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Fully Informed Consent for Prospective Egg Donors

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Jessica saw the ads on her college campus: egg donor wanted, high SAT scores, willing to pay, contact Egg Donors R Us. She was a financially struggling college junior, and the idea of helping people have children appealed to her. She called Egg Donors R Us and, after the receptionist asked her a few questions, she was invited to come to the clinic and fill out a questionnaire. It asked, for example, if she had dimples and freckles but not if she understood the medical procedures or risks involved in egg donation. She was given a provisional acceptance, had an interview with a nurse and a psychological consultant, and then had blood drawn for final eligibility checks.

A few months later, she was matched with a recipient and finally given the clinic's informed consent form. She barely looked at it before signing; she was excited to begin the process that would help another woman as well as pay her tuition bills.

So just what did Jessica sign? What did it tell her? What legal requirements surround the informed consent form for donating eggs and sperm? Although approximately 12 percent of all assisted reproductive cycles in the United States (more than 18,000 cycles each year) involve donor eggs [1], and countless pregnancies are achieved every year using donor sperm, the donation process is only lightly regulated, particularly in the realm of informed consent.

Regulations

The federal regulations that do exist fall into two categories: safety testing and truth in advertising. Neither deals directly with informed consent. With regard to safety testing, donor gametes—sperm, eggs, and embryos—are regulated by the FDA under the category of human cells, tissues, and cellular and tissue-based products (HCT/Ps) [2, 3]. The applicable regulations focus on donor testing and record keeping and require that all entities handling sperm, eggs, or embryos register with the FDA [4, 5]. In addition, the FDA requires screening for each donor that includes a physical examination and a medical history interview [6]. With very limited exceptions, donors are also subject to testing aimed primarily at preventing communicable diseases [7]. Following the testing, semen must be frozen and quarantined, to be released six months later when certified as “disease-free.” States may impose their own licensing requirements above and beyond the federal regulations [8].

A second set of federal requirements, based on the 1992 Fertility Clinic Success Rate and Certification Act, focuses on truth in advertising and relates primarily to

reporting requirements by fertility centers engaging in assisted reproductive technology (defined as the manipulation of both eggs and sperm) to ensure that clinics are not claiming inaccurate pregnancy rates [9]. These truth-in-advertising laws do not regulate entities that only handle sperm.

Because no federal laws regulate the informed consent process by, for example, specifying what information donors must be given before they provide gametes, the conscientious fertility center must look elsewhere.

One possible source is the American Society for Reproductive Medicine (ASRM), the self-regulatory association for assisted reproductive technology (ART) professionals, which has developed recommendations applicable to sperm, egg, and embryo donations. Unlike the FDA's, which apply only to donors, the ASRM's guidelines address both donors and recipients [10]. The ASRM, of course, has no enforcement authority apart from excluding noncomplying entities from membership. Accordingly, it "strongly recommends" rather than mandates.

Psychological evaluation and counseling are strongly recommended for donors, and genetic evaluation "should" be performed [11]. If a psychological assessment is done, then the guidelines recommend that it "ensure that the donor has been informed about all relevant aspects of the medical treatment" [12]. With respect to the possibility of identity disclosure, the guidelines note that the assessment should determine whether the donor has been "well informed about the extent to which information about [him or her may] be disclosed and about any plans that may exist relating to future contact" [13]. In short, the guidelines are detailed about the type of testing to be performed, but provide only summary recommendations concerning the scope and details of psychological counseling and evaluation that are recommended.

Finally, a few states have laws specifically focused on the egg-donation consent process [14]. Since 2010, egg donors in Arizona must be provided with specific information about the hormones they will be taking, the surgical procedures, and the risks [15]. California also has specific requirements concerning most steps involved in egg donation, requiring all entities that post advertisements offering "financial payment or compensation of any kind" for oocyte donation to certify that they have complied with ASRM requirements or include a notice stating:

Egg donation involves a screening process. Not all potential egg donors are selected. Not all selected egg donors receive the monetary amounts or compensation advertised. As with any medical procedure, there may be risks associated with human egg donation. Before an egg donor agrees to begin the egg donation process, and signs a legally binding contract, she is required to receive specific information on the known risks of egg donation. Consultation with your doctor prior to entering into a donor contract is advised [16].

New York has imposed requirements that the donor receive information about the “risks of any drugs, surgical procedures and/or anesthesia administered,” as well as the potential uses of the gametes [17].

Analysis

In this haphazard array of guidelines and state laws, the value of informed consent may be easy to overlook, but it is vitally important for several key reasons. First, state health care and tort law (particularly in the form of medical malpractice law) require informed consent to ensure that patients are involved in their own medical decision making, and physicians face tort liability for a failure to obtain informed consent. While there are problems with informed consent procedures in the United States—for example, the focus is on the physician providing information, rather than ensuring patient understanding [18]—the general principle is to promote patient autonomy. The focus of informed consent in ART has so far been on egg donors, but sperm donors also need adequate information to consent to the procedures.

Second, certainly for egg donors, donation involves potential risks. In one of the few studies of egg donors, the authors found that only a third knew about the possibility of ovarian hyperstimulation, only one-fifth knew about the possibility of infertility and the risk associated with the egg collection procedure, and only one in eight knew about the risks from the anesthesia used during egg recovery [19]. When it came to psychological aspects of the donation process, less than a third anticipated that they might feel a sense of loss or any type of emotional connection to their donated eggs or the resulting children, and only five percent were aware of the risk that a child might try to find them [19]. In addition, there is little research on the long-term impact of egg donation, including psychological aspects, and informed consent to unknown risks is particularly problematic.

Finally, gamete donation differs from most other medical procedures in three critical ways:

The end result is the creation of a child. Both egg and sperm donors may report complex emotions about their feelings towards resulting children [20, 21], and, notwithstanding promises of anonymity, donors may become interested in searching for offspring and offspring may search for their donors [22]. But the federal regulations say nothing about identity disclosure, and, as discussed earlier, even the ASRM guidelines only briefly mention disclosure, given that their primary foci are safety and recruitment, not the children who are born from donor gametes.

Egg donation is a medical procedure that involves significant medical risk yet provides no medical benefit to the donor. Indeed, the procedure is being done for someone else’s benefit. The most analogous situation is that of a living organ donor (although organ donation is not compensated). The Organ Procurement and Transplantation Network takes this risk so seriously that it requires provision of an independent donor advocate to ensure donors understand, among other issues, that

they “will undertake risk and will receive no medical benefit from the operative procedure of donation” [23].

Decisions regarding egg donation can be impacted by outside sources. Just as the organ transplant donor’s decision may be influenced by pressure from family members, prospective egg donors can be influenced by external factors, particularly the potentially distorting factor of financial payment. The importance of financial compensation in egg donors’ decision-making processes is plainly demonstrated by the fact that countries that have banned the practice of compensation for egg donors have faced significant egg shortages [24]. Yet the ASRM guidelines barely mention this issue. They only urge the minimization of the amount of payment so donors are not “unduly induce[d]” and evaluation for coercion during the psychological assessment, but do not suggest including a discussion of this issue in the informed consent process so donors can consider whether their judgment is in fact being impacted by the promise of financial reward.

Recommendations

So what is a reasonable fertility center to do when it comes to donors? (Disclosure to recipients is important but is outside the scope of this article.) At the least, centers should mandate counseling and, potentially, even require the use of independent donor advocates during an informed consent process comparable to the one used in the context of organ donation. The informed consent forms should ensure not only that information is conveyed but also that the donor understands and is making the decision voluntarily [25]. For example, an intriguing new tool provides feedback on whether prospective donors comprehend the information they have received [25]. To develop that tool, researchers adapted a validated questionnaire used for cancer patients enrolling in clinical trials to assess whether egg donors had both a subjective and objective appreciation of the donation process, that is, “how well informed the donor feels about” the egg donation process and the “facts and concepts relevant to oocyte donation” [26]. The tool proved both reliable and readable—a common challenge for many medical documents—in pilot testing at the UCSF Center for Reproductive Health [25], and it would be useful in evaluating existing consent forms. In addition, the informed consent process should start at the time of initial screening and agreement to participate rather than later in the process, when a donor may already feel psychologically invested in seeing the donation process through to completion.

At a minimum, counseling should cover the following points, all of which should also be addressed in writing in the informed consent documentation:

1. *Detailed medical risks.* While the ASRM guidelines do recommend disclosure of the risks involved, they do not specify what the disclosure must include [27]. Although there are essentially no risks for sperm donors, the medical risks for egg donors are significant and need to be adequately addressed. The information provided should go beyond the basic acknowledgement that there is “a small risk (1 in 200 women) of developing ovarian hyper-stimulation syndrome (OHSS)” and include details about the

symptoms of the syndrome and under what circumstances a woman should call the clinic. In addition, donors must be told that there has been very little research about the long-term impact of egg donation and at least some physicians believe infertility and death are possible risks [28, 29].

2. *Information about whether donor eggs may be used for research purposes.* A recent study concluded that only a small percentage of clinics inform potential donors that their eggs may be used for research, including stem cell research, and recommended that, in light of the moral or religious objections some donors may have, this information be disclosed in plain language in informed consent documents [30]. The ASRM urges that informed consent be obtained from donors if egg sharing is “contemplated” [31].
3. *A warning about the risks of multiple donations and donating at multiple clinics.* There is currently no mandatory nationwide egg donor registry in the United States and no coordination between different clinics. Thus, it is quite possible for a woman to donate eggs at more than one clinic. This poses risks in two ways. First, it is believed that the medical risks increase with the number of cycles [32]. Second, donating at more than one clinic increases the possibility of creating unknown half-siblings [33].
4. *Confidentiality issues.* The ASRM guidelines currently state only that donors “should be assured that their confidentiality will be protected insofar as federal and local statutes permit” [34]. This essentially provides the donors with no information at all. Donors should be informed that: (a) current regulations are subject to revision; (b) children resulting from their donation may one day contact them; and (c) donors have been identified even when clinics and donors have attempted to maintain confidentiality through registries. Donors should also be informed whether or not they have control over potential recipients.
5. *Compensation.* A frank discussion of the possibility that the promise of significant financial payment may be influencing the donor’s assessment of risk, and disclosure of who is paying the fees for counseling and legal services—if it is the clinic, for example, that fact needs to be disclosed to donors. This discussion could occur while addressing the donor’s motivations. Money will certainly figure as one reason for donating; the important issue is assuring that there is no coercion.

Although fertility centers should take these steps voluntarily, legal regulation must provide the enforcement necessary to ensure uniform implementation. Self-regulation works much of the time, but not always [35]. Studies increasingly show that, at least with respect to egg donation, even fertility centers that are located in California, with its legal requirements for egg-donor advertisements, and that are members of the Society for Assisted Reproductive Technologies are not in full compliance when it comes to advertising and information disclosure [36, 37]. While professional standards are critical to promoting good medical care, outside monitoring will protect gamete donors, recipients, and children.

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Read a [response by Susan L. Crockin and Judith Daar to this article](#) in the April issue of *Virtual Mentor*.

Related in VM

[Egg-Donor Price Fixing and *Kamakahi v. American Society for Reproductive Medicine*](#), January 2014

[AMA Code of Medical Ethics' Opinions on Assisted Reproductive Technology](#), January 2014

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