



Clinical Guidelines for Assisted Reproductive Technology Service Providers for Screening of Gestational Surrogates

This guidance sets forth the New York State Department of Health’s criteria for screening of potential gestational surrogates (hereinafter, “surrogates”), as required by NYS Public Health Law¹. Suggested resources are provided at the end of this document.

Background:

Gestational surrogacy is when one bears a child with whom they do not share genetic material. Specifically, gestational surrogacy involves a person called a gestational carrier or surrogate to become pregnant through assisted reproductive technology on behalf of an individual or couple who will be the legal parent(s), referred to as the intended parent(s). Surrogacy provides another option for people to expand their families, but it also involves consideration of ethical, medical, psychosocial/psychological, and legal issues.

Purpose:

The purpose of this document is to specifically set forth expectations that gestational surrogacy health services in NYS be provided in accordance with the highest health care standards. Health care providers must provide respectful and holistic care to potential surrogates and surrogates. This includes supporting their psychosocial health, including social and emotional well-being, in addition to their physical health in determining if they can serve as a surrogate. Surrogates should be fully informed of the risks to their health and well-being for serving as a surrogate. These guidelines establish an expectation for high-quality services, but must be read in conjunction with recognized professional standards

Reminder regarding Legal and Ethical Considerations:

This document does not address the myriad of legal and ethical considerations which must be considered in caring for potential surrogates, surrogates and/or intended parent(s); instead, this guidance is limited to best practices as they relate to health care services. This is not to say that understanding the ethical and legal complexities are not instrumental in providing high-quality care. Health care providers caring for these patients should understand that surrogacy laws vary from state to state, and health care providers who care for potential surrogates, surrogates and/or intended parent(s) must understand the laws of the state(s) in which they practice and ensure their patients have appropriate legal counsel to support their legal needs and rights.

Health Care:

Potential surrogates, their partners (including spouses, domestic partners, or significant other), and intended parent(s) should receive appropriate assessments, evaluations and/or tests based on current professional medical standards, such as those issued by ASRM and ACOG. To minimize conflicts of

¹ Public Health Law § 2599-cc(1); see also General Business Law, Art. 44.

interest, potential surrogates, their partners, and intended parent(s) should, when practicable, have different health care providers.

1. Psychosocial evaluation and counseling are recommended for all potential surrogates and their partners to assess social supports and relationships that can support the surrogate (and their family) during the surrogacy process and pregnancy, including how to talk about the pregnancy and the anticipated potential emotional impact of the pregnancy and birth. This assessment should include a clinical interview and psychological testing as appropriate and in accordance with current guidelines of the American Psychological Association. Here are several factors that should be taken into consideration:
 - i. Relationships. The impact of surrogacy on any relationships between the surrogate and intended parent(s), as well as with the surrogate's family and community.
 - ii. Age. A potential surrogate must be between 21 and 45 years of age; there may be limited situations for surrogacy beyond 45 years of age; in these cases, all parties must be notified of and understand the risks of advanced obstetrical age;
 - iii. History and Environment. The following criteria are strongly recommended for screening of potential surrogates, within the context of clinical decision-making and patient-centered care:
 - a. The surrogate should have had at least one term uncomplicated delivery;
 - b. The surrogate should have had no more than five (5) previous deliveries, of which no more than 3 deliveries by cesarean delivery; and
 - c. the surrogate should have a stable family environment with adequate support to help the surrogate cope with the added stress of pregnancy.
2. Physical health and personal health history. This includes sexual health history and clinical examination, which should be conducted to ensure the potential surrogate is physically healthy. This review and examination should include:
 - i. A complete medical evaluation by a qualified medical professional, and the potential surrogate cleared for pregnancy before being considered as a surrogate for intended parents. Evaluation by a board-certified obstetrician or maternal-fetal medicine specialist who has experience with surrogacy is strongly encouraged.
 - ii. Discussion of the medical protocol, including scheduling demands, risks of cancelled cycle and unsuccessful cycle, risks and complications associated with pregnancy, multiple pregnancy, multifetal pregnancy reduction, prenatal diagnostic testing, and elective termination.
 - iii. A complete personal and sexual history to identify individuals who may be at high risk for HIV, sexually transmitted infection (STI) or other acquired infections that may be transmissible to the fetus.
 - iv. Testing for STIs including HIV testing and testing for other communicable infectious diseases that may harm the fetus, which should be conducted within 30 days prior to embryo transfer, for both the surrogate and their sexual partner(s). Specific laboratory tests are recommended in accordance with ASRM guidelines. Additional tests as determined by the health care professional and professional medical standards issued by ASRM and ACOG should also be conducted.
3. Informed Consent. A discussion of the elements of the informed consent, including risks and potential adverse effects of the process, and information regarding the source of gametes.

4. Psychological consultation should be conducted by a qualified licensed mental health practitioner to minimize any psychological harm from serving as a surrogate and cover specific topics such as:
 - i. Informing the potential surrogate and their partner(s) regarding the potential psychological issues and risks associated with the process.
 - ii. Individual and/or group counseling session on topics as identified by ASRM, ACOG and other professional organizations.
 - iii. Religious or spiritual beliefs that may influence behavior.
 - iv. Personality style, coping skills, capacity for empathy, maturity, judgement, assertiveness, and decision-making skills.
 - v. Current major life stressors or anticipated changes within the next two years.
 - vi. Personal histories, including social history (including occupational, financial, sexual and reproductive history, alcohol/tobacco/other substance use, legal history); psychiatric history; and history of emotional, physical, and/or sexual abuse.
 - vii. Gestational history and surrogacy history, including previous gestational carrier experience not limited to New York State, motivation to become a surrogate, desire for more children of their own, anticipated impact of surrogacy on the surrogate's children and partner(s), support of the surrogate's partner(s), and other social support networks.
 - viii. Negative medical consequences as it relates to the psychosocial adjustment of being a surrogate (e.g., bed rest, gestational diabetes, preeclampsia, previous postpartum disorder(s) and other unresolved negative reproductive events).
 - ix. Discussion of the requirement of intended parent(s)' agreement with the potential surrogate regarding all medical issues, and feelings about clinical aspects and potential outcomes of surrogacy, including:
 - a. Possible sexual abstinence;
 - b. Multiple pregnancy;
 - c. Need for bed rest, hospitalization, and pregnancy loss;
 - d. Decisions about termination of pregnancy, multifetal pregnancy reduction, amniocentesis, chorionic villi sampling, and other prenatal diagnostic testing; and
 - e. Reactions to the possibility of becoming infertile because of the process.
5. Disqualifying Factors. High-risk contraindications. Some conditions may serve make certain individuals unqualified or poorly qualified to serve as surrogates due to the impact on their health and wellbeing or that of the fetus. Potential surrogates should be screened for high-risk contraindications in the following areas:
 - i. Clinical factors that should lead to absolute rejection include:
 - a. HIV diagnosis;
 - b. Laboratory-confirmed Hepatitis B or active/untreated Hepatitis C infection, or physical evidence of hepatitis infection or risk factors (i.e., jaundice, hepatomegaly, icterus; recent tattooing or piercing within the past 6-12 months where sterile technique was not used); and
 - c. Evidence of substance use disorder.
 - ii. Clinical factors that may lead to rejection include:
 - a. Laboratory-confirmed sexually transmitted infection, or physical evidence of sexually transmitted infection;

- b. Recent history or evidence of smallpox vaccination (within 4 weeks);
- iii. Psychosocial factors that should lead to absolute rejection include:
 - a. Cognitive or emotional inability to comply or consent;
 - b. Abnormal psychological evaluation/testing as determined by the qualified mental health professional;
 - c. Unresolved or untreated addiction, child abuse, sexual abuse, physical abuse, depression, eating disorders, or traumatic pregnancy, labor, and/or delivery;
 - d. History of major depression, bipolar disorder, psychosis, or a significant anxiety disorder;
 - e. Chaotic lifestyle or current major life stressor(s);
 - f. Inability to maintain a respectful and caring relationship with the intended parent(s);
 - g. Evidence of emotional inability to separate from or surrender the child at birth; or
 - h. Evidence of financial, emotional or reproductive coercion, human trafficking or sex trafficking.
- iv. Relative psychosocial factors that may lead to rejection, include:
 - a. Failure to exhibit altruistic commitment to become a gestational carrier;
 - b. Insufficient emotional support from partner or support system;
 - c. Excessively stressful family demands;
 - d. History of conflict with authority;
 - e. Inability to perceive and understand the perspective of others;
 - f. Motivation to use compensation to solve own infertility; or
 - g. Unresolved issues with a negative reproductive event.

Conclusion:

Gestational surrogacy allows intended parent(s) to expand their families. Health care providers have an important role in supporting the holistic health and well-being of surrogates and intended parent(s). Surrogacy has many risks and benefits making it imperative that all parties involved seek appropriate legal and health care services to minimize risks for all parties. This is an evolving field and health care providers need to be aware of not only clinical best practices for the screening of surrogates, as articulated here and in professional standards (including ACOG and ASRM), but also the many state laws that impact surrogacy arrangements as well as the ethical issues involved.

Resources

American Psychological Association. (2017, January 1). *Ethical principles of psychologists and code of conduct*. Retrieved from American Psychological Association: <https://www.apa.org/ethics/code/index>

American Society for Reproductive Medicine. (2017, February). Recommendations for practices utilizing gestational carriers: a committee opinion. *Fertility and Sterility*, 107(2), e3-e10.

Ethics Committee of the American Society for Reproductive Medicine. (2018). Consideration of the gestational carrier: an Ethics Committee opinion. *Fertility and Sterility*, 1017-1021.

Swanson, K., Ayala, NK, et. al. (2020, April). Understanding gestational surrogacy in the United States: a primer for obstetricians and gynecologists. *American Journal of Obstetrics and Gynecology*, 330-337.

Additional Guidelines

NYSDOH Guidelines for Assisted Reproductive Technology Service Providers – Ova Donation:
http://health.ny.gov/community/pregnancy/surrogacy/docs/oocyte_donation_guidelines.pdf