who participate in third-party ART arrangements should obtain a medical release from each of their patients before medical treatment and ascertain that the parties have a written contract between them.
- In an arrangement involving non-identified gamete or embryo donation there should be written contracts between all involved parties.
- In some instances, ethically, it is permissible for the physician to either disclose material information to an affected party, professional oversight authorities, or law enforcement, or to withdraw from the case, or the physician may have professional and/or legal obligations to do so. Physicians should seek legal counsel in such cases. In all cases involving the legal status or rights of the parties, physicians should recommend that patients seek independent legal professional advice.
- Physicians should be informed of the agreed-upon provisions that relate to patient care.

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- Physicians or members of the medical team who become aware of material misconduct or undisclosed information on the part of any party or professional participant in ART arrangements may need to reconcile conflicting professional duties, including the duties to obtain informed consent, maintain patient confidentiality, and comply with applicable law.
- A medical release by any patient involved in collaborative reproduction as part of a physician's informed consent documentation, which authorizes the physician to disclose and share otherwise protected health information with another party, should be signed in advance of any treatment as a means of addressing the Health Insurance Portability and Accountability Act and other applicable health privacy legal requirements, and meeting otherwise potentially conflicting duties.
- Physicians who become aware of material misconduct or undisclosed information should seek guidance from the terms of their patient(s)'s medical release regarding confidentiality between or among the parties.
- In the rare situation where there is no or insufficient guidance, physicians should advise a patient who is a breaching party to disclose his and her intent or behavior to his and her attorney and/or the affected party(ies). Disclosure is supported by the principle of avoiding harm to the party(ies) or to the offspring.
- When a patient or other party refuses to disclose material misconduct or information to a party to an ART arrangement, the physician may ethically refuse to participate in the ART arrangement. Alternatively, depending on the circumstances, the obligation of confidentiality owed to the breaching party may be overridden by the threatened harm to the other party(ies) or to offspring, which may render it permissible for a physician to make a disclosure to the affected party(ies) or their attorney(s). It is advisable for the physician to seek legal counsel before making such disclosure.
- In contrast to the privacy of natural reproduction, the involvement of third parties, other participants, and medical professionals' attendants in ART and third-party ART (collectively "assisted conception") is vulnerable to mishaps or malfeasance and can result in physical, emotional, psychological, financial, and reputational harms.
- The use of a physician's own gametes for the purpose of reproduction without the informed consent of the recipient(s) is both unethical and illegal and is never permissible.

Mishaps and malfeasance by assisted reproductive technology (ART) physicians and practitioners have, in part, been previously considered by the American Society for Reproductive Medicine (ASRM) Ethics Committee in its opinion discussing disclosure of medical errors involving gametes and embryos (1). This opinion focuses on misconduct by two groups of third-party participants in what is sometimes referred to as "third-party ART" or "collaborative reproduction": (1) gamete and embryo donors, gestational carriers (GCs), and intended parents (the parties); and (2) nonmedical entities or individuals who work in the third-party ART field to assist the parties, including recruiting programs, gamete or embryo banks, and attorneys. Ideally, all potential conduct and remedies for breaches by the parties to a collaborative reproduction arrangement should be addressed by preconception contracts in which all parties participate voluntarily, transparently, with independent legal counsel, and in good faith. Contracts directly between the parties may not be feasible and instead may involve different contracting parties where, for example, cryopreserved gametes or embryos were previously donated to and stored by a third party, such as a frozen gamete or embryo bank. In the event a contract is absent, deficient, or breached, ART physicians can benefit from generalized analysis of certain conflict scenarios. The aim of this opinion is to identify areas of potential misconduct and discuss the range of possible responses by ART physicians. Misconduct may include behavior that is illegal, unethical, or in breach of the parties' agreement with one another or with a third party. In some cases (e.g., child abuse), mandatory reporting requirements may be triggered. The Committee recognizes that each scenario involving nonphysician malfeasance is unique and will require an individualized response. Moreover, it is possible that certain situations will require or benefit from professional outreach, including consultation with legal counsel.

In circumstances in which a physician is considering disclosing a patient's health information to another person, the restrictions of the federal Health Insurance Portability and Accountability Act (HIPAA) and other state laws may be implicated. Obtaining a medical release or authorization in advance should, unless rescinded by a patient, address this issue, and third-party reproductive agreements should ideally also expressly address disclosure of each of the parties' material, HIPAA-protected information by the physician to the other party.

MISCONDUCT BY GAMETE DONORS, EMBRYO DONORS, AND GCs

The growing use of gamete and embryo donors and GCs in assisted conception provides expanded opportunities for individuals and couples to become parents (2, 3). At the same time, it may complicate the procreative process, and the interests of the parties may come into conflict. Conflict-of-interest scenarios in third-party reproduction may include the withholding or misrepresentation of material information or the engagement in expressly prohibited or harmful conduct. A physician who becomes aware of a conflict of interest may consider a range of possible responses.

Conflicts Involving Gamete Donors

Gamete donors are individuals who agree to provide sperm or eggs directly to an individual or couple or indirectly through an independent entity such as a gamete bank, often with compensation for the time, effort, and expenses associated

with gamete retrieval, and who do not intend to parent any resulting offspring. In some instances, when gamete donors are recruited by an independent entity, their identities may not be disclosed to the intended parent(s) who select a donor on the basis of the provided demographic, personal, health, and other information. These are referred to as "nonidentified donors." In these cases, it is possible that the intended parent's treating physician will never meet or encounter the donor, such as when the gametes are frozen on retrieval by another ART practitioner, stored by a gamete bank, and sent to the physician to be thawed for later use by one or more intended parents. In other instances, intended parents work openly with directed gamete donors ("directed donors"). Several specific problems can arise in cases of directed donation where the gamete donor is known to the intended parent(s).

A Directed Donor's Intent to Parent

Intended parents who solicit gamete donors usually expect that the donors will neither retain nor assert any parental rights with respect to the resulting child. A number of court cases over the years have revealed that in a relatively small number of instances, donors initially represent their lack of intent to parent any resulting child but harbor, or later develop, a desire to exercise parental rights over the donor-conceived offspring. This is an evolving area of the law, and as same-sex and nontraditional families have become more prevalent and gained greater legal recognition, the role of genetic relatedness has diminished as a factor in determining legal parentage. Family laws and ART laws may not be fully developed or consistent, however, and, in the absence of clear statutory or judicial precedent, court decisions have been mixed in this area (4–7).

Disputes over parental rights can involve an ART physician who unwittingly becomes aware of the donor's intent to claim parental rights. What action, if any, should a physician take when an egg or sperm donor reveals during the informed consent process or elsewhere that, despite their representations to the intended parent(s), they plan or wish to parent the child as their own? When the physician knows the intended parent(s) has no intent to share or yield rights to the donor, does the physician have a duty to inform them of the donor's expressed intent? Similarly, what duties does a physician have when an intended father reveals that he intends to divorce or abandon the intended mother and claims he was solely a sperm donor? Should the physician reveal this before initiating treatment, or should the physician regard the revelation as private conduct between the parties that does not implicate the provider?

Physicians who become aware of potential conflicts between gamete donors and intended parents may face the difficult task of reconciling professional duties, including the duty to obtain informed consent, the duty to maintain patient confidentiality, and the duty to warn one or more of the participants or others (8, 9). Assisted reproductive technology physicians will want to have informed consent documents that clearly and unambiguously state their patients' anticipated status as a donor or intended parent. In the event they receive contradictory information, their duties to each of their patient(s) are relevant. Obtaining informed consent from a patient means disclosing information that would be material to a person's decision to undergo or refuse treatment. Although the doctrine of informed consent does permit withholding or postponing disclosure of material information in limited circumstances, these exceptions are on the basis of the patient's inability to process the information and would not apply in the case of another party's misrepresentation (10).

Considered alone, the duty of informed consent counsels in favor of disclosure because such information would clearly be material to a patient's decision to proceed with the ART arrangement. The disclosure analysis is less clear-cut when the concomitant duty to maintain patient confidentiality is considered. Physicians treating both a gamete donor and one or more intended parents form patient-physician relationships in each instance and owe equal duties of care to each patient. Disclosures regarding parental or nonparental intent can be considered within the physician's duty to maintain patient confidentiality. However, this duty is not absolute, and disclosure to third parties is permitted under certain circumstances, including permission by the patient(s) (as could be contained in the physician's informed consent or release document(s) for each patient) or to avoid serious harm to a third party (9). When physicians obtain consent from the parties at the outset that otherwise confidential information may be shared, unless that consent has been withdrawn, they remain free to proceed accordingly. In the absence (or withdrawal) of such consent or a contract provision waiving confidentiality by the donor of which the physician is notified, a physician should encourage the donor or intended parent(s) to discuss the issue of parental rights with their lawyer and/or directly with the intended parent(s) or donor. When the donor or intended parent(s) is unwilling to disclose, the physician may consider revealing the confidential information to their other patient to avoid harm in the event the future child's parentage is disputed. Alternatively, the physician may consider withdrawing from the case, in which case all parties should be notified of this decision in a timely manner. A physician has no duty to participate in a patient's act of wrongdoing.

Newly Discovered Donor Health Information

Medical, psychological, and social screening of prospective gamete donors is a field unto itself, susceptible to a modest regulatory scheme and a highly competitive market environment that aspires to promote best practices (11). Professional gamete recruiters are well aware of the motivations and strategic thinking that cause donors to offer their services and are generally equipped to detect evasions and misrepresentations in the interview and screening process. Still, it is possible for an applicant to be placed into the pool of available donors with the donor, or recruiter, having lied about or failed to disclose information that would be material to an intended parent (12). Moreover, it is possible for a physician or other member of the medical team to discover this information in the course of interacting with the chosen donor.

What action, if any, should physicians take when they discover previously undisclosed information about the donor's

health or psychological or social well-being that is potentially material to the donor's participation in the ART arrangement? Federal and professional guidelines governing gamete donation clearly spell out exclusion criteria, including certain medical, genetic, psychological, social, and familial histories, such that any donor who presents, at any point in the treatment cycle, with an excludable characteristic should be considered unsuitable for gamete donation (11, 13). When a physician discovers undisclosed information that would exclude a donor from being an acceptable donor, such as a family history of a heritable disease, mental illness, or illicit substance use or abuse, the physician should consider taking steps to dismiss the donor from the treatment plan. Likewise, discovery that an oocyte donor has undergone repetitive oocyte donation cycles in excess of ASRM practice guidance or that a sperm donor has not followed this guidance regarding sperm donations might warrant dismissal from the treatment plan (2).

The scenario becomes more complex in the case of "directed donation," when a donor is known to and selected by the intended parent(s) ("directed donor"). Published guidance and commentary present different views on whether the intended parent(s) should be informed about the discovery of exclusion criteria in directed donors. Federal regulations do not require informing gamete recipients of a directed donor's medical test results. In contrast, ASRM recommends that the intended parent(s) be informed and counseled about proceeding with treatment when potential risks to one or more of the parties are identified (11).

Although not explicitly stated, the federal regulations assume that a directed donor has already disclosed possible exclusion criteria to the potential recipients and that the parties have agreed to assume the associated risks of treatment. The scenario discussed herein imagines that no such disclosure to the intended parent(s) or in the course of any preliminary screening has been forthcoming, thus warranting action to dismiss the donor from the proposed donation or to inform the intended parent(s) of the donor's potential unsuitability for gamete donation, or both. Once a directed donor's previously undisclosed health-related information is verified, the physician should discuss these findings with the donor. A donor's request to withdraw from the ART arrangement without disclosing the clinical findings to the intended parent(s) should be honored. In such cases, the intended parent(s) can be informed that the prospective donor has been excluded as a directed donor, but specific health-related findings need not be disclosed. A donor who expresses a desire to continue in the treatment plan and who would not be prohibited by law from serving as a donor should be advised that the donation will not continue unless the relevant clinical findings are disclosed to the intended parent(s) for their consideration.

CONFLICTS INVOLVING EMBRYO DONORS AND INTENDED PARENTS

Unlike gamete donors, embryo donors do not receive compensation for their donations and are typically former in vitro fertilization (IVF) patients with cryopreserved embryos remaining after the completion of their own IVF treatment. As a result, the potential for misrepresentations or omissions of material information is lessened compared with gamete donors, and embryo donation is addressed more fully in a separate opinion (14). Nonetheless, there is the potential for misrepresentations or a lack of clarity around the legal parentage or legal relationship as to any offspring, which should be addressed in legal agreements between donors and recipients when possible. When a direct agreement is not feasible (e.g., the donations were made to a different IVF program or embryo bank), agreements between each participant and the entity providing the embryos are advisable to address such issues.

CONFLICTS INVOLVING GCs AND INTENDED PARENTS

Physicians providing fertility or obstetric care in the context of a GC arrangement can become aware of deceptive practices on the part of the GC or intended parent(s). Although some professional guidelines (11) recommend that GCs and intended parents obtain independent medical services, it may be that one physician will treat both parties at the same time (for example, during the preconception and early gestation stages), thus entering a patient-physician relationship with both parties (11, 13). What happens when one party confides in the physician that he or she now has breached, or no longer intends to fulfill, one or more of the terms of a preconception contract? This could mean, for example, a GC declaring her intent to claim parental rights over an in utero embryo or fetus or an intent to use illicit substances or drugs contraindicated during pregnancy. This could also include an intended parent declaring the inability to fulfill a contractual term because of a lack of financial resources or an undisclosed change of marital status. Discovery of one party's intended or completed breach or malfeasance that occurs before reproductive treatment or pregnancy can be addressed in the same manner as matters of gamete donor misconduct discussed above. More problematic are the instances of misconduct that occur or come to light after an embryo transfer (ET), including as pregnancy progresses.

Misconduct by the GC

Ideally, the parties to a GC agreement should discuss and memorialize in a legal contract all possible contingencies that can arise in the course of the relationship before beginning a treatment cycle (12). In some jurisdictions, parties to a GC arrangement are required to be represented by separate, independent legal counsel in order for the contract to be considered valid and enforceable; separate, independent legal counsel is recommended by ASRM, ACOG, and other professional organizations and is required by some state laws (12, 15–19). In all cases, parties to a GC arrangement should enter into a contract voluntarily, transparently, and in good faith. Physicians who participate in third-party reproduction arrangements should have a HIPAA-compliant release of information form completed before treatment for each party. Some professional organizations recommend that physicians may wish to inform themselves, to the extent possible, of the provisions of the parties' agreements that specifically address material aspects of a patient's care (12), although a medical

release will be more protective of the physician and avoid the need to review and attempt to interpret legal agreements that do not directly involve the physician, as express waivers of confidentiality create an exception to a physician's duty to maintain patient confidentiality.

In the rare instances where there is no express waiver or explicit contractual guidance, however, the discovery of a breach by a GC or intended parents can present physicians with a profound dilemma, as they must weigh the benefits and burdens of nonconsensual disclosure. In some instances, particularly before ET, physicians may consider withdrawing from the case, in which case all parties should be notified of this decision in a timely manner. A physician has no duty to participate in a patient's act of wrongdoing.

A hypothetical scenario is illustrative. What happens when a physician becomes aware that a GC has breached the terms of a signed legal agreement by engaging in some prohibited or risky conduct such as drug or alcohol consumption, a risky sport, or traveling across state lines where the parties have agreed otherwise? Is disclosure to the intended parent(s) a breach of patient confidentiality owed to the GC? Or, alternatively, does the physician have a duty to warn, and when doing so, is nondisclosure a breach of that duty?

Physicians who provide fertility or obstetric care to GCs enter patient-physician relationships that include traditional duties of confidentiality. However, when a GC engages in conduct that is potentially harmful to the resulting child or that would have excluded her from being considered a GC at the outset, the physician should take steps to have the intended parent(s) informed about the GC's behavior (12). Initially, the physician should encourage the GC to self-disclose to her attorney or to the intended parent(s). However, when, after a brief period, disclosure does not appear to the physician to have been given to the intended parents, the physician should seek legal advice about confidentiality, HIPAA, and the option to discuss the GC's actions with the intended parent(s). In some instances, the intended parents may have grounds for a legal remedy against the GC, and such legal issues may be taken up by the parties' legal counsel.

Misconduct by the Intended Parents

A second hypothetical scenario involves potential wrongdoing by the intended parent(s). What happens when a physician becomes aware that the intended parents have breached the terms of a signed agreement by engaging in conduct that the GC expressed as material to her consent and agreement to provide services? For example, what happens when intended parents who present themselves as a married couple confide in the practitioner that they are not legally married or are married but contemplating divorce and do not plan to share this fact with the GC? When a GC made it clear that having her intended parents be a married couple was material to her agreement and consent to be a GC, should the physician reveal this marital status information to the pregnant woman? When the information is obtained before ET, the physician may decline to participate in an arrangement tainted by misconduct. Before or after ET, however, the physician can seek to restore transparency by encouraging the intended parents to self-disclose. When they refuse, the physician should seek legal counsel to assess the confidentiality considerations surrounding disclosure to the GC. In some instances, the GC may have grounds for a legal remedy against the intended parents, and such legal issues may be taken up by the parties' legal counsel.

MISCONDUCT BY RECRUITING ENTITIES AND ATTORNEYS

In the United States, third-party ART involves lawful commercial activity in which intended parents pay compensation to gamete donors, GCs, and/or professional gamete or GC recruiters in exchange for agreed-upon services. The monies paid include fees paid to donors and GCs, as well as fees paid to any professional recruiters who assist in bringing the parties together and to attorneys who may represent individual parties to draft, negotiate, and memorialize their agreement through executed contracts and their legal status through court filings. Attorneys also may potentially bring parties together as a separate service when consistent with applicable professional rules. As a general rule, ART professional recruiters are not typically licensed by any local, state, or federal authority and thus are not subject to governmental credentialing or inspection. Attorneys are licensed by the state bar association in the jurisdiction(s) in which they are authorized to practice law. In some instances, and subject to state conflict of interest rules, attorneys may act as both professional recruiters and lawyers on behalf of a party to an ART arrangement and will have the requisite duties applicable to each role. Independent legal representation of the respective parties to and throughout an ART arrangement is required by some state surrogacy laws (16–19) and recommended by ASRM and other professional organizations (11, 12).

There have been verified instances of misconduct involving the misappropriation of funds paid in connection with ART. Law enforcement has investigated and prosecuted entities and individuals who have absconded with funds paid for ART services or who have procured funds through active fraud and misrepresentation (20, 21). Such conduct causes tremendous reputational harm to the entire ART community. Often, physicians are not involved with or aware of these schemes, but when they are, the following examples may guide their response.

What happens when a GC mentions to her doctor at a routine appointment that she has not received an agreed-upon payment? Because this can be a sign of deeper financial misconduct, should the physician advocate on behalf of the patient by contacting the relevant entity or professional or encouraging her to do so? Although physicians treating parties to a GC arrangement are encouraged "to be familiar with pertinent preconditions and contingencies in [the] contract" by at least one professional organization, it is not practical and may not be advisable for physicians to review or be aware of the contents of legal contracts between the parties (12). Preconditions to payment can include verification of pregnancy or progress to a certain stage in the pregnancy, all involving the physician's expertise. Thus, when a physician knows that a GC has met the terms of her contract and

is experiencing financial or other mistreatment by a recruiter, escrow agent, attorney, or other responsible professional, the physician should encourage his or her patient to contact that entity or individual and offer to be available to support her concerns directly on her behalf.

Should law enforcement be contacted to flag potential fraud involving a GC arrangement? At least one professional society admonishes physicians who provide medical care in connection with GC agreements "to be aware of the policies of the agency and avoid participation in arrangements in which the financial or other arrangements are likely to exploit any of the parties" (15). Physicians who become aware of potentially exploitative conduct on the part of ART entities or professionals are encouraged, and possibly duty-bound, to inquire and advocate on behalf of their patients. This advocacy can take the form of contacting the professional recruiter, escrow agent, or relevant lawyer(s), notifying law enforcement, and/or reporting suspected misconduct to any relevant licensing authorities. Misconduct on the part of lawyers can and should be reported to the state bar association that issued the attorney's license to practice law (16, 17).

CONCLUSION

Assisted reproductive technology physicians may find themselves in the position of discovering deceptive or dishonest conduct on the part of individuals or other entities, such as third-party participants engaged in collaborative reproduction. When a third-party ART arrangement presents an actual or potential conflict of interest between the intended parent(s) and their donors, GCs, or other third-party participants, physicians should consider to whom and to what extent they owe professional and/or legal duties. Physicians who are told or discover undisclosed information that would be material to another party's participation in the ART arrangement should encourage their patient(s) to disclose it to their attorney and/or that party. In some instances, it is ethically permissible for the physician to either disclose material information to an affected party, professional oversight authorities, or law enforcement, or to withdraw from the case, or the physician may have professional and/or legal obligations to do so. Physicians should seek legal counsel in such cases. In all cases involving the legal status or rights of the parties, physicians should recommend that patients seek independent legal professional advice.

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Mala conducta en tecnología de la reproducción asistida de terceros por parte de participantes y profesionales o entidades no médicas: una opinión del Comité de Ética

Médicos involucrados acuerdos con terceros sobre tecnología de reproducción asistida que descubran una mala conducta material u otra información no divulgada por parte de una parte del acuerdo (como un donante de gametos o embriones, una portadora gestacional o un futuro padre) o por un participante o entidad profesional no médico (como un programa de reclutamiento, un banco de gametos o embriones, o un abogado) debe alentar a esa parte o participante profesional a revelar dicha mala conducta o información. En algunos casos, es éticamente permisible que el médico revele información importante a la parte afectada o se niegue a brindar o continuar brindando atención. En todos los casos que involucren el estatus legal o los derechos de las partes, los médicos deben recomendar que los pacientes busquen asesoramiento profesional legal independiente. Este documento reemplaza el documento ''Mala conducta en la reproducción asistida por terceros'', publicado por última vez en 2018. El uso de gametos propios de un médico con fines de reproducción sin el consentimiento informado de los destinatarios no es ético y es ilegal, así como nunca permitido.