

INFORMED CONSENT FOR EGG DONORS

PRACTITIONER'S GUIDE TO USING THE MODEL FORM

A. GENERAL GUIDELINES AND COMMENTS

Purpose and Use of the Model Form – This is a guide for practitioners to using the Model Informed Consent Form For Egg Donors (Model Form) to obtain informed consent from egg donors.

Family Members and Friends as Egg Donors – Most egg donors are matched by their program to recipients who do not know their identity. A small percentage of egg donors are family members or friends of the recipient and have already agreed to donate eggs to their relative or friend before contacting an infertility or egg donation program. Although the Model Form may be used for egg donors who are family members or friends of the recipient, these donors raise additional issues that programs need to address during the informed consent process, such as the donor's motivation to donate her eggs, and the possible disclosure of the donor's identity and other information to the resulting offspring. See the discussion below on psychological screening and counseling under item (a).

Program's SART Name and Number – If your program is a current member of the Society for Assisted Reproductive Technology (SART), an affiliate society of the American Society for Reproductive Medicine, your program should be identified by the name that it currently uses to register with SART. At the top of the Model Form, in addition to its SART name, the program should also provide its current SART number so that egg donors can obtain additional information about the program from SART. If your program is not a current SART member, your program does not have a SART number and should not use or be identified by any other program's SART name or number. For example, a new program should not use or be identified by the SART name and number of its practitioners' former programs. Nor should a new program use or be identified by the SART name and number of its former practitioners' programs. There should be a footnote explaining what SART is and where egg donors can obtain additional information.

Attachments to the Model Form – In order to be both comprehensive and user-friendly, the Model Form addresses the issues of informed consent in broad and simple terms. The underlying details – such as medical information, risks of the procedures, and other program-specific information – are to be provided to egg donors separately in attachments (prepared by the program) to the Model Form. These should, at a minimum, provide a detailed *description* of the procedures for egg donation (*item (b) of the Model Form*) as well as detailed information on the *risks* of egg donation (*item (c) of the Model Form*). Programs may wish to provide additional information and/or program-specific materials in the attachments provided to patients.

Updating the Attachments – Each program should have a written policy regarding periodic assessments (at least annually) of the attachments to the Model Form and should revise or

supplement the attachments in accordance with current medical practice and advances in egg donation procedures.

Additional Attachments – Programs should also generate attachments on egg donors’ financial obligations and egg donor compensation. See items “h” and “i” below.

Timing of the Informed Consent Process – Programs should use a two-stage consent process for egg donors: (a) full disclosure of the risks of egg donation to applicants before they consent to entering the screening phase, and (b) a more complete discussion after screening.

Obtaining Informed Consent – Programs should provide the information specified in the Model Form and attachments (prepared by the program) to the egg donor before her cycle of egg donation begins and before she signs the Model Form. The physician responsible for the egg donor’s care should personally provide and explain the information to the egg donor or, alternatively, direct the staff at the program to do so. However, regardless of who provides and explains the information to the egg donor, the physician responsible for the egg donor’s care should meet with her to discuss the information, should give her the opportunity to ask any questions, and should fully answer such questions. The Model Form directs the egg donor not to sign the document if she has not received all of the information specified in the Model Form or has not met with her physician to discuss the information.

Each program should have written guidelines and procedures for obtaining informed consent. Program staff responsible for obtaining informed consent from egg donors should be knowledgeable and properly trained to do so. When using the Model Form and attachments (prepared by the program), program staff should review the information in the attachments with the egg donor and be reasonably assured that she understands the information. Program staff should be able to answer all questions from egg donors or, alternatively, refer egg donors to resources to obtain answers or additional information.

Duration of Consent – Programs should explain to egg donors that their written consent applies to only one cycle of egg donation and advise egg donors about the program’s policy on their right to withdraw consent. If an egg donor undergoes more than one cycle of egg donation at the program, the program must obtain a separate consent from that egg donor for each donation cycle. The egg donor may consent to each additional cycle with a new signature at the end of the Model Form.

Physician-Patient Relationship – The physician responsible for the egg donor has a physician-patient relationship with that egg donor during the screening and donation process. If the physician discovers a medical condition that requires medical treatment, the physician should offer to treat the condition or refer the egg donor to appropriate care.

Signature Page – Since the written consent applies to only one cycle of egg donation, a new signature page should be executed for each subsequent cycle of egg donation. The program should write the nth cycle of egg donation (e.g., first cycle, second cycle, etc.) in the blank at the top of the page.

The physician responsible for the egg donor's care should sign the physician certification. Although the physician may delegate to his or her staff the task of providing and explaining to the egg donor the information specified in the Model Form and any attachments, the physician who signs the Model Form should have met with the egg donor to discuss the information, should have given her an opportunity to ask any questions, and should have fully answered such questions.

B. SPECIFIC GUIDELINES AND COMMENTS

Labeled sections below (a, b, etc.) correspond to matching sections of the Model Form

- a. Describe the screening process and the criteria for disqualifying applicants based on their screening results. Explain how the program maintains confidentiality for the applicant's screening results. (*See section (o) below.*)

Programs are strongly advised to require screening for all applicants and to reject applicants who refuse to be screened by the program, even if they have been screened by brokers.

If the program has screening requirements for the applicant's spouse or partner, advise the egg donor of such requirements. For example, some programs require the applicant's partner to be tested for infectious disease or require the applicant's spouse to participate in the psychological screening. Even if there are no such requirements, programs may wish to discuss with the egg donor the option of and the process for including her spouse or partner, if any, in the informed consent process.

- a.1. Explain what information about the applicant's personal and family history is required. If the program has verification requirements, explain those requirements to the applicant.
- a.2. Describe all medical tests and procedures required by the program, such as testing for infectious diseases, toxicology screens, and genetic testing. Programs should provide pre- and post-test counseling for medical tests and procedures. For genetic testing, programs should comply with requirements under New York State law (NYS Civil Rights Law), including the provision of genetic counseling for genetic testing, and any applicable provisions under New York State tissue bank regulations.
- a.3. Programs should require psychological screening and counseling for all applicants. Programs should refer to ASRM's statement of psychological assessment of donors in October 1998 Supplement issue of *Fertility and Sterility* (70, no. 4 Supp. (1998): 9S), which recommends psychological assessment by a qualified mental health professional for all egg donors, and ASRM's Guidelines for Gamete and Embryo Donation: A Practice Committee Report.

Programs may choose to provide counselors who are employed by the program or, alternatively, refer applicants to independent counselors. However, in either case, applicants should not have to pay for the psychological screening. In programs

where psychological screening is performed in-house, applicants should not be screened or counseled by their treating physician.

Known donors raise additional issues that programs should address during the screening process. This discussion should be part of the psychological screening for known donors. Since many known donors are a relative of the recipient, such as a sister or cousin, there is some concern that the known donor's decision was based on pressure from family members or feeling guilty that she is able to have a child when a family member cannot. Programs should discuss the issue of motivation with known donors and should be reasonably assured that each known donor freely agreed to donate her eggs without any coercion from her family. In addition, programs should discuss with known donors the possibility that the recipient may later disclose the known donor's identity or other information to the resulting offspring.

- a.4. Explain the program's policy on how applicants can obtain their screening results and what counseling resources are available to applicants if they are disqualified by any screening test or procedure. Programs should provide counseling to applicants both before and after they learn their results.
- b. Along with the primary informed consent form, which addresses the issues of informed consent in broad and simple terms, patients should be provided with an attachment (prepared by the program) giving more detailed descriptions of the procedures for egg donation. Programs may add program-specific or additional information. (*See Part A, "General Guidelines and Comments," above.*)
- c. Along with the primary informed consent form, which addresses the issues of informed consent in broad and simple terms, patients should be provided with an attachment (prepared by the program) giving more detailed information on the risks of egg donation. Programs may add program-specific or other information about risks associated with egg donation. (*See Part A, "General Guidelines and Comments," above.*)
 - c.1. The risks associated with drugs should be presented in terms of general classes or categories of drugs.
 - c.2. Clearly describe all symptoms relating to ovarian hyperstimulation and explain to the egg donor how she can recognize symptoms. Emphasize that the egg donor should be on her guard for any symptoms of ovarian hyperstimulation and should see her physician immediately about possible symptoms. If she visits a physician who is not affiliated with the program, the egg donor should also contact the program about her symptoms.

Explain to the egg donor her chances of developing ovarian hyperstimulation from taking drugs to induce ovulation. Programs should discuss the number of mature eggs the program plans to produce by stimulating her ovaries with fertility drugs. Explain how many eggs are thought to be safe to plan to produce during a single

donation cycle and that the egg donor is more likely to develop ovarian hyperstimulation if the program plans to produce more than this number of eggs.

- c.3. Describe the egg retrieval process and explain that a minor surgical procedure is involved.
- c.4. Explain any other complications that might occur as a result of the egg donation, including any potential long-term problems that might develop later in the egg donor's life (e.g., infertility, ovarian cancer).
- d. Explain any physical pain or discomfort that the egg donor may have from the drugs or the procedures, and how it may restrict her work and other activities.
- e. Advise the egg donor about the psychosocial and emotional support, including psychological counseling, provided by the program to help egg donors deal with the psychosocial and emotional aspects of egg donation, and explain the process and the approximate costs to obtain those services. Programs should provide at least some support and counseling services at no cost to egg donors. Programs may choose to provide counselors who are employed by the program or, alternatively, refer egg donors to independent counselors.

Regardless of whether support and counseling are available within the program, programs should provide each egg donor with a list of counseling resources that are not affiliated with the program.

- f. Explain which of the following categories best describes each procedure of egg donation:
 - 1. Generally accepted within the relevant medical community, or
 - 2. New and innovative and not generally accepted within the relevant medical community

“Generally accepted within the relevant medical community” would include both (i) procedures that are supported by strong and clear clinical evidence, and (ii) procedures that are generally accepted within the relevant medical community even though they are not supported by strong clinical evidence.

If the selected procedures are part of a formal research protocol that has been submitted to an IRB, follow the IRB-approved process for obtaining consent.

- g. “Program’s experience” refers to the number of years the program has been in operation, including the experience of its laboratory facilities, if any. With respect to any particular procedure of egg donation, the experiences of the overall program and its individual physicians may be different. For example, a particular procedure may be new to a program, but the treating physician at the program may have prior experience with that procedure at

another program. Programs should provide egg donors with information about the level of training of its professional staff for each procedure of egg donation.

- h. Programs will need to prepare a program-specific attachment(s) (apart from those on risks and description of treatment) on financial obligations. The attachment(s) should make clear – and program staff should emphasize to egg donors – the following:
 - 1. What is and is not covered by the program and/or its insurance;
 - 2. Any costs associated with the egg donation that the egg donor should expect to pay or obtain insurance for, including whether the egg donor has any potential financial responsibility for certain medical problems that the resulting offspring might develop later in life;
 - 3. Who is responsible for the cost of medical complications associated with the egg donation, including expenses related to any potential long-term problems that might not occur until later in the egg donor’s life.
- i. Programs will need to prepare a program-specific attachment(s) (apart from those on risks and description of treatment) on compensation. Discuss the amount of compensation and when the egg donor should expect to receive the compensation.

Explain to the egg donor that she is compensated for her time and expenses and that the amount of compensation is not based on the number or quality of eggs retrieved from her or on whether any pregnancy results from her egg donation. If the program has a policy on partial payment for donation cycles that are cancelled before egg retrieval, explain clearly what that policy is.

Advise the egg donor that her compensation is taxable income and that at year-end the program will issue a Form 1099 to her for tax reporting purposes.

- j. Explain clearly the program’s policy on the egg donor’s right to withdraw consent. Programs are advised to allow donors to withdraw consent at any time before egg retrieval.
- k. Explain clearly the program’s policy on whether egg donors may object to or restrict the use of their eggs, including whether egg donors may limit or specify the number of recipients for her eggs. If the program has a policy to reduce the compensation if the egg donor insists that all of her eggs must go to only one recipient (rather than splitting her eggs between two or more recipients), explain the policy to the egg donor. Programs are advised to use the following policy:

If programs permit egg donors to object to or restrict the manner in which their eggs can be used, they should make a good faith effort to ensure that those objections or restrictions are respected, but they should inform egg donors that they cannot guarantee that the recipients will abide by the egg donor’s objections or restrictions.

- l. Most programs do not inform egg donors about the outcomes of their egg donation (i.e., whether the donation resulted in a pregnancy or live birth). Regardless of what the policy is, discuss the policy with the egg donor.
- m. Advise the egg donor that she should not assume that she will have any rights and responsibilities to any resulting offspring, although state laws on these issues remain unclear and unsettled and would likely change in the future.

New York State: If the *donee* (the recipient of the eggs) is a married woman, the *donor* gives up all rights and responsibilities (New York State Domestic Relations Law, section 73). If the *donee* is an unmarried woman, the law is unclear.

- n. If the program has a policy on the maximum number of donation cycles in the donor's lifetime, advise the egg donor what that policy is.

Explain what consanguinity is and discuss the risk of consanguinity from multiple egg donations or multiple recipients within a single cycle. Advise the egg donor that consanguinity is a serious problem, especially in densely populated areas, such as New York City, where many donors live within close proximity to their matched recipients. Programs must comply with state regulations that require programs to take the likelihood of consanguinity into account when using gamete donors for multiple cycles or multiple recipients within a single cycle.

- o. Discuss the program's policy on confidentiality and how it maintains the confidentiality of the egg donor's medical record. Programs and brokers should seek the egg donor's consent before using or disclosing her medical record and other information to others, including the recipients, any resulting offspring, or the public through advertisements or Internet postings. Programs may offer the egg donor the option to consent to the release and disclosure of any identifying information to the recipients or any resulting offspring (when the offspring becomes an adult or with the consent of the parent). If the program has such options, clearly explain them to the egg donor.

Programs and brokers should not use or disclose the medical record or other information of any woman who did not become a donor or is no longer a donor for that program or broker, unless she has consented to such use or disclosure.

- p. Programs Contacting the Egg Donor – Programs may have a policy to contact an egg donor in the future in the event that any offspring resulting from her egg donation should develop a serious or life-threatening illness for which the egg donor may be uniquely able to offer assistance. Programs also may wish to contact egg donors in the future to request follow-up interviews or other testing for research purposes. Explain any such policies to the egg donor.

Egg Donors Contacting the Program – Programs may ask the egg donor to contact the program in the future about any new personal or family medical developments that might

impact the health of any offspring resulting from her egg donation. If the program has such a policy, explain it to the egg donor.

Research – The application of the paragraph entitled “Research” on the Model Form is limited to:

1. Tissue drawn in the ordinary course of the procedures for egg donation, not extra tissue drawn specifically for use in research;
2. Eggs that are no longer viable, not eggs that are viable, which would come under item (k) on the Model Form;
3. Anonymized uses of tissue samples, not identifiable uses, which would require IRB approval and a separate consent process.