

INFORMED CONSENT FOR IN VITRO FERTILIZATION AND RELATED PROCEDURES

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 of assisted reproductive technologies (ART) to using the Model Informed Consent Form For In Vitro Fertilization and Related Procedures (Model Form) to obtain informed consent from patients undergoing in vitro fertilization (IVF) or related procedures. Although the Model Form may be used for GIFT and ZIFT cycles, programs may need to modify certain provisions of the Model Form to reflect any differences among the treatments that are relevant to the consent process. In addition to the Model Form, programs may use other consent forms for specific procedures (e.g., ICSI or cryopreservation). The Model Form should not be used for other ART treatments, such as intrauterine insemination (IUI).

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 patients 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 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 patients 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, program success rates and national averages, and other program-specific information such as cost of treatment – are to be provided to patients separately in attachments to the Model Form (Model Attachments).

The Model Attachments (which can be found on the CD-ROM included in this mailing) provide a ***description*** of the treatment (*item (a) of the Model Form*) as well as information on the ***risks*** of the treatment (*item (e) of the Model Form*). They represent the minimum amount of information that programs should provide to IVF patients. Programs may wish to provide additional information and/or program-specific materials in the actual attachments provided to patients.

Updating the Model 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 ART treatments.

Additional Attachment(s) – Programs should also generate an attachment(s) on the cost of treatment. Additionally, the attachments provided to patients should be clear about whether the program offers emotional and psychosocial support. See items “f” and “i” below.

Obtaining Informed Consent – Programs should provide the information specified in the Model Form and its attachments to the patient before treatment begins and before the patient signs the Model Form. The physician responsible for the patient’s care should personally provide and explain the information to the patient or, alternatively, direct the staff at the program to do so. However, regardless of who provides and explains the information to the patient, the physician responsible for the patient’s care should meet with the patient to discuss the information, should give the patient the opportunity to ask any questions, and should fully answer such questions. The Model Form directs the patient 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 patients should be knowledgeable and properly trained to do so. When using the Model Form and its attachments, program staff should review the information in the attachments with the patient and be reasonably assured that the patient understands the information. Program staff should be able to answer all questions from patients or, alternatively, refer patients to resources to obtain answers or additional information.

Duration of Consent – Programs should explain to patients that their written consent applies to only one treatment cycle and that they have the right to withdraw their consent at any time. If a patient undergoes more than one treatment cycle at the program, the program must obtain a separate consent from that patient for each treatment cycle. The patient may consent to each additional cycle with a new signature at the end of the Model Form.

Signature Page – Since the written consent applies to only one treatment cycle, a new signature page should be executed for each subsequent cycle of treatment. The program should write the nth cycle number of treatment (e.g., first cycle, second cycle, etc.) in the blank at the top of the page. If the patient has a partner, programs may wish to discuss with the patient the option of and the process for obtaining a separate consent from the partner.

The physician responsible for the patient’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 patient the information specified in the Model Form and any attachments, the physician who signs the Model Form should have met with the patient to discuss the information, should have given the patient 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. See Model Attachment, “Description of In Vitro Fertilization” (which can be found on the CD-ROM included in this mailing). Programs may supplement these attachments with program-specific or additional information about IVF, GIFT or ZIFT treatments. (See Part A, “General Guidelines and Comments,” above.)

Each program should have on file attachments for all current treatments relating to IVF, GIF or ZIFT. For each patient, programs should provide only the relevant attachments pertaining to the patient’s selected treatment likely to be used before and during the pregnancy.

- b. Explain to the patient that her chances of having a baby from her treatment are different from her chances of becoming pregnant.
- b.1. Use CDC/SART data for national success rates. Use data for live births rather than pregnancies. Explain that national averages are useful because they can give patients an idea of their *general chances of success*. However, emphasize to the patient that national averages do not necessarily apply to her particular case because many factors influence a woman’s chances of having a child through ARTs. Moreover, explain that the national averages are not data specifically for the patient’s selected treatment but rather data for *broader* categories of similar treatments that include the patient’s selected treatment. (For example, the data for IVF with fresh, nondonor eggs do not specify whether ICSI was used.)
- b.2. Program-specific success rates and other data may – but need not – be CDC/SART data. Use data for live births rather than pregnancies. If program-specific information is not CDC/SART data, it must cover a comparable time period (one year) and be based on comparable numerators/denominators. Explain to patients any differences between the program’s data and CDC/SART data. Also, note any special characteristics of the program’s patients (e.g., their age, cause of infertility, or the number of previous unsuccessful attempts) and explain how these facts might have affected the program’s success rates. Advise the patient of the following cautioning language from the CDC/SART report, *1996 Assisted Reproductive Technology Success Rates*:

Many people considering ART will want to use this report to find the “best” [program]. However, comparisons between [programs] must be made with caution. Many factors contribute to the success of an ART procedure. Some factors are related to the training and experience of the ART [program] and laboratory professionals and the quality of services they provide. Other factors are related to the patients themselves, such as their age and the cause of their infertility.

Some [programs] may be more willing than others to accept patients with low chances of success or may specialize in different ART treatments that attract particular types of patients. (p. 27)

- b.3. Explain how the specific factors and characteristics of the patient’s case – such as her age and medical history, any special medical condition, the number of children that she has already had, the cause of infertility, the length of time that infertility has been a problem, and the number of previous unsuccessful ART attempts – may affect her likelihood of having a baby. Explain the patient’s chances of having a baby based on her individual characteristics: better than average, average, or worse than average.
- b.4. Explain the patient’s chances of becoming pregnant and having a baby without any treatment.
- c. Explain which of the following categories best describes each component of the patient’s selected treatment:
 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.

In addition, programs may explain to the patient the following:

- How the selected treatment differs from other treatments;
- The benefits and risks (including any medical uncertainties) of the selected treatment, as compared to the benefits and risks of standard treatments;
- How the above information applies to the patient’s particular circumstances.

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

- d. “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 component of the treatment, 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 patients with information about the level of training of its professional staff for each component of the treatment.

- e. See Model Attachment, “Risks of IVF Procedures” (which can be found on the CD-ROM included in this mailing). The program may supplement these attachments with program-specific or other information about risks associated with treatment. (See part A, “General Guidelines and Comments,” above.)
 - e.1. The risks associated with drugs should be presented in terms of general classes or categories of drugs, including the risk of hyperstimulation caused by the use of ovulation drugs.
 - e.2. Describe and explain any other complications that are more likely to occur for this patient than for other pregnant women because of the treatment, including the possibility that pregnancy may aggravate a pre-existing medical condition, and the risks of those complications to both the patient and her offspring. This includes both prenatal and postnatal complications, including long-term problems that might develop later in the offspring’s life (e.g., long-term birth defects caused by ICSI). This does not include general risks that exist for all pregnancies.
 - e.3. **MULTIPLE PREGNANCIES** – Describe and explain both the likelihood and consequences of multiple gestation, the possibility that fetal reduction might be recommended as a response to a multiple pregnancy, and the process of fetal reduction, including the benefits and risks of fetal reduction. Programs should provide patients with CDC/SART data on multiple pregnancies in ART cycles. Explain the factors that should be considered in choosing the number of eggs or embryos to transfer for each cycle of treatment. For each patient, the program may recommend a specific number of eggs or embryos to transfer based on the specific circumstances of the patient’s case. However, explain to all patients that they have the right to limit the number of eggs or embryos transferred in a treatment cycle in order to reduce the likelihood of having a multiple pregnancy. Programs may have a policy that specifies an upper limit on the number of eggs or embryos to transfer for patients in certain age groups.
- f. Programs will need to prepare a program-specific attachment(s) (apart from those on risks and description of treatment) on the cost of treatment. The attachment(s) should make clear – and program staff should emphasize to patients – that these are only *estimates* of costs and that the patient’s actual costs may be somewhat higher or lower. The cost information should include the following:
 - 1. The standard fees for the treatment;

2. The charges for any procedures, medications, and services that are necessary for the treatment but are not covered in the standard fees;
 3. An explanation about the possibility of additional costs related to complications that might occur during the treatment and any pregnancy resulting from the treatment.
- g. Explain to patients the options that are available at the program or at other programs. Explain the benefits and risks of each option and its ramifications for the patient. Explain the process involved with each option and approximate costs, if any, associated with each option.
- h. Treatment Options – Programs should describe and explain other treatment options that are offered at the program or at other programs and compare the benefits and risks of these options to the patient’s selected treatment. In addition, programs may choose to explain the availability of other “adjunct” therapies and their benefits and risks.

Alternatives to Treatment – Programs should explain the alternatives to treatment, including adoption, trying to have a child without treatment, and not having a child. Program staff should discuss the relative benefits and risks of these alternatives.

Programs should provide patients with a list of resources to obtain further information about treatment options and alternatives to treatment.

- i. Attachments provided with the informed consent form should be clear about whether the program offers emotional and psychosocial support, including psychological counseling, and if so, the process and approximate costs to obtain such support or counseling. Programs should also provide patients with a list of counselors who are not affiliated with the program.

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

1. Tissue drawn in the ordinary course of treatment, 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 (g) on the Model Form;
3. Anonymized uses of tissue samples, not identifiable uses, which would require IRB approval and a separate consent process.