

Recommendations for practices using gestational carriers: a committee opinion

Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology

American Society for Reproductive Medicine, Birmingham, Alabama

This document provides the latest recommendations for the screening, evaluation, and psychoeducational and legal counseling of gestational carriers and intended parents. It incorporates recent information from the US Centers for Disease Control and Prevention, US Food and Drug Administration, and American Association of Tissue Banks, with which all programs offering gestational carrier services must be thoroughly familiar. This document replaces the previous document of the same name, last published in 2017 (Fertil Steril 2017;107:e4–10). (Fertil Steril® 2022;118:65–74. ©2022 by American Society for Reproductive Medicine.)

El resumen está disponible en Español al final del artículo.



DIALOG: You can discuss this article with its authors and other readers at <https://www.fertstertdialog.com/posts/35212>

TABLE OF CONTENTS

- Introduction and statement of purpose
- Care of the intended parents
- Care of the gestational carrier
- Psychoeducational screening and counseling
- Legal considerations
- Embryo transfer
- Acknowledgments
- References

INTRODUCTION AND STATEMENT OF PURPOSE

The recommendations in this document are intended to provide guidance for appropriate timing to consider the use of a gestational carrier (GC); provide recommendations for screening and testing of intended parents (IPs) or genetic contributors and GCs to reduce the possibility of complications; and address the complex medical and psychologic issues that confront the GC and IPs, as well as the resultant children. A GC is defined as a person who carries a pregnancy resulting from the

transfer of a preimplantation embryo created by one or more genetic parents or gamete donors. Genetic contributors may be the IP(s) and/or gamete donor(s). A gamete donor is defined as an individual who donates their gametes for procreation through assisted reproductive technology (ART) and has no intention to parent any resulting child(ren). This guidance incorporates recent information on optimal screening and testing for sexually transmitted infections (STIs) and psychologic assessments.

The current document represents an effort to make the screening procedures for individuals involved in third-party reproduction using a GC more consistent with and incorporates recent information from the US Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), and American Association of Tissue Banks (AATB). These recommendations use terminology from the federal agencies in addition to the AATB. In that context, the term “screening” refers to specific historical factors that place an individual at a higher risk of

a given disease, such as human immunodeficiency virus (HIV) and transmissible spongiform encephalopathy, or Creutzfeldt-Jakob disease. “Testing” refers to specific laboratory studies, such as serologic tests. The distinction between screening and testing is consistent in the article. The term “ineligible” does not mean excluded, but acceptable with appropriate informed consent. These recommendations for the screening and testing of GCs and genetic parents apply to individuals in the United States. Because the prevalence of STIs and genetic diseases may vary in other geographic areas, these recommendations may not be appropriate for other countries or individuals who come to the United States from other countries. Although the FDA does not require screening or testing of the GC, the American Society for Reproductive Medicine (ASRM) recommends testing these individuals as described in this document.

Other areas where the ASRM recommendations may be more stringent than the FDA minimum requirements are further discussed. Additionally, state requirements may be more restrictive than the FDA, and clinics should be aware of, and follow, minimum or required screening and testing requirements for their state.

Received April 29, 2022; accepted May 2, 2022.

Correspondence: Practice Committee, ASRM, 1209 Montgomery Hwy, Birmingham, AL 35216 (E-mail: asrm@asrm.org).

Fertility and Sterility® Vol. 118, No. 1, July 2022 0015-0282/\$36.00

Copyright ©2022 American Society for Reproductive Medicine, Published by Elsevier Inc.

<https://doi.org/10.1016/j.fertnstert.2022.05.001>

CARE OF IPs

Indications for the Use of a GC

Gestational carriers may be used when a true medical condition precludes the IP from carrying a pregnancy or would pose a significant risk of death or harm to the woman or the fetus. The indication must be clearly documented in the patient's medical record. Examples of such medical indications include the following:

- Absence of uterus (congenital or acquired);
- Significant uterine anomaly (e.g., irreparable Asherman syndrome; unicornuate uterus associated with recurrent pregnancy loss);
- Absolute psychologic or medical contraindication to pregnancy (e.g., pulmonary hypertension);
- Serious psychologic or medical condition that could be exacerbated by pregnancy or cause significant risk to the mother or fetus;
- Biologic inability to conceive or bear a child, such as single male or homosexual male couple.

Additionally, in the presence of an unidentified endometrial factor, such as for patients with multiple unexplained previous in vitro fertilization failures despite transfer of good-quality embryos, consideration may be given to the use of GCs. Further, no owner, operator, laboratory director, or employee of the practice may serve as a carrier or IP in that practice.

IPs AND GENETIC CONTRIBUTORS

The US FDA Required Screening and Testing of IPs and Genetic Contributors

All genetic contributors, including genetic parents and gamete donors, must be screened in the same manner (1, 2).

The US FDA screening and testing for infectious diseases

There is no method to completely ensure that infectious agents will not be transmitted. However, this guidance (Table 1), including screening for risk factors associated with infectious diseases; assessing for physical signs of infectious diseases; and testing for infectious diseases should significantly reduce these risks.

- If the sperm or oocyte source is a non-identified (“anonymous”) donor, refer to the ASRM Practice Committee document titled “Guidance Regarding Gamete and Embryo Donation,” last published in 2021 (3, 4).
- If an embryo was created with an initial intent to be used by sexually intimate partners but is later decided to be transferred to a GC or a donor embryo recipient, refer to the ASRM document titled “Guidance Regarding Gamete and Embryo Donation” (3).
- Questionnaire—see FDA Medical History Questionnaire (2, 5);
- Physical examination—see FDA Physical Examination (6);
- Laboratory testing—see FDA Laboratory Testing within 7 days of semen production and 30 days before or 7 days after oocyte acquisition (7).

Prospective genetic contributors with any identified risk factors based on screening questionnaires, physical examina-

tion, or laboratory testing are considered ineligible for anonymous (non-identified donor) tissue donation according to guidelines issued by the FDA. According to current FDA guidelines, embryos created by such individuals can still be transferred into a GC provided that the tissue is labeled to indicate any associated increased risks and that both the IPs and GC are aware of the theoretical increased risk and have verbally consented to moving forward with transfer. Although the FDA does not require that the GC be informed of the results of the screening, the ASRM strongly recommends that embryos created using gametes from individuals considered ineligible should only be transferred to a GC who is adequately informed and counseled regarding the associated potential risks.

The US FDA eligibility physical examination A physical examination should be performed to determine whether individuals might be at high risk of HIV, STIs, or other infections that might be transmissible by using a GC. Prospective egg or sperm sources should be marked as “ineligible” when specific findings are identified on the physical examination.

- Guidance for industry: Eligibility determination for donors of human cells, tissues, and cellular and tissue-based products: <https://www.fda.gov/media/73072/download> (6);
- Sample donor physical examination form: <https://www.aatb.org/sites/default/files/AATB%20Guidance%20Document%20No.%201%2C%20v2%20%286.27.05%29.pdf> (4).

The US FDA eligibility medical questionnaire Complete personal and sexual history should be obtained to determine whether individuals might be at high risk of HIV, STIs, or other infections that might be transmissible via use of a GC. Prospective egg or sperm sources should be marked as “ineligible” when specific findings are identified on history. For the complete list of the medical history findings that would make a gamete source ineligible, please see the ASRM Practice Committee document on gamete and embryo donation (3).

The US Food and Drug Administration eligibility laboratory testing Laboratory requirements for FDA donor eligibility are outlined in Table 2.

Laboratory testing resources.

- Guidance for industry: Eligibility determination for donors of human cells, tissues, and cellular and tissue-based products: <https://www.fda.gov/media/73072/download> (6);
- Guidance for industry: Donor screening recommendations to reduce the risk of transmission of Zika virus by human cells, tissues, and cellular and tissue-based products: <https://www.fda.gov/media/96528/download> (4).

Managing laboratory results A positive test should be verified before notifying the potential genetic parent. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.

Individuals with false-positive test results for syphilis using nontreponemal assays that are confirmed to be negative using a treponemal-based assay are considered eligible.

TABLE 1

Sperm and oocyte US Food and Drug Administration requirements and American Society for Reproductive Medicine recommendations (1–3).**Sperm and oocyte sources and intended parents^a**

FDA requirements

Physical examination

Medical questionnaire

Laboratory testing (Table 2)

Sperm source: Infectious laboratory tests at an FDA-approved laboratory (including CMV IgM and IgG and HTLV-1 and -2 on sperm source) within 7 days of sperm acquisition.

Oocyte source: Infectious laboratory tests at an FDA-approved laboratory 30 days before, or up to 7 days after, oocyte acquisition.

May use “ineligible” tissue but must label and consent appropriately

Note: ASRM = American Society for Reproductive Medicine; FDA = US Food and Drug Administration; CMV = cytomegalovirus; HTLV = human T-cell lymphotropic virus; IgG = immunoglobulin G; IgM = immunoglobulin M.

^a If the sperm or oocyte source is an unidentified (previously termed “anonymous”) donor, refer to the ASRM bulletin ASRM gamete and embryo donation (6).

ASRM. Gestational carriers. *Fertil Steril* 2022.

ASRM recommendation (in addition to FDA requirements)

Legal consultation and laws may vary by state

Psychologic counseling

Genetic screening

Medical evaluation

Legal consultation, laws may vary by state

Individuals found to be positive for syphilis, *Neisseria gonorrhoeae*, or *Chlamydia trachomatis* should be treated, retested, and deferred from creating embryos for use in a GC for 3 months after documentation that treatment was successful before being reconsidered. If evidence is presented that treatment occurred more than 3 months ago and was successful, no further deferral is needed as long as current testing does not indicate an active infection.

Men who test positive for active cytomegalovirus (CMV) infection (positive urine or throat culture or paired serum samples demonstrating a 4-fold rise in immunoglobulin G (IgG) antibody and immunoglobulin M (IgM) antibody at least 30% of the IgG level) should be excluded until signs of active infection are no longer present. Ideally, CMV IgM should be negative at time of sperm acquisition. There are many strains of CMV, and superinfection in the GC is possible even if she is CMV IgG positive. The risk of CMV transmission and newborn CMV infection from an embryo transfer is extremely low, and such infants appear to have no significant illness or other abnormality.

The American Society of Reproductive Medicine Recommended Testing, Screening, and Procedures

Psychologic counseling The decision to proceed with a GC is complex, and IPs may benefit from psychologic counseling. The physician should strongly recommend psychosocial education and counseling by a qualified mental health professional to all IPs. If involved, gamete donors should undergo psychoeducational evaluation as detailed in the ASRM document on gamete and embryo donation (3). The assessment should include a clinical interview and, where appropriate, psychologic testing described in Psychoeducational Counseling.

Genetic screening Any genetic source of oocytes, sperm or embryos (“genetic contributors”) should be offered appropriate genetic evaluation. Screening for cystic fibrosis, spinal muscular atrophy, and thalassemia or

hemoglobinopathy carrier status should be performed for all genetic parents (8). Additional expanded carrier screening may also be appropriate. Panethnic expanded carrier screening is recommended over ethnicity-based panels, given the limitations of self-reported ethnicity, increasing multiethnic populations, and rare recessive conditions that can occur in any ethnic group, despite lower carrier frequencies. It is important to note that different panels may test for different conditions; ideally, the oocyte and sperm sources should be screened for the same conditions. If carrier screening is performed using different panels through the same or different laboratories, ideally a professional should review the results to evaluate and disclose the reproductive risk to help determine whether additional screening is warranted.

Medical evaluation The IPs and any genetic contributor(s) should undergo a complete medical evaluation, including a thorough history and targeted physical examination, to ensure that they are healthy enough to proceed with applicable procedures involving ART.

Quarantine of embryos The quarantining of embryos is not required by the FDA for use in a GC. However, the ASRM recommends that potential GCs should be offered the option of cryopreserving and quarantining embryos derived from the genetic contributors for 35 days, with the release of embryos only after each genetic contributor has been retested and has received confirmed negative results.

Record keeping The FDA requires that records pertaining to each genetic contributor (screening and test results) be maintained for at least 10 years. However, in the opinion of the ASRM, a permanent record of each genetic contributor and each IP(s)’ initial screening, testing, and subsequent follow-up evaluations should be maintained. To the extent possible, the clinical outcome for each cycle should be recorded. A mechanism should exist to maintain such records as a future medical resource for any offspring produced.

CARE OF GCs

Selection of GCs

The recommended screening and counseling of gestational carriers is outlined in [Table 3](#).

- Carriers must be of legal age, and preferably between the ages of 21 and 45 years. Certain situations may dictate the use of a carrier older than 45 years, but all parties involved must be informed about the potential risks of pregnancy with advancing maternal age.
- Ideally, the carrier should have had at least one, term, uncomplicated pregnancy before being considered as a GC for another couple.
- Ideally, the carrier should not have had more than a total of five previous deliveries or three deliveries via cesarean section.
- Carriers must have a stable family environment with adequate support to help her cope with the added stress of pregnancy.

Infectious Disease Screening and Testing of a GC

Complete personal and sexual history should be obtained to identify individuals who might be at high risk of HIV, STIs, or other acquired infections that might be transmissible to the fetus. In addition, a physical examination report should be obtained to determine whether individuals might be at high risk for HIV, STIs, or other infections that might be transmissible to the fetus. The carrier should not be used when any of the following findings are present:

- Physical evidence for the risk of sexually transmitted disease, such as genital ulcerative lesions, herpes simplex, chancroid, and urethral discharge;
- Physical evidence of risk for syphilis or evidence of syphilis;
- Physical evidence of nonmedical percutaneous drug use, such as needle tracks; the examination should include the examination of tattoos, which might obscure needle tracks;
- Physical evidence of recent tattooing, ear piercing, or body piercing (within the past 12 months) where sterile technique was not used.
- Disseminated lymphadenopathy;
- Unexplained oral thrush;
- Blue or purple spots consistent with Kaposi sarcoma;
- Unexplained jaundice, hepatomegaly, or icterus;
- Large scab consistent with recent history of smallpox immunization;
- Eczema vaccinatum, generalized vesicular rash, severely necrotic lesion (consistent with vaccinia necrosum), or corneal scarring (consistent with vaccinia keratitis).

Laboratory Testing

There is no method to completely ensure that the GC will not have infectious agents that could be transmitted to the fetus. However, the following guidance, combined with an adequate medical history and specific exclusion of individuals at high risk of HIV and other STIs, should dramatically reduce these

risks. Although FDA does not require screening or testing of GCs for possible transmissible infectious diseases to the fetus, the ASRM recommends the testing of all GCs and their partners before embryo transfer to protect the health and interests of all parties involved.

- HIV-1 antibody;
- HIV-2 antibody;
- HIV group O antibody;
- HTLV-1 and HTLV-2 (male partner of GC only);
- Hepatitis C antibody;
- Hepatitis B surface antigen;
- Hepatitis B core antibody (IgG and IgM);
- HIV, HBV, and HCV nucleic acid test;
- Serologic test for syphilis;
- CMV (IgG and IgM) (Male partner of GC only);
- *N. gonorrhoeae* and *C. trachomatis* testing using the nucleic acid test on urine or a cervical or urethral swab using an FDA-licensed, -approved, or -cleared test labeled for the detection of these organisms in an asymptomatic, low-prevalence population.

Before acceptance, the potential GC should undergo a complete medical evaluation by a qualified medical professional, including preconception counseling and evaluation (9). In addition, the medical professional should provide counseling regarding screening, uterine preparation, embryo transfer, and hormonal support. A uterine cavity evaluation by saline-infusion sonogram or another modality is highly recommended.

Preconception Testing

- Blood type and Rh factor. If there is potential for Rh incompatibility, couples should be informed about the obstetric significance of this condition.
- Cervical cancer screening per guidance from the American College of Obstetricians and Gynecologists (ACOG);
- Mammogram according to ACOG guidance;
- Titers for varicella and rubella;
- Urine drug screen;
- Clinics should strongly consider requiring vaccination for GCs against diseases (such as Coronavirus Disease 2019 and other diseases per CDC, ACOG, and ASRM) and advise IPs to include the requirement of the vaccination of GCs in their contracts.

Managing Laboratory Results

- A positive test should be confirmed before notifying the individual. If a test is confirmed positive, the individual should be referred for appropriate counseling and management.
- Individuals who test positive for HIV-1, HIV-2, HIV group O antibody, hepatitis B, or hepatitis C should generally not be allowed to serve as GCs. Exceptions to this recommendation require careful counseling, informed consent, and the documentation of risks in the medical records.

TABLE 2

Laboratory tests required for US Food and Drug Administration eligibility determination.**Chlamydia (NAT)**

Gonorrhea (NAT)
 Hepatitis B surface antigen
 HIV-2 antibody
 HIV-2 antibody
 HIV group O antibody
 Hepatitis C antibody
 HIV, HBV, HCV NAT
 RPR
 West Nile virus NAT
 HTLV-1 and -2 (sperm only)
 CMV IgM and IgG (sperm only)

Note: CMV = cytomegalovirus; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; HTLV = human T-cell lymphotropic virus; IgG = immunoglobulin G; IgM = immunoglobulin M; NAT = nucleic acid test; RPR = rapid plasma reagin test for syphilis.

ASRM. Gestational carriers. Fertil Steril 2022.

- Individuals found to be positive for syphilis, *N. gonorrhoeae* or *C. trachomatis* should be treated, retested, and deferred from use as a GC until after documentation that treatment was successful and no longer considered to be infectious before being reconsidered.
- Individuals with false-positive results for syphilis using non-treponemal assays that are confirmed to be negative using a treponemal-based assay are eligible to be used as GCs.
- Women or their partners who test positive for active infection with CMV (positive urine or throat culture or paired serum samples demonstrating a 4-fold rise in IgG antibody and IgM antibody at least 30% of the IgG level) should be excluded from serving as a carrier until signs of active infection are no longer present.

Psychosocial evaluation and counseling by a qualified mental health professional is recommended for all potential GCs and their partners (See Psychoeducational Counseling)

Cross-Border GCs The use of a GC in a country remote from the IPs introduces potential ethical challenges as well as legal and logistic issues. For detailed discussion of cross-border reproductive care, refer to the document of the ASRM Ethics Committee on this topic (10).

PSYCHOEDUCATIONAL COUNSELING

The arrangement between a GC and IPs is a multistep process that begins with an evaluation of the GC and their partner (if applicable) and a separate psychoeducational consultation for IPs, both led by a mental health professional trained to work in the area of third-party reproduction (11). The final step in this process is a joint session for prospective GCs and IPs, whether or not they have a pre-existing relationship.

GCs

The psychologic evaluation and counseling of GCs and their partners is one aspect of the overall selection of a GC. The psychologic evaluation should occur before legal counseling and the signing of legal contracts with any IP(s). The psychologic evaluation and implication counseling is the same for directed and agency recruited GCs.

A psychologic evaluation and implication counseling by a qualified mental health professional experienced in GC evaluations is required for all potential GCs and their partner and/or primary support person or family member. If done by telehealth, telehealth guidance must be adhered to when conducting any type of consultation or evaluation remotely in the guidance that applies to all sections.

Psychologic evaluation The psychologic assessment of a GC includes a clinical interview, psychologic testing (9), and implication counseling. An evaluation should be administered any time a new surrogacy contract is initiated, and if an evaluation was conducted over a year before the new contract, a new evaluation should be conducted.

- The purpose and content of the assessment will be described, and informed consent will be obtained.
- The evaluation includes standardized, empirically validated testing that is designed for the assessment and/or screening of mental and behavioral disorders, which should adhere to the established standards of professional and ethical practice (12). The examples of assessments include personality inventories (i.e., Personality Assessment Inventory, Minnesota Multiphasic Personality Inventory) (13, 14).
- Collateral contact with other treating mental health professionals (i.e., psychiatrists, psychotherapists).
- A clinical interview should be conducted and include the following:
 - Social and educational history, including family of origin;
 - Religious or other belief systems that may influence behavior;
 - Strengths and Resources (e.g., approach to solving conflict and managing stressors).
- Psychiatric or psychologic history, included but not limited to the following:
 - Perinatal mood and anxiety disorders;
 - Major depression;
 - Significant anxiety disorder;
 - Bipolar disorder;
 - Psychosis;
 - Eating disorders;
 - Prior hospitalizations, suicide attempts, psychotropic medication(s), and counseling.
- Social and interpersonal history:
 - Current relationships;
 - Support of significant other (if applicable);
 - Social network/support system.
- Occupational history;

TABLE 3**Screening and counseling of gestational carriers.****Medical evaluation and counseling**

Infectious disease screening and testing
 Medical history (questionnaire)
 Physical examination
 Laboratory testing
 Psychosocial evaluation and counseling
 Preconception testing
 Uterine cavity evaluation
 Legal counseling

ASRM. *Gestational carriers. Fertil Steril* 2022.

- Flexibility and stability of employment to support the demands of a GC arrangement;
- Sexual history, reproductive trauma, and unresolved negative reproductive events;
- Substance use history, included but not limited to tobacco, alcohol, marijuana, recreational drugs, prescription drugs;
- History of physical, emotional, or sexual abuse;
- Current and past legal history including but not limited to bankruptcy, custody dispute, involvement of local child welfare services, and termination of parental rights;
- Personality (e.g., maturity, judgment, assertiveness, and empathy);
- Current major life stressors or anticipated life changes;
- GC experience:
 - Previous GC experience or application to another facility or rejection from another facility;
 - Motivation to become a GC;
 - Discussion of the identities of all parties and the ways in which these might impact the arrangement. These may include race, ethnicity, religion, and socioeconomic status;
 - Ideas on attachment and ability to detach from a pregnancy;
 - Desire for more children of her own;
 - How GC compensation will be used.
- Assess for coercion including but not limited to the following:
 - Financial including primary source of income and government assistance programs;
 - Personal;
 - Familial;
 - Dual relationships (e.g., employee/employer).
- Mental status evaluation.

Additionally, directed GC arrangements should also consider the following while assessing appropriateness of a specific match:

- Stability of current/past relationship;
- Impact on overlapping social networks;
- Potential for negative outcome to impact relationship;
- History of successful conflict management.

Implication counseling Gestational carriers and their partners or support person both need to participate in implication counseling that explores the following:

Treatment plan

- Discuss their understanding of the medical protocol, including source of gametes, sexual abstinence, scheduling demands, risks of cancelled cycles or unsuccessful cycles, number of embryos transferred, multiple pregnancy, multifetal pregnancy reduction, prenatal diagnostic testing, and elective termination;
- Provide psychoeducation on ASRM and Society for Assisted Reproductive Technology (SART) guidance related to single embryo transfer (SET) (15);
- Discuss attitudes toward prenatal diagnostic testing, multifetal pregnancy reduction, pregnancy loss, and the termination of pregnancy;
- Informing the GC about her right to make choices for her body;
- Elucidate concerns about the potential complications of pregnancy and the potential loss of own fertility.

Psychosocial impact of pregnancy

- Ability to separate from and relinquish the child and anticipated future feelings toward them;
- Risks of both GC and her family's attachment to the child;
- The impact of the pregnancy on relationship dynamics (e.g., family, friends, faith communities, workplace).

Lifestyle choices Expectations of the GC regarding travel, exercise, diet, sexual activity, alcohol, tobacco use, etc. should be discussed

Relationship with IP(s) Expectations and management of present, and future relationship between GC and her family with the IP(s) and their children

Hospital preferences

- Comfort level with IP(s) in delivery room;
- Openness to baby caretaking/interaction after delivery;
- Preferences regarding breast milk.

Criteria for rejection of a GC candidate

- Inadequate cognitive functioning to support informed consent;
- Evidence of financial or emotional coercion;
- Abnormal psychologic evaluation or testing results as determined by the qualified mental health professional;
- Unresolved or untreated alcohol and/or drug abuse or addiction, child abuse, sexual abuse, physical abuse, depression, anxiety, eating disorders, or traumatic pregnancy, labor and/or delivery;
- Current use of psychoactive medication;
- History of major depression, postpartum mood disorder, bipolar disorder, psychosis, or a clinically significant anxiety disorder with impaired functioning;
- Interpersonal or environmental instability, for example:
 - Current marital or relationship instability;
 - Insufficient emotional support from partner/ spouse or support system;

- Chaotic lifestyle, current major life stressor(s).
- Inability to maintain respectful and caring relationship with others;
- Evidence of an inability to emotionally separate from/surrender the child at birth;
- Failure to exhibit altruistic commitment to become a GC;
- Excessively stressful family demands;
- History of conflict with authority;
- Inability to perceive and understand the perspective of others;
- Motivation to use compensation to solve own infertility;
- Unresolved issues with a negative reproductive event.

IPs

The decision to use a GC is complex, and patients and their partners (if applicable) will benefit from psychosocial education to aid in this decision. The physician must require psychosocial education and counseling by a qualified mental health professional (11) trained in GC evaluation and psychoeducation to all IPs.

Psychoeducational consultation for IPs

- A clinical interview that should explore the IP(s)' history of infertility or family building efforts as well as coping strategies for these challenges;
- The potential impact of the relationship between the IP and GC and future contact;
- Discussion of the identities of all parties and the ways in which these might impact the arrangement. These may include race, ethnicity, religion, and socioeconomic status;
- Exploring with IPs about significant psychologic issues that could compromise successful collaboration with the GC;
- Discussion about use of donor gametes in creating the embryo(s);
- Expectations related to privacy and disclosure to friends and family including use of social media;
- Exploring with the IP(s) the potential for communication challenges, degree and locus of control issues, as well as other emotional risks, e.g., grief, guilt, jealousy, and concerns, regarding bonding that may be associated with the GC process;
- Discussion of the medical protocol, scheduling demands, risks of cancelled cycles or unsuccessful cycles, number of embryos transferred, multiple pregnancy, multifetal pregnancy reduction, prenatal diagnostic testing, and elective termination;
- Requirement of IP(s) alignment with the GC regarding medical decision-making;
- Meeting the emotional and psychosocial needs of the GC and her family;
- Expectations about the GC's behavior during pregnancy and methods for resolving conflicts (e.g., eating habits, prescription drugs, alcohol);
- Expectations of disclosure of the GC's role to any born child(ren) and scope of relationship between GC, IP(s), and children after birth;
- Disposition of extra embryos;
- Need for separate legal consultation and a written contract.

Criteria for rejection of IPs

- Inability to maintain respectful and caring relationship with GC;
- Current or previous perpetrators of sexual or physical abuse or involvement of local child welfare services and termination of parental rights;
- Gross marital or relationship instability;
- Intended parents' failure to follow ASRM guidance on number of embryos transferred and inability to agree with GC's decision on number of embryos transferred, selective reduction, and pregnancy termination;
- Ongoing legal disputes;
- History of noncompliance or ongoing problematic interactions with program or medical staff;
- Intended parents' reproductive plan is to pursue concurrent pregnancies by embryo transfers to more than 1 GC or by seeking concurrent pregnancies for a GC and an IP.

Joint Session for GC and Partner (If Applicable) With IP(s)

The physician should require a joint session led by a mental health professional knowledgeable about these arrangements and appropriately trained to review the topics outlined below. The joint session is a meeting with the prospective GC, and their partner, and IP(s) with the mental health professional; this meeting is held to ensure that everyone begins the treatment phase aligned in their expectations of each other and the process.

Joint session topics The joint session topics include, but are not limited to, the following:

- An agreement on the expected timeline of treatment;
- Understanding of the medical procedures involved;
- Discussion of number of embryos to be transferred and number of cycles planned in their contract;
- Discussion of each party's feelings about prenatal testing, multifetal pregnancy reduction and termination of a pregnancy to determine whether all are in agreement as to how they would proceed in the event decisions about these issues arose during their treatment or the pregnancy;
- Expectations for how the IPs would like to participate in the pregnancy and delivery;
- Expectations for communication between the IPs and the GC, including frequency and preferred format;
- Strategies for managing and resolving conflicts that may arise during the pregnancy;
- Discussion of the identities of all parties and the ways in which these might impact the arrangement. These may include race, ethnicity, religion, and socioeconomic status;
- Expectations for the GC's behaviors following the transfer and during the pregnancy (e.g., diet, exercise, travel, social media, vaccinations);
- Discussion of expectations for behaviors that may be affected by current medical events (e.g., Coronavirus Disease 2019, traveling, vaccination, Zika);
- Discussion about the IPs' interest in receiving breast milk from the GC after the birth and whether the GC is willing to attempt pumping after the birth;

- Expectations for how each party envisions their relationship after their GC arrangement has ended.

Criteria for rejection of the arrangement between the GC and IP(s)

- Gestational carrier's unavailability for the IP(s)' preferred timeline for treatment (e.g., due to schedule conflicts, travel);
- Disagreement on the plan for medical treatment (e.g., number of embryos transferred);
- Any evidence of discordance in how decisions would be made during the present GC arrangement in regard to prenatal testing, multifetal reduction, induction of labor, cesarean section, or termination of a pregnancy;
- Evidence of incompatibility in communication preferences;
- Disagreement between the GC and IPs on expectations for behaviors following the transfer and during the pregnancy (e.g., diet, exercise, travel, social media, vaccinations);
- Disagreement between the GC and IPs regarding the GC's behaviors in response to a medical event during the GC arrangement;
- Divergent expectations about the relationship between the parties both during and following the GC arrangement;
- Special consideration should be given to matches where a pre-existing relationship exists, that participating as a GC is voluntary, without evidence of coercion, and will do no harm to the current relationship.

LEGAL COUNSELING AND CONSIDERATIONS

Laws relevant to GC arrangements vary from state to state and may also change, as to both legal parentage and conduct of the participants. It is imperative that each participant or participant couple, meaning the GC with any spouse, and any single IP or partnered IPs in a GC arrangement, have independent legal counsel who is licensed in the applicable state, to represent, advise, and assist them before entering into a GC agreement and in executing a legal agreement. The legal counsel should remain available to represent, advise, and assist them throughout the GC arrangement. Before initiation of any treatment, a fully executed legal agreement, a clearance letter attesting to the completion of a legal agreement, and all informed consent documents, including a medical release that authorizes the ART practitioner to share with all participants otherwise privileged medical information pertinent to the GC arrangement, should be in place.

The central issues legal agreements should address: establishment of legal parentage and non-parentage; conduct of the parties; expectations and decision-making as to prenatal testing, pregnancy management, and delivery; coverage for medical expenses; financial arrangements for agreed on fees and expenses; allocation of risk(s) and responsibility, and escrow arrangements. Although mutual understandings as to selective reduction and/or termination should be addressed, no agreement should contradict constitutionally protected reproductive decision-making

by a GC as to prenatal and pregnancy decision-making. Experienced ART legal counsel is strongly recommended as GC arrangements involve a novel area of the law with many state law nuances and potential overlap or conflicts with other jurisdictions as well as other potential areas of the law. Before medical treatment, and no later than the initiation of an in vitro fertilization cycle, legal counsel for the parties should present the ART practitioner with a legal clearance letter attesting to the completion and execution of a contract between the participants with independent legal counsel, and the relevant information for the treating physician such as the maximum number of embryos to transfer, maximum number of transfer attempts agreed to, and any time limits for those procedures or the arrangement.

Protection of Confidentiality

Individuals participating in GC programs should be assured that their confidentiality and medical information will be protected insofar as federal and local laws and regulations permit. Medical records detailing the eligibility of the IPs and GC should be maintained as stipulated by federal and local requirements.

EMBRYO TRANSFER

Single embryo transfer is strongly recommended in all GC cycles, given the health risks associated with multiple gestations for the GC (15). The ASRM recommends that at a minimum, age-related limits on the number of embryos to transfer should be followed. However, this could result in the transfer of multiple embryos to a GC when the provider of the oocyte is 38 years of age or older. In cycles for which the provider of the oocyte is 38 years or older, selection techniques such as pre-implantation genetic testing for aneuploidy, may be considered. Testing and subsequent elective, single, euploid embryo transfer may result in a higher likelihood of implantation and a lower chance of multiple gestations (13). This may obviate the temptation for multiple embryo transfers when the oocyte source is of an older age.

Acknowledgments: This report was developed under the direction of the Practice Committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Practice Committee and the Board of Directors of the American Society for Reproductive Medicine have approved this report. This document was reviewed by ASRM members and their input was considered in the preparation of the final document. The following members of the ASRM Practice Committee participated in the development of this document: Alan Penzias, M.D.; Kristin Bendikson,

M.D.; Marcelle Cedars, M.D.; Tommaso Falcone, M.D.; Karl Hansen, M.D., Ph.D.; Micah Hill, D.O.; Sangita Jindal, Ph.D.; Suleena Kalra, M.D., MSCE; Jennifer Mersereau, M.D.; Robert Rebar, M.D.; Richard Reindollar, M.D.; Anne Steiner, M.D., M.P.H.; Cigdem Tanrikut, M.D.; and Belinda Yauger, M.D. The Practice Committee acknowledges the special contribution of Anne Steiner, M.D., M.P.H.; Paula Amato, M.D.; Susan Crockin, J.D.; and Jennifer Kawwass, M.D.; along with the Mental Health Professional Group Document Working Group in the preparation of this document. All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.



DIALOG: You can discuss this article with its authors and other readers at <https://www.fertstertdialog.com/posts/35212>

REFERENCES

- American Association of Tissue Banks. Guidance Document. Tissue donor physical assessment form [No. 1, version 2, June 27, 2005]. Available at: <https://www.aatb.org/sites/default/files/guidance-docs/AATB-Guidance-Documents-No1-v2-06-27-05.pdf>. Accessed November 30, 2021.
- US Food and Drug Administration. Donor eligibility final rule and guidance questions and answers. Available at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/donor-eligibility-final-rule-and-guidance-questions-and-answers>. Accessed November 30, 2021.
- Practice Committee of the American Society for Reproductive Medicine and the Practice Committee for the Society for Assisted Reproductive Technology. Guidance regarding gamete and embryo donation. *Fertil Steril* 2021;115:1395–410.
- US Department of Health and Human Services. Guidance for industry: donor screening recommendations to reduce the risk of transmission of Zika virus by human cells, tissues, and cellular and tissue-based products. Available at: <https://www.fda.gov/media/96528/download>. Accessed December 22, 2020.
- US Food and Drug Administration. Human cells, tissues, and cellular and tissue-based products; donor screening and testing; and related labeling 6/19/2007 final rule questions and answers. Available at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/human-cells-tissue-s-and-cellular-and-tissue-based-products-donor-screening-and-testing-and-related>. Accessed November 30, 2021.
- US Department of Health and Human Services. Guidance for industry: eligibility determination for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). Available at: <https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Eligibility-Determination-for-Donors-of-Human-Cells-Tissues-and-Cellular-and-Tissue-Based-Products-Guidance-for-Industry.pdf>. Accessed November 30, 2021.
- US Food and Drug Administration. Testing donors of human cells, tissues, and cellular and tissue-based products (HCT/P): specific requirements. Available at: <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/testing-donors-human-cells-tissues-and-cellular-and-tissue-based-products-htcp-specific-requirements>. Accessed November 30, 2021.
- American College of Obstetricians and Gynecologists. Committee opinion no. 691: carrier screening for genetic conditions. *Obstet Gynecol* 2017;129:e41–55.
- Riddle M. Psychological assessment of gestational carrier candidates: current approaches, challenges, and future considerations. *Fertil Steril* 2020;113:897–902.
- Practice Committee and the Mental Health Professional Group of the American Society for Reproductive Medicine. Guidance on qualifications for fertility counselors: a committee opinion. *Fertil Steril* 2021;115:1411–5.
- Ethics Committee of the American Society for Reproductive Medicine. Cross-border reproductive care: an ethics committee opinion. *Fertil Steril*. In press.
- American Psychological Association. APA Guidelines for psychological assessment and evaluation. 2020. Available at: <http://www.apa.org/about/policy/guidelines-psychological-assessment-evaluation.pdf>. Accessed November 30, 2021.
- Leslie MC. The personality assessment inventory (PAI). Lawrence Erlbaum Associates Publishers, 2004.
- James JN. Minnesota multiphasic personality inventory. The Corsini Encyclopedia of Psychology, 2010:1–3.
- Practice Committee of the American Society for Reproductive Medicine and the Practice Committee for the Society for Assisted Reproductive Technologies. Guidance on the limits to the number of embryos to transfer: a committee opinion. *Fertil Steril* 2021;116:651–4.

Recomendaciones para prácticas que utilizan gestantes subrogadas: una opinión del comité.

Este documento ofrece las últimas recomendaciones para el cribado, evaluación, y asesoramiento legal y psicoeducacional de gestantes subrogadas y futuros padres. Incorpora la información reciente del centro americano para el control y prevención de enfermedades infecciosas, la administración americana de alimentos y medicamentos, y la asociación americana de bancos de tejidos, con lo que todos los programas que ofrecen servicios de gestantes subrogadas deben estar totalmente familiarizados. Este documento reemplaza al previo con el mismo nombre publicado en 2017.