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OVARIES, TESTICLES, AND UTERUSES, OH MY! REGULATING REPRODUCTIVE TISSUE TRANSPLANTS

VALARIE K. BLAKE*

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INTRODUCTION

Thirty-five years ago, the world watched in anticipation as Louise Brown, the first test-tube baby, was born.¹ Will Maya Butscher be the next miracle baby marked by history? Her mother became the first woman to receive a whole ovary transplant in 2008, after suffering

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1. *The World's First Test Tube Baby*, PBS AM. EXPERIENCE, <http://www.pbs.org/wgbh/americanexperience/features/general-article/babies-worlds-first/> (last visited Jan. 18, 2013).

premature menopause thirteen years prior.² Physician researchers at the Infertility Center of St. Louis, Missouri, transplanted Susanne Butscher's sister's ovary into Susanne and, within three months, she began ovulating naturally and became pregnant not long post-transplant.³ Only months before in Denmark, a woman gave birth to her second child; both children were a consequence of cryopreservation and transplantation of her own ovarian tissue.⁴ After cancer treatment threatened to rob her of the opportunity to have children, Mrs. Bergholdt gave birth to her first daughter, post-transplant, with the aid of in vitro fertilization (IVF), and baby boy Lucca was born naturally only a year later without the use of assisted reproduction.⁵ Spurred on by the successes of other types of reproductive transplants, researchers at the Gotheburg University of Sweden have permission to pursue attempted uterus transplants in ten women at the end of 2012 and have thus far transplanted uteruses into four women.⁶ Some of the potential participants are receiving donated wombs from their mothers, making it possible for them to give birth to children out of the same wombs that they themselves were conceived in.⁷ Meanwhile, doctors in the U.K. have set up a charity to pay for the final stages of their research and to begin experimental uterus transplants with five infertile women.⁸ All of these children, as a collective, represent the next possible breakthrough in the battle against infertility using reproductive tissue transplants (RTTs).

At the intersection of organ transplantation and assisted reproductive technology (ART), RTTs usher in a host of new ethical and legal challenges which could change the face of both fields of medicine. RTTs are the transplant of whole reproductive organs or organ slices, and currently include ovary, uterus, and testicle transplants.⁹ RTTs

2. See Gordon Rayner & Rebecca Smith, *Ovary Transplant Mother Speaks of Her "Indescribable" Joy After Giving Birth*, TELEGRAPH (Nov. 14, 2008), http://www.telegraph.co.uk/health/women_shealth/3460954/Ovary-transplant-mother-speaks-of-her-indescribable-joy-after-giving-birth.html.

3. See James Randerson, *Woman to Give Birth After First Ovary Transplant Pregnancy*, GUARDIAN (Nov. 9, 2008), <http://www.guardian.co.uk/science/2008/nov/09/health>.

4. See Helen Briggs, *Mother Has Second Child After Ovary Transplant*, BBC NEWS, Feb. 24, 2010, <http://news.bbc.co.uk/2/hi/8534227.stm>.

5. *Id.*

6. See Andrew Levy, *Woman Set to Give Birth from Her Own Mother's Womb After World-First Transplant*, DAILY MAIL (June 14, 2011), <http://www.dailymail.co.uk/health/article-2002938/Sara-Ottosson-Womb-transplant-mother-offer-25-year-old-chance-baby.html>.

7. See Linda Burke-Galloway, *Is Using Your Mother's Uterus an Option?* (Oct. 24, 2011, 10:51 AM), <http://drlindagalloway.wordpress.com/tag/sara-ottosson/>.

8. *Uterine Transplantation (UK) Charity*, WOMB TRANSPLANT U.K., <http://wombtransplantuk.org/index.php/uterine-transplantation-uk-charity> (last visited Jan. 18, 2013).

9. See Valarie K. Blake, *The New Frontier in Ethics and Infertility: Reproductive Tissue Transplant, A Case Study of the U.S. and the U.K.*, 3 AMSTERDAM L. F. 25, 25 (2011).

are still in their research phases, with even ovarian tissue transplants, the most advanced of all of the procedures, still requiring Institutional Review Board (IRB)– approved research protocols and all of the ethical and legal requirements therein.¹⁰ Yet with all of their promise, RTTs bring uncertainty as well. Mainly, these uncertainties include whether we will be able to regulate these unique new procedures if and when they roll out of research phases and transition into clinical practice, and if they would be treated like ART or like organ transplants. Such questions have implications for how we seek informed consent from both donors and recipients of reproductive tissues, who we permit to consent on behalf of a donor, how we decide who gets prioritized access to these resources, whether people who would decide to donate their reproductive tissues could get paid or whether that would be forbidden under the law, whether donors would have any particular parental rights over resulting offspring, disposition issues over cryopreserved organs, and proper research standards. Though RTTs are still in research phases, it is not too early for policymakers, lawyers, and ethicists alike to begin thinking about these new and unusual fertility treatments and what they mean for legal and clinical practice.

This article will explore key regulatory and ethical challenges presented by RTTs as they are currently developing, recognizing that additional issues may reveal themselves as the technologies progress. Part I of this article will begin with a discussion of the current status of the technology, including the results and status of animal and human experiments for all three types of transplants. Part II will explore the demand for RTTs—who might consider such a transplant and why RTTs might be considered by some patients as more favorable than other reproductive options. Part III will explore the different regulatory channels which might apply to RTT, including organ transplant ART and tissue regulations, mainly at the federal level. Having analyzed which rules are likely to apply to RTT, Part IV will discuss five key regulatory and ethical issues raised by RTT: research requirements for fair and safe research of RTT, informed consent of

10. The majority of these statements deal exclusively with ovarian tissue cryopreservation and transplantation, rather than uterus or testicle transplant, because the latter is much further advanced. Testicle transplant is currently mainly underway and uterus transplant research is only now beginning in humans. See, e.g., Ethics Comm. of the American Soc'y for Repro. Med. (ASRM), *Fertility Preservation and Reproduction in Cancer Patients*, 83 FERTILITY & STERILITY 1622 (2005) [hereinafter *Fertility Preservation*]; Practice Comm. of the ASRM & Practice Comm. of the Soc'y for Assisted Repro. Tech., *Ovarian Tissue and Oocyte Cryopreservation*, 90 FERTILITY & STERILITY S241 (2008) [hereinafter *Ovarian Tissue and Oocyte Preservation*]; Comm. on Gynecologic Practice, *Ovarian Tissue and Oocyte Cryopreservation*, 111 OBSTETRICS & GYNECOLOGY 1255 (2008); FIGO Comm. for the Ethical Aspects of Human Repro. and Women's Health, *Ethical Considerations and Recommendations on Oocyte and Ovarian Cryopreservation*, 2006 INT'L J. GYNECOLOGY & OBSTETRICS 92 (2006).

donors and recipients if RTTs become clinically available, allocation of reproductive organs, payment for potential donors, parental rights of donors, and disposition of cryopreserved organs.

I. TECHNOLOGICAL ADVANCEMENTS IN REPRODUCTIVE TISSUE TRANSPLANTS

Research on RTTs must undergo a number of phases before the procedures are shown to be suitable as a clinical treatment for infertile patients. First, animal studies typically precede experiments in humans to ensure certain levels of efficacy and safety and to develop and improve technique.¹¹ Even at the human level, researchers are looking at the viability and efficacy of different sources of RTT organs, particular surgical techniques, and best methods for cryopreservation. In terms of transplant location, researchers have several options to explore. Autograft occurs when the reproductive tissue is removed and then transplanted in the same individual's body.¹² In isograft, tissue is transplanted between identical twins, and in allograft, tissue is donated from one human donor into a separate human recipient.¹³ In addition, RTTs are being experimented with in the original location of the reproductive organ (orthotopic transplant), and also in other body regions, like the forearm or stomach.¹⁴ The success and attempt of each of these levels varies with each type of RTT.

A. Ovarian Tissue Transplant

Ovarian tissue transplant (OTT) is, to date, the most technologically advanced and successful of all the RTTs, with a number of human experiments showing great promise.¹⁵ Still, OTT is considered experimental, and all major reproductive societies recommend that protocols for human experimentation be regulated by research standards and undergo IRB approval before human participation.¹⁶ OTT would hold potential for a wide variety of individuals with ovarian-factor infertility, most notably women undergoing cancer treatment

11. See Anna S. Olsson et al., *Animal Research Ethics*, in HANDBOOK OF LABORATORY ANIMAL SCIENCE, 13, 18 (2d ed. 2003).

12. *Organ Transplant Ethics*, FOUNTIA, <http://www.fountia.com/organ-transplant-ethics> (last visited Jan. 18, 2013).

13. *Id.*

14. The latter type of transplant, of course, would require more extensive use of technology to achieve pregnancy. The woman would need to undergo treatments to harvest eggs from the arm or stomach and then have those eggs be fertilized in vitro, before the resulting embryos were implanted into the woman.

15. See *Fertility Preservation*, *supra* note 10, at 1624–25.

16. *Id.* at 1625.

who may be able to bank ovaries prior to undergoing chemotherapy.¹⁷ The first successful OTT occurred in 2004, when a patient rendered infertile from treatment for Hodgkins lymphoma gave birth after receiving an autografted transplant of ovarian tissue.¹⁸ The patient had biopsy samples of her ovarian tissue frozen in 1997 prior to the initiation of chemotherapy, and in 2003, when her cancer was in remission, physicians freeze-thawed the tissue and laparoscopically transplanted the tissue orthotopically.¹⁹ Eleven months after transplantation, physicians were able to confirm the presence of a live pregnancy.²⁰ The researchers recommended, as a consequence of their success, that all young women with cancer be given the choice to cryopreserve their ovarian tissue prior to onset of chemotherapy as a mechanism to preserve fertility.²¹ In a different study, sixteen young female cancer patients underwent ovarian autotransplantation with frozen tissue, with all women experiencing the return of normal menstruation.²²

In that same study, isograft of fresh ovarian tissue was attempted in nine women with identical twin sibling donations.²³ Again, all recipients who had previous premature ovarian failure developed normal menstrual cycles within five months post-transplant.²⁴ In a combination of the fresh and frozen tissue transplants, fourteen total pregnancies were established and eight healthy live births occurred, and two ongoing conceptions were present.²⁵ Six transplant recipients were able to conceive naturally, and one individual conceived twice.²⁶ The same study suggested that transplanted tissue can function as

17. *Ovarian Tissue and Oocyte Cryopreservation*, *supra* note 10, at S241–42 (noting a variety of other conditions which might indicate oocyte or ovarian tissue cryopreservation including: patients undergoing bone marrow or stem cell transplants, oophorectomy for benign tumors and endometriosis, autoimmune diseases like some severe forms of lupus).

18. See J. Donnez et al., *Livebirth After Orthotopic Transplantation of Cryopreserved Ovarian Tissue*, LANCET 1 (Sept. 24, 2004), available at <http://www.uclsluc.be/presse/communiques/2004/2004-tamara-lancet-complet.pdf> (showing that the patient had biopsy samples of her ovarian tissue frozen in 1997, and in 2003, physicians freeze-thawed the tissue and laparoscopy transplanted the tissue. Between five and nine months, regular ovulation cycles began.).

19. See *id.* (finding that menstrual cycles and hormonal measurements began to show signs of success at five months, with the woman experiencing menstruation from five to nine months post-transplant).

20. *Id.*

21. *Id.*

22. See Sherman Silber et al., *Duration of Fertility After Fresh and Frozen Ovary Transplantation*, 94 FERTILITY & STERILITY 2191, 2191 (2010) (showing that researchers were able to use a thawing technique for frozen tissue which resulted in a 89 percent preservation rate).

23. See *id.* (showing a twin sister who had undergone unexplained menopause at age fourteen received grafted ovarian tissue from her sister at age twenty-four. She became pregnant during her second menstrual cycle and delivered a full-term baby.).

24. *Id.*

25. *Id.*

26. *Id.* at 2193.

long as eight years post-transplant.²⁷ In both autograft and isograft cases, women did not need to undergo anti-rejection therapies because the tissue was a biological match. Moreover, in isograft, the donor egg genetic materials were identical to the recipient's gametes because the siblings were identical.

In 2007, a transplantation of ovarian tissue between non-identical siblings became the first successful allograft.²⁸ Allograft between siblings—and thus successful use of anti-rejection therapies—paves the way for donation between non-related persons and opens the gate for ovarian tissue transplants to be applied to a much wider population of infertile women. With increased efforts in this area, women without the opportunity or ability to bank their own tissue—and without twin siblings—may be able to participate in RTT. This last type of transplant poses the greatest number of legal and ethical challenges because of the use of an outside donor.²⁹ Of course, allograft would necessarily involve some measure of anti-rejection therapy, which also raises controversy.³⁰

Data to date has suggested that not only is ovarian tissue transplant possible, but it is also quite robust and effective for some individuals.³¹ In 2010, a woman in Denmark gave birth to her second baby resulting from transplant, nearly four years after having undergone transplant and without the aid of assisted reproduction.³² Thus, unlike ART, where the woman must undergo interventions each time she wishes to have a child, RTTs have the possibility of being a one-time intervention which can provide women years of reproductive viability.

27. *Id.* at 2194.

28. Jacques Donnez et al., *Live Birth After Allografting of Ovarian Cortex Between Genetically Non-Identical Sisters*, 26 HUM. REPROD. 1384, 1384–85 (2011).

29. Mohamed A. Bedaiwy et al., *Reproductive Organ Transplantation: Advances and Controversies*, 90 FERTILITY & STERILITY 2031, 2050 (2008).

30. See Tiffany Sharples, *A Hope to Preserve Fertility: Ovarian Transplants*, TIME, Mar. 10, 2009, <http://www.time.com/time/health/article/0,8599,1883894,00.html> (arguing that an individual will require less anti-rejection medication when she is related to the individual donating. Compared to other types of transplants, RTTs will also require less anti-rejection therapy because maintenance of the organ is not necessary for life, thus physicians will be more willing to take a risk in the transplant failing, says Dr. Sherman Silber, a leading expert in the area of RTT.). See also Bedaiwy et al., *supra* note 29, at 2043 (arguing that controversy over whether anti-rejection regimes are safe for the developing fetus is ripe. The gold standard for determining whether a transplant is considered successful now includes whether a woman undergoing anti-rejection medication was able to become safely pregnant without harm to the resulting child.).

31. See Briggs, *supra* note 4.

32. See *id.* (showing that Stinne Holm Bergholdt and her physicians were very surprised when she became pregnant naturally several years post-transplant. Ms. Bergholdt underwent autograft of her own cryopreserved tissue through the aid of physicians in Denmark.).

B. Uterus Transplant

Uterus transplants are less advanced and have shown promise only in animal models to date.³³ In its most simplistic terms, uterine transplants involve the transplantation of a uterus—from a deceased or living donor—into a woman, the onset of anti-rejection therapies, and then embryo implantation into the transplanted uterus to produce a pregnancy.³⁴ Because of the difficulties in attaching the uterus to other reproductive organs, researchers are not currently contemplating a transplant which would involve natural conception or birth. Instead, some artificial means of fertilization and cesarean birth would be necessary.³⁵ Once the woman has completed birth, the uterus would be surgically removed and immunosuppression drugs would eventually be stopped.³⁶

In animal models, researchers have succeeded at autotransplanting uteruses in both sheep and dogs and have a successful record of live births in mice.³⁷ Attempts with rhesus monkeys have been successful for autotransplant, but not donor transplant, and no viable, living pregnancies have resulted.³⁸ Moreover, physicians anticipate several hurdles in applying animal studies to the human model, given differences in “anatomy, graft size and tissue resistance in humans compared with non-human animals” as well as the complexity of the organ itself and the large number of blood supplies necessary to reconnect in order to make transplant successful.³⁹

The world’s first human uterus transplant was attempted in 2000 in Saudi Arabia when a young woman underwent allograft from a donor uterus.⁴⁰ Though the woman experienced two cycles of menstruation, the blood supply to the uterus became inadequate due to a kink

33. Mats Brännström et al., *Experimental Uterus Transplantation*, 3 HUM. REPROD. UPDATE 329, 329 (2010).

34. Helen Pearson, *Infertility Researchers Target Uterus Transplant*, 445 NATURE 466 (2007), available at <http://www.nature.com/nature/journal/v445/n7127/pdf/445466a.pdf>.

35. Otherwise, physicians would also have to master attaching the uterus to ovaries, fallopian tubes, and the vaginal canal, further complicating the procedure and drawing upon an already limited blood supply. The failure of the uterus to be connected to the birth canal poses greater risk than traditional pregnancy, however, because there is no mechanism for the child to be birthed other than surgical intervention.

36. Brännström et al., *supra* note 33, at 338.

37. *Id.* at 339; Anjana Nair et al., *Uterus Transplant*, 1127 ANNALS N.Y. ACAD. OF SCI. 83, 86 (2008).

38. See Albert Altchek, *Uterus Transplantation*, 70 MT. SINAI J. MED. 154, 162 (2003).

39. Bedaiwy et al., *supra* note 29, at 2037; Ruby Catsanos et al., *The Ethics of Uterus Transplantation*, 27 BIOETHICS 59, 67 (2013), available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1467-8519.2011.01897.x/pdf>.

40. Castano et al., *supra* note 39, at 59.

in a nearby artery, and the tissue became necrotic, forcing removal ninety-nine days post-transplant.⁴¹ Yet, the progress of certain surgical techniques has led researchers to hope that uterus transplant will someday be possible in humans. First, in 2007, a human uterus was successfully removed from a patient who was dead by neurological criteria.⁴² Additionally, uterus reattachment is possible and is a surgical technique currently used clinically to preserve the uterus of patients with cervical cancer.⁴³ The 2000 transplant failed because of poor surgical placement, not rejection of the uterus, showing some promise for future applications.⁴⁴

A current uterus transplant attempt was made in Turkey in August of 2011.⁴⁵ To date, the organ remains viable with no signs of rejection.⁴⁶ This transplanted uterus was sourced from a cadaver.⁴⁷

Researchers continue to seek approval from their institutions to attempt uterus transplant in female volunteers.⁴⁸ New York Downtown Hospital and its team of researchers have received IRB approval to begin recruiting female subjects for transplant with cadaver uteruses.⁴⁹ Moreover, a research team in Sweden began recruiting participants for an attempt at transplant and has so far achieved transplant in four participants.⁵⁰ The group has had success in animal models, including primates, which they believe are the best predictor of human success because of their similarity to human's vascular connections, pelvis shape, and uterus.⁵¹ At least two women have already been selected as participants for the experiment.⁵² U.K. physicians believe that they are ready to experiment on humans and have been recruiting research funds and volunteers for attempted

41. See Denise Grady, *Medical First: A Transplant of a Uterus*, N.Y. TIMES, Mar. 7, 2002, <http://www.nytimes.com/2002/03/07/world/medical-first-a-transplant-of-a-uterus.html> (involving a transplant from a forty-six-year-old woman to a twenty-six-year-old female who had underwent hysterectomy for a hemorrhage post-childbirth. The procedure had particular importance in Saudi Arabia and other Muslim countries where transplant of genetic material—like embryos or gametes—is impermissible but transplant of a uterus is permissible.).

42. See Pearson, *supra* note 34, at 467.

43. *Id.* at 466.

44. See Grady, *supra* note 41.

45. *Transplanted Uterus 120 Days Old*, UTERUS TRANSPLANTATION PROJECT (Dec. 8, 2011, 1:22 PM), <http://www.uterustransplantation.se/en/content/transplanted-uterus-120-days-old>.

46. *Id.*

47. *Id.*

48. Arthur L. Caplan et al., *Moving the Womb*, 37 HASTINGS CENTER REP. 18, 18 (2007).

49. *Id.*

50. *Where Are We Today?*, UTERUS TRANSPLANTATION PROJECT (2012), <http://www.uterustransplantation.se/en/patient/where-are-we-today> (last visited Jan. 18, 2013).

51. *Id.*

52. See Burke-Galloway, *supra* note 7.

transplants.⁵³ The physicians have yet to seek ethics approval for their experiments.⁵⁴

Like ovarian tissue transplants, women will need to undergo anti-rejection therapies to avoid rejection of the foreign organ.⁵⁵ Moreover, unlike OTT, a uterus transplant will involve a surgical procedure for the donor—whether deceased or living—chronologically close to the donee's surgery, because freezing methods for uteruses are not as advanced as in ovaries.⁵⁶

C. Testicular Tissue Transplant

Testicle transplants have received much less attention, likely due to the fact that sperm retrieval and storage is fairly cheap and effective and resolves most male-factor infertility.⁵⁷ However, sperm retrieval is not an option for pre-adolescent boys, and thus testicle cryopreservation and transplants would present a new reproductive option for young males facing infertility from chemotherapy or otherwise.⁵⁸ To date, research has focused on isolating and cryopreserving the germ cells which give rise to testicles in hopes that they could be autotransplanted back into the individual and successfully produce sperm.⁵⁹ Attempts to cryopreserve testicles have been successful in animal models since the mid-1990s, and spermatogenesis has been restored post-transplant in mice.⁶⁰ Human testicular freezing has been reported in a number of cases, but spermatogenesis was not reported.⁶¹ Reports of successful transplants in humans are minimal. Dr. Sherman Silber claims to have successfully transplanted a testicle between identical twin brothers in the 1970s, with the infertile brother having five children as a result.⁶²

53. *Womb Transplantation in the Future*, WOMB TRANSPLANT U.K., <http://wombtransplantuk.org/index.php/current-research/future> (last visited Jan. 18, 2013).

54. *Id.*

55. *Risks and Signs of Rejection*, UTERUS TRANSPLANTATION PROJECT, <http://www.uterustransplantation.se/en/patient/risks-and-signs-rejection> (last visited Jan. 18, 2013).

56. *Operation*, UTERUS TRANSPLANTATION PROJECT, <http://www.uterustransplantation.se/en/patient/operation> (last visited Jan. 18, 2013).

57. See Kanit Samanpachin et al., *Super-Microsurgery for Testis Organ Transplantation and Cryopreservation*, 1 ACAD. COLLABORATIONS FOR SICK CHILDREN 42, 42 (2009) (noting that successful sperm cryopreservation dates as far back as the 1950s when researchers successfully froze bovine sperm, closely followed in 1953 with the preservation of human sperm. Sperm preservation is much easier than egg freezing because the quantity of water in eggs crystallizes when frozen and essentially warps the resulting thawed egg.).

58. *Id.*

59. Robert E. Brannigan, *Fertility Preservation in Adult Male Cancer Patients*, in ONCOFERTILITY 28 (T.K. Woodruff & K.A. Snyder eds., 2007).

60. *Id.* at 45.

61. Samanpachin et al., *supra* note 57, at 43.

62. Sharples, *supra* note 30.

Like uterus and ovary transplants, anti-rejection therapies will be necessary with any allograft attempts of testicle transplants.

II. A DEMAND FOR REPRODUCTIVE TISSUE TRANSPLANTS

Transplantation of ovaries, uteruses, and testicles present new possibilities for patients with a variety of fertility conditions, including some conditions which were previously untreatable. The types of patients that might benefit from RTT over other types of fertility options will depend greatly on the type of RTT, whether a donor is necessary, the individual's preferences, the benefits and burdens of current alternative options, and how well RTTs develop into more cost-effective and efficacious treatments when compared with existing options.

Currently, without further advancement of RTTs, a number of options exist for infertile patients. Adoption is one option for individuals wanting a child, though it can be an expensive process and does not satisfy some people's goals of having a genetically related child.⁶³ For some types of infertility, hormonal therapies or artificial insemination may work.⁶⁴ Other types of assisted reproduction may treat more complex fertility issues. Gamete intrafallopian transfers (GIFT) and zygote intrafallopian transfers (ZIFT) involve the transfer of eggs and sperm or zygote into a woman's fallopian tubes.⁶⁵ Intracytoplasmic sperm injection (ICSI) allows for direct insertion of sperm into a woman's egg, and can treat many male-factor infertilities.⁶⁶ The most expensive and invasive of all the ARTs is in vitro fertilization, where a woman undergoes hormonal therapies and egg retrieval before fertilization of the egg outside the woman's body in a petri dish.⁶⁷ The resulting embryo(s) are implanted directly into the woman's uterus.⁶⁸ For uterine-factor infertilities, gestational surrogacy is an

63. See Melissa B. Jacoby, *The Debt Financing of Parenthood*, 72 LAW & CONTEMP. PROB. 147, 150 (2009) (showing that "[a]doption costs vary greatly depending on the type of adoption and the characteristics of the child." Whereas foster care adoptions can be relatively inexpensive, some adoptions can cost as much as \$30,000 or more. Additionally, foreign adoptions can be time-consuming and expensive.).

64. See James Ringo ed., *Assisted Reproductive Technologies*, 10 GEO. J. GENDER & L. 859, 860–61, 880 (2009) (showing that artificial insemination is a fairly simple and inexpensive procedure—approximately \$1,000 per attempt—when sperm is inserted into the female reproductive tract).

65. Debora Spar & Anna M. Harrington, *Building a Better Baby Business*, 10 MINN. J. L. SCI. & TECH. 41, 45 (2009).

66. ICSI is of course only appropriate for sperm mobility issues. When a man does not have any viable sperm—as in post-cancer scenarios—ICSI will not be possible.

67. Elizabeth A. Pendo, *The Politics of Infertility: Recognizing Coverage Exclusions as Discrimination*, 11 CONN. INS. L. J. 293, 300 (2005).

68. See *id.* (suggesting that IVF is more complex than another form of artificial insemination and showing that IVF resolves the largest portion of fertility deficits, because

option. Here, a woman agrees to gestate and birth another's child; this is another expensive option, with a price tag typically around \$20,000.⁶⁹ All of the above procedures may or may not involve the use of donated eggs and/or sperm as necessary.

Given current reproductive options for women with ovarian-factor infertility—including use of egg donors—OTT could present promising new options for many of these patients. Until the development of OTT, women with ovarian-factor fertility could not preserve their own genetic reproductive materials because egg cryopreservation techniques are not yet perfected.⁷⁰ Thus, for women who are undergoing autotransplant, OTT enables them to have genetically related children, which gamete donation does not permit.⁷¹ Particularly, young women with cancer in their reproductive years can bank their cryopreserved ovarian tissue to preserve their fertility before undergoing chemotherapy.⁷² Egg cryopreservation techniques have not yet been perfected, thus the clinical standard has been for women to cryopreserve embryos if they wish to preserve their fertility prior to the onset of chemotherapy.⁷³ Cryopreservation of embryos is a poor or impossible choice for many patients. To cryopreserve embryos, the woman must undergo hormonal therapies which initiate ovulation and increase the number of harvestable eggs.⁷⁴ The eggs are then fertilized with sperm outside of the body, and the resulting embryos are frozen and stored for later use.⁷⁵ Women with hormone-responsive cancers—when the cancer worsens as a result of hormonal increase—are not able to undergo the treatment necessary to harvest eggs, and some women are in need of such immediate treatment that there is no time to undergo egg harvesting first.⁷⁶ Additionally, adolescent females and children who have not begun ovulating cannot undergo egg harvesting, even though they have intact ovaries.⁷⁷ Moreover, for

it offers the greatest amount of intervention. However, cycles of IVF can cost upwards of \$10,000 per cycle, and a birth resulting from IVF can cost a total of approximately \$67,000.); Spar & Harrington, *supra* note 65, at 49–50 (providing data on costs of IVF).

69. See Jennifer Watson, Note, *Growing a Baby for Sale or Merely Renting a Womb: Should Surrogate Mothers Be Compensated for Their Services?*, 6 WHITTIER J. CHILD & FAM. ADVOC. 529, 531–32 (2007) (“Currently, the typical fee for a first time surrogate mother ranges from \$14,000 to \$18,000, with an average of \$15,000.” Costs can be even greater when the surrogate agrees to additional medical tests or to carry or implant multiple fetuses.).

70. Teresa K. Woodruff, *The Oncofertility Consortium—Addressing Fertility in Young People with Cancer*, 7 NATURE REV. CLINICAL ONCOLOGY 466, 471 (2010).

71. Blake, *supra* note 9, at 25–26.

72. Woodruff, *supra* note 70, at 470–71.

73. *Id.* at 467.

74. *Id.* at 470.

75. *Id.* at 467.

76. *Id.* at 470–71.

77. *Id.* at 473.

single women without a reproductive partner, preservation of their fertility required a male partner and may be less desirable than preservation of one's own fertility singularly.⁷⁸

For women who require donated ovary tissue, though genetic reproduction is not possible, OTT may still be preferable to gamete donation for a number of reasons. For some patients, a single surgical procedure may be preferable to repeated IVF attempts with donor gametes. RTT allows for pregnancy the natural way—without the use of technology—and the individual can have multiple children, rather than singularly with each attempt at ART.⁷⁹ For example, Stephanie Yarber elected to have her sister's ovarian tissue transplanted into herself after several failed attempts at IVF and because she always dreamed of having children “the old-fashioned way.”⁸⁰ There is also the possibility that RTT could someday be more effective than IVF, as well as less expensive. One patient who underwent tissue banking paid \$5,000 for the procedure instead of the \$15,000 it would have cost for egg donation.⁸¹ The woman who undergoes OTT will also experience ovulation. This is not present in gamete donation but may be psychologically important to the individual.⁸²

OTT may someday also enable women without disease-related infertility to put their reproductive potential on ice while they pursue social, financial, or professional goals.⁸³ This is a highly contested use

78. Woodruff, *supra* note 70, at 470.

79. *Id.* at 471.

80. Sharples, *supra* note 30.

81. See Sylvia Pagán Westphal, *New Way to Extend Fertility: Freeze Tissue from Ovaries*, WALL ST. J., Apr. 26, 2007, <http://online.wsj.com/article/SB117755381630982975.html>. Costs are estimated at around \$10,000–\$20,000 for the process of stimulation and retrieval, \$500 for freezing and storage, \$1,000 for thawing, and then \$1,200 for an intracytoplasmic sperm injection—when multiple efforts may be necessary. Alison Motluk, *Growth of Egg Freezing Blurs 'Experimental' Label*, 476 NATURE 382, 383 (2011). In terms of efficacy, a survey of sixty-four percent of U.S. clinics, forty-five out of 140 clinics had not yet thawed a cryopreserved egg for clients, at least thirty clinics had yet to have a successful birth, and eleven have achieved only one live birth, with only eight clinics achieving greater than ten live births for patients. *Id.*

82. All of the above considerations may be viewed as important factors in a woman undergoing autotransplant, as well.

83. See Westphal, *supra* note 81 (arguing that the issue is not applicable to uterus transplant because a woman's uterus does not deteriorate with time, and male fertility remains later into life. In contrast, women are born with hundreds of thousands of eggs which dwindle over her life span until only about 1000 eggs remain at age fifty); see also *Ovarian Tissue and Oocyte Cryopreservation*, *supra* note 10, at S243 (noting that, given the current risk-to-benefit ratio of oocyte and ovarian tissue preservation and the lack of current knowledge about who is a proper candidate, as well as best methods for tissue collection and freezing, and lower rates of successful pregnancy versus normal IVF, ASRM does not yet recommend that ovarian tissue cryopreservation be marketed or offered for women who wish to delay reproduction); Motluk, *supra* note 81, at 383 (arguing that while this is the policy, there are critiques that this is not occurring in practice and that women

of the technology which, as OTT develops, will certainly raise ethical and legal controversy.⁸⁴

Uterine factor infertility (UFI), except for some minor malformations, has always been untreatable.⁸⁵ With the new possibility of uterine transplant, however, there may now be a medical solution for UFI patients who wish to carry and birth their own genetically related offspring without the use of a gestational surrogate.⁸⁶ A uterine transplant could be medically indicated for a number of conditions, including congenital absence of the uterus or acquired absence due to fibroids, intrauterine adhesion, or hysterectomy—including cesarean hysterectomies and hysterectomy indicated from cancer of the cervix—among others.⁸⁷ One study estimates that of the 62 million women of reproductive age in the United States, approximately 9.5 million, or about 15.4 percent of this population, has UFI.⁸⁸ Given current fecundity rates, a majority of these women could be expected to want to reproduce.⁸⁹

Testicle transplants could enable men without these sex organs—due to congenital, accidental, or disease-related absence—to conceive naturally without the use of IVF or other forms of ART.⁹⁰ For some male cancer patients, testicular tissue preservation could enable

are banking eggs to delay reproductive aging without proper research protections in place to ensure data is shared and efficacy is proven before becoming standard clinical practice. For example, it is estimated that 2000 people worldwide have been born from frozen eggs, including 400 in the United States, demonstrating somewhat widespread use of the practice.).

84. See Imogen Goold & Julian Savulescu, *In Favour of Freezing Eggs for Non-Medical Reasons*, 23 *BIOETHICS* 47, 47 (2009) (listing arguments in favor of allowing egg freezing for reproductive delay or “social IVF” including: equal participation for women in employment, delay in allowing women time to find a suitable reproductive partner, more time for couples to become financially stable and thus better opportunities for resulting children, increasing the pool of available eggs and embryos for the medically infertile, and avoidance of moral concerns raised by freezing of embryos—a significant problem as personhood debates persist in the United States); Shiri Shkedi-Rafid & Yael Hashiloni-Dolev, *Egg Freezing for Non-Medical Uses: The Lack of a Relational Approach to Autonomy in the New Israeli Policy and in Academic Discussion*, 38 *J. MED. ETHICS* 154, 156 (2012) (citing controversy over Israel’s new policies authorizing and regulating the freezing of eggs for non-medical reasons).

85. Bedaiwy et al., *supra* note 29, at 2041.

86. *Id.*

87. Nair et al., *supra* note 37, at 83.

88. *Id.* at 84–85.

89. See *id.* One New York hospital recently published data on women seeking information about uterine transplant at their hospital and determined that, of the over 500 women who sought information, the majority were Caucasian, with ages ranging from twenty-four to thirty-six, most were married, over half had some form of college education, and the largest portion had hysterectomy from endometriosis. A. R. Nair et al., *Applicants for Uterine Transplantation: Description of Candidates*, 90 *FERTILITY & STERILITY* S170 (2008).

90. Victoria Lambert, *Fertility: Stop All the Clocks*, *TELEGRAPH* (Nov. 26, 2009), http://www.telegraph.co.uk/health/women_health/6651648/Fertility-stop-all-the-clocks.html.

them to preserve fertility when sperm banking is not possible. For example, such a procedure can be used if they have already had to initiate chemotherapy and are not producing sperm.⁹¹ Preservation of whole testicle tissue may also be an option for pre-pubescent males who have not started producing sperm, where before there was never a possibility of fertility preservation among this group.⁹² Testicle transplants with a donor, like autotransplant of ovaries, may be preferred in cases where the individual wants to conceive naturally, when a single surgery is preferred over repeated ART attempts, or if testicle transplant someday becomes more effective or cheaper than other options.⁹³

All three types of RTTs may also have special implications in different cultures where ART—or certain iterations of it—is not permitted.⁹⁴ For example, in some cultures, the use of a gestational surrogate or a gamete donor is forbidden or more strictly regulated because each option is viewed as a form of adultery or incest.⁹⁵ Moreover, in some countries—and even in some states in the United States—where parental rights are uncertain with respect to surrogates and gamete donors, RTT may be preferable, depending on how the courts will view them.⁹⁶

III. POTENTIAL REGULATORY MECHANISMS

Reproductive tissue transplants (RTT) hold elements of both organ transplantation and reproductive technology, making regulation a challenging and unique prospect.⁹⁷ From a medical perspective, they involve the transfer of human tissue either within the same body or between a donor and a recipient body, in much the same way as transplantation.⁹⁸ Issues of allocation, consent for donation, consent for retrieval, and payment are all raised as in transplantation.⁹⁹

91. Brannigan, *supra* note 59, at 45.

92. Samanpachin et al., *supra* note 57, at 42.

93. Steve Connor, *Doctors Plan First Testicle Transplant*, INDEPENDENT (Sept. 24, 1999), <http://www.independent.co.uk/life-style/health-and-families/health-news/doctors-plan-first-testicle-transplant-742015.html>.

94. See, e.g., *Guidelines & Legal: Embryo Research*, EUR. SOC'Y OF HUM. REPROD. & EMBRYOLOGY, <http://www.eshre.eu/ESHRE/English/Guidelines-Legal/Legal-documentation/Italy/page.aspx/167> (last visited Jan. 18, 2013) (indicating that, for instance, Italy strictly forbids the practice of egg donation. Whether they would permit oocyte banking for self-use is uncertain.).

95. Rhonda Schuz, *Surrogacy in Israel: An Analysis of the Law in Practice*, in *SURROGATE MOTHERHOOD: INTERNATIONAL PERSPECTIVES* 35, 47 (Rachel Cook et al. eds, 2003) (showing, for example, that traditional Jewish faith views surrogacy as akin to adultery).

96. See *infra* Part IV.E.

97. Blake, *supra* note 9, at 26.

98. *Id.* at 25.

99. *Id.* at 26.

However, more akin to reproductive technologies, RTT raises issues related to reproductive potential, who has authority to make reproductive decisions, and parental rights questions which are entirely new and foreign in transplant medicine. How these medical procedures are classified impacts which regulations apply and how many ethical and legal issues will be decided with respect to RTT.¹⁰⁰ However, because of their uniqueness, RTTs do not fit wholly under a single regulatory mechanism, and future clinical regulation will likely have to involve an amalgamation of regulations to appropriately capture the complexities of these new technologies.¹⁰¹

Four federal regulatory mechanisms are discussed which may play a defining role in RTT: 21 C.F.R. Parts 1270 and 1271 Food and Drug Administration (FDA) rules on tissue transplantation; Department of Health and Human Services (DHHS) organ transplant rules; the Fertility Clinic Success Rate and Certification Act (FCSRCA), which regulates assisted reproductive technologies; and the Uniform Anatomical Gift Act (UAGA), which regulates cadaver donation of organs. Some of these regulations will or will not apply depending on how RTTs are statutorily classified—DHHS versus FDA purview—whereas others will depend on the specifics of the individual RTT, such as whether it involves transplantation of a cadaver donor (UAGA) or the use of assisted reproductive technology (FCSRCA).

A. Food and Drug Administration Rules vs. Department of Health and Human Services Rules

The classification of RTTs has major implications on whether they are regulated under FDA or the DHHS—and their encompassing organ transplantation regulations. The division of labor hinges on whether RTTs meet the classification for an organ or a tissue.

The FDA is the foremost government agency tasked with regulating food, drugs, and medical devices.¹⁰² It was originally created as a consumer protection agency dealing with agricultural products in the 1800s and later shifted its focus in the early part of the twentieth century to the protection of the public from adulterated or misbranded food and drug products.¹⁰³ Among its purview are vaccines, bloods, and biologics.¹⁰⁴ This includes all “human cells or tissues that are intended

100. *Id.* at 27.

101. *Id.*

102. John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last updated June 18, 2009).

103. *History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last updated July 29, 2010).

104. *Vaccines, Blood & Biologics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/default.htm> (last visited Jan. 18, 2013).

for implantation, transplantation, infusion, or transfer into a human recipient.”¹⁰⁵ The regulations specifically cover “bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen” and exclude “[v]ascularized human organs for transplantation.”¹⁰⁶

Human cell, tissue, and cellular and tissue-based product (HCT/P) regulations require three main things. First, tissue establishments must screen and test tissue donors in an effort to reduce communicable disease transmission through tissue transplant.¹⁰⁷ Second, tissue establishments must follow written procedures that are current good tissue practices established by the FDA.¹⁰⁸ Third, these groups must maintain records, including registering and listing their practices of tissue transplant with the FDA.¹⁰⁹

Vascularized human organ transplants are reserved for the regulatory power of the Department of Health and Human Services (DHHS).¹¹⁰ It achieves its work through the Organ Transplant and Procurement Network (OPTN), which was enacted by the National Organ Transplant Act (NOTA) of 1984.¹¹¹ NOTA was mainly enacted to ensure fair and consistent allocation of a finite and life-saving resource across the nation.¹¹² Once a specific type of transplant is accepted under DHHS rules, it is no longer in the purview of the FDA.¹¹³

Currently, OPTN applies to the following organs: “a human kidney, liver, heart, lung, or pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract).”¹¹⁴ In December of 2011, DHHS proposed a new rule which would include vascularized composite allografts (VCAs) on the list of vascularized human organ transplants that are covered under OPTN.¹¹⁵ DHHS proposes that a VCA be defined by a number of common characteristics. First, the transplant must require connection of blood vessels (vascularization).¹¹⁶ It must contain multiple types of tissue that are recovered from donors, transplanted into

105. 21 C.F.R. § 1271.1(d) (2011).

106. *Id.*

107. 21 C.F.R. § 1270.21(a) (2011).

108. 21 C.F.R. § 1270.31 (2012).

109. 21 C.F.R. § 1271.10(b) (2012).

110. 21 C.F.R. § 1270.3(j) (2012).

111. *Organ Procurement and Transplantation Network*, 76 Fed. Reg. 78,216, to be codified at 42 C.F.R. 121 (Dec. 16, 2011), available at <https://www.federalregister.gov/articles/2011/12/16/2011-32204/organ-procurement-and-transplantation-network>.

112. *Id.*

113. *Id.*

114. *Id.* at 78,218.

115. *Id.* at 78,220

116. *Id.*

recipients as a structural unit, and minimally manipulated so as not to alter the organ's original utility.¹¹⁷ The transplant must involve homologous use, which means that it was used for the same function in the donor as in the recipient.¹¹⁸ It must not be combined with another item, like a device.¹¹⁹ It must be susceptible to ischemia, and thus be only temporarily storable, and it must require immunosuppression.¹²⁰ DHHS intends this to cover "faces, hands, fingers, toes, larynges, and abdominal walls," but the list is not exclusive.¹²¹

If DHHS applies to RTTs, then the National Organ Transplant Act (NOTA) applies.¹²² NOTA established rules to qualify organ transplant procurement groups. It regulates these groups and requires standards for allocation, proper retrieval, and transportation of organs.¹²³ NOTA also calls for the OPTN to be operated by a non-profit, private and federally contracted group, which has been accomplished through the United Network for Organ Sharing (UNOS).¹²⁴ UNOS has its own rules for operations, mainly dealing with how to transport, procure, and allocate organs among those in need of them.¹²⁵ If DHHS has regulatory authority, then NOTA rules, specifically its organ allocation rules, will apply to RTT. They will follow the unique allocation rules set forth by both NOTA and UNOS.¹²⁶ UNOS distributes organs based on a point system which assigns points according to three principles: "sickest-first (current medical condition); first-come, first-served (waiting time); and prognosis (antigen, antibody, and blood type matching between recipient and donor)."¹²⁷ The principles are weighted differently depending on the organ, with some, like heart transplants, weighing "sickest" the heaviest, whereas transplants like kidney and pancreas emphasize "first-come, first-served." UNOS also considers geographic proximity to the available organ.¹²⁸

However, before an individual can be listed on UNOS, local transplant centers must agree to list the patient based on "medical,

117. *Organ Procurement and Transplantation Network*, *supra* note 111, at 78,220.

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. *About OPTN*, U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/optn/history.asp> (last visited Jan. 18, 2013).

123. 42 U.S.C. § 273 (2006).

124. *Id.*

125. *Policy Development*, UNITED NETWORK FOR ORGAN SHARING, http://www.unos.org/donation/index.php?topic=policy_development (last visited Jan. 18, 2013).

126. 42 U.S.C. § 273.

127. Govind Persad et al., *Principles of Allocation of Scarce Medical Interventions*, 373 LANCET 423, 426 (2009).

128. *OPTN*, UNITED NETWORK FOR ORGAN SHARING, <http://www.unos.org/donation/index.php?topic=optn> (last visited Jan. 18, 2013).

surgical, and psychosocial suitability for transplantation.”¹²⁹ There is no standard requirement for what psychosocial factors must be considered to be listed for transplant, so these vary among transplant centers and are at the sole discretion of the center’s committees and/or transplant teams.¹³⁰ Potential psychosocial factors considered may include substance abuse and treatment, family and support network, financial resources, past and present medical noncompliance, employment history, spiritual beliefs, access to transportation, psychiatric illness, future goals, adaptation to stress and coping skills, relationship with the care team, hobbies and interests, and military experience, among others.¹³¹ If RTTs were to follow an allocation scheme like that of other organ transplants, it would be important to determine whether, and to what extent, psychosocial criteria and medical criteria such as those described above would be included in the decision of who should get an RTT and why.

It remains unclear whether RTTs, collectively or individually, will classify as VCAs under the DHHS rule or as tissues under the FDA rule. Of course, the DHHS rule has not been finalized and definitions may change.¹³² Uterus, ovary, and testicle transplants all require vascularization, are minimally manipulated, are subject to ischemia, and serve the same biological function for both donors and recipients.¹³³ However, not all RTTs appear to be transferred as structural units. The uterus must be transplanted whole, but ovaries and testicles can be transplanted whole or as tissue slivers.¹³⁴ Moreover, it is unclear whether these reproductive organs contain multiple types of tissues and whether multiple types of tissues will be used in each type of transplant.¹³⁵ Additionally, not all RTT procedures involve immunosuppression. Transplant of one’s own tissues or of an identical sibling’s does not risk rejection, but allografts will require anti-rejection therapies, making it quite possible that auto and isograft transplants

129. Nancy E. Flamme et al., *The Influence of Psychosocial Evaluation on Candidacy for Liver Transplantation*, 18 *PROGRESS IN TRANSPLANTATION* 89 (2008).

130. *Id.*

131. *Id.*

132. *Policy Management*, U.S. DEP’T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, available at <http://optn.transplant.hrsa.gov/plainlanguage.asp> (last visited Jan. 18, 2013).

133. Roger G. Gosden, *Focus on Fertility Preservation: Ovary and Uterus Transplantation*, 136 *REPROD.* 671, 676 (2008).

134. *Id.*

135. The uterus contains both smooth muscle and epithelial tissue, the testicle and ovary are both epithelium, and all three are encased in some form of connective tissue. Depending on how these different transplants continue to develop and whether they include casings as part of the transplant, this will impact whether they constitute an RTT. It is possible, given this reading, that despite the similarities of RTTs, some RTTs may be classified as VCA and subject to the DHHS whereas others will not.

could be regulated under FDA whereas other donor transplants will come under DHHS.¹³⁶

The distinction between FDA and DHHS regulation in organ transplant may be the first of its kind, given that autotransplant of whole organs was never a preferred treatment before this.¹³⁷ Individuals did not put a kidney or a liver “on ice” for later use. Likewise, although organ transplants with identical siblings raised a similar concern, this has never been an issue because NOTA’s purview was previously defined by specific types of organs—liver, kidney, etc.—and not by whether the transplant required immunosuppression.¹³⁸ Although transplant of one’s own tissue does not raise many of the key issues that should be covered by NOTA—like informed consent and protection of the donor—transplantation by a sibling does.¹³⁹

Although it is unclear whether the new DHHS rule will apply to RTTs—at least those involving a donor—the intent of the new rule argues for its application to RTTs. The FDA regulations were originally designed to protect the public from adulterated products, whereas the DHHS rules establish fair allocation of limited resources.¹⁴⁰ The new rule anticipated broader types of organ transplant, like hand and face. RTTs, like these transplants, involve issues of distribution and allocation, more than just whether the product is safe for human use.¹⁴¹ Consequently the DHHS rules can handle some of the complicated issues that will arise with respect to donation, retrieval, storing, and allocation of these materials, whereas the FDA regulations only provide guidance on safety and registries.¹⁴²

B. Fertility Clinic Success Rate and Certification Act and Assisted Reproductive Technology Regulation

RTTs do not fall under the Center for Disease Control’s definition of assisted reproductive technologies (ART), which requires that “both eggs and sperm are handled.”¹⁴³ However, RTTs are a high-tech

136. Gosden, *supra* note 133, at 671.

137. *Id.*

138. 42 U.S.C. § 273(d)(2).

139. Kendra D. MacLeod et al., *Pediatric Sibling Donors of Successful and Unsuccessful Hematopoietic Stem Cell Transplants (HSCT): A Qualitative Study of Their Psychosocial Experience*, 28 J. PEDIATRIC PSYCHOL. 223, 226 (2003).

140. 42 C.F.R. § 121.8 (2000).

141. *Id.*

142. U.S. FOOD & DRUG ADMIN., FDA FOOD CODE 2009, available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm186464.htm> (last visited Jan. 18, 2013).

143. *What Is Assisted Reproductive Technology?*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/art> (last updated Aug. 1, 2012).

manipulation of the reproductive system, not unlike in vitro fertilization and other forms of ART, and additionally, many applications of RTT will require some form of ART to achieve pregnancy.¹⁴⁴

Federal regulation of ART is highly minimal. The Fertility Clinic Success Rate and Certification Act (FCSRCA) applies to regulate all labs where embryos are handled, including clinics where IVF is performed.¹⁴⁵ It provides minimal regulation—mostly administrative and reporting requirements—and will likely apply to some phase of RTT, even if only when the patient requires the use of IVF, such as during a possible uterus transplant.¹⁴⁶

Otherwise, ART is regulated on a state-by-state basis, with some states simply not regulating and others regulating a patchwork of issues, including embryo storage and disposition, gestational surrogacy, and inheritance for posthumously conceived children.¹⁴⁷ To the extent that RRTs require some form of ART, the FCSRCA will at least apply to the application of the ART itself.¹⁴⁸

C. Uniform Anatomical Gift Act

The Uniform Anatomical Gift Act (UAGA) developed by the National Conference of Commissioners on Uniform State Laws (NCCUSL) applies in all states that have adopted its most recent 2006 iteration.¹⁴⁹ The UAGA regulates all cadaver donations of anatomical gifts, whether for organ transplantation or for scientific use.¹⁵⁰ The Act defines “anatomical gift” as a “donation of all or part of a human body to take effect after the donor’s death for the purpose of transplantation, therapy, research, or education.”¹⁵¹ Donors can consent to donate their organs during life, typically through a designation on their driver’s license, will, or other legal document.¹⁵² The UAGA also permits certain representatives of the decedent to donate bodily

144. *Id.*

145. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 [hereinafter FCSRCA].

146. *Id.*

147. Valarie Blake & Kavita Shah, *Reproductive Tissue Transplants Defy Legal and Ethical Categorization*, 14 AM. MED. ASS’N J. ETHICS 232, 233 (2012).

148. *Policy Documents*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/art/Policy.htm> (last updated July 24, 2012).

149. *Unif. Anatomical Gift Act*, UNIFORM LAW COMM’N (2006), <http://www.uniformlaws.org/Act.aspx?title=Anatomical%20Gift%20Act%20%282006%29> (introducing the UAGA in 1968 and revising it in 1987 and 2006. The UAGA has been adopted in 45 states and the District of Columbia.).

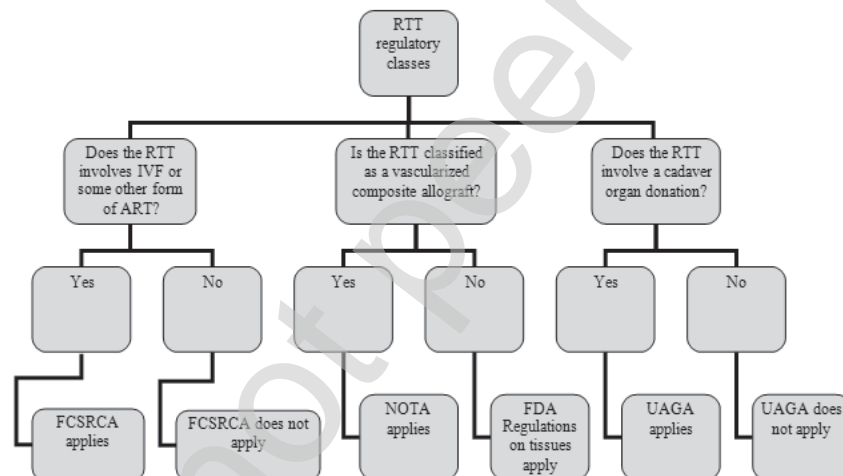
150. Revised Uniform Anatomical Gift Act (2006) (last amended 2009), at 3, *available at* http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf [hereinafter UAGA].

151. *Id.* § 2(3).

152. *Id.* § 2(6).

organs and tissues when the wishes of the deceased are not known.¹⁵³ Basically, this amounts to any close family member or caretaker, or anyone who has authority to dispose of the decedent's body.¹⁵⁴ If the deceased party's wishes with respect to donation are unknown, the spouse, adult child, parent, sibling, grandchild, etc. may have the authority to donate the individual's organs.¹⁵⁵ The UAGA does not specifically speak to reproductive organs, and reproductive organs are not explicitly excluded from the regulation.¹⁵⁶ The UAGA will apply in any instance of RTT when a deceased person's body is donated, whether for research or clinical purposes.¹⁵⁷ The Flowchart of Applicable Regulations in RTT shows which regulations apply in any given type of RTT.

FLOWCHART OF APPLICABLE REGULATIONS IN RTT



IV. ETHICAL AND REGULATORY ISSUES RAISED BY REPRODUCTIVE TISSUE TRANSPLANT

RTTs, as a class and individually, raise unique ethical and legal questions, in addition to echoing some prior legal challenges raised

153. *Id.* § 9 (including an agent of the deceased—who had the power to make a donation during the decedent's life like a guardian—and then in the following descending order: a spouse, adult child, parents, adult sibling, adult grandchild, grandparents, "adult who exhibited special care and concern for the decedent," person who was acting as guardian to decedent at time of death, or any other person who has authority to dispose of the decedent's body).

154. *Id.* § 9.

155. *Id.*

156. See UAGA, *supra* note 150.

157. Blake & Shah, *supra* note 147, at 233.

by reproductive technologies and/or by transplant. Though RTTs are still in their research phases, the unprecedented nature of these procedures calls for critical engagement on the issue of regulating them. Particularly when donors are involved, informed consent will need to capture aspects of both transplant and reproductive technology.¹⁵⁸ Allocation of the resources, if donor transplant is possible, will also be key, as will decisions about compensating donors for their efforts, a major contradictory issue when comparing ART versus transplant. Moreover, parental rights claims and dispositional authority issues are raised, and for all RTTs, the issue of proper research ethics.

A. Research Ethics

Because all RTTs are currently in research phases, the issue of proper research regulation and ethics is dispositive.¹⁵⁹ Testicle transplant is currently only in animal phases, but ovarian tissue transplant is currently underway in human participants, and uterus transplant studies of human participants are currently forming.¹⁶⁰ Whether RTT clinical trials are regulated under FDA or DHHS human subjects protections depends on which agency has authority over the research.¹⁶¹ However, the distinction makes little difference because the two bodies of regulations mirror each other in most key provisions.¹⁶² The FDA and the DHHS are virtually identical with respect to key provisions like IRB approval of studies, definitions of minimal risks, authorized representatives, etc.¹⁶³ The UAGA and The FCSRCA provide no guidance here, as they presume clinical practice rather than research.¹⁶⁴

In general, all RTT human subject trials will need to seek IRB approval and will need to obtain robust informed consent from both recipients and, where applicable, donors.¹⁶⁵ Moreover, in the case of uterus and ovary tissue transplant cases, if DHHS regulations apply, special rules exist for research involving pregnant women, human fetuses, and neonates.¹⁶⁶ Generally, such regulations require a minimization of risks and require proper preclinical studies—on animals

158. *Id.*

159. *Id.* at 232.

160. W. Fageeh et al., *Case Report: Transplantation of the Human Uterus*, 76 INT'L J. GYNECOLOGY & OBSTETRICS 245, 247 (2002).

161. Blake & Shah, *supra* note 147, at 233.

162. *Comparison of FDA and HHS Human Subject Protection Regulations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112910.htm> (last updated Mar. 10, 2009).

163. *Id.*

164. See UAGA, *supra* note 150, at 1; FCSRCA, *supra* note 145, § 2(a).

165. *Ovarian Tissue & Oocyte Cryopreservation*, *supra* note 10, at S243.

166. 45 C.F.R. § 46.201(a) (2009).

and, when possible, nonpregnant women.¹⁶⁷ Participants must be informed of reasonably foreseeable impact on the fetus, and the research may need to offer either direct benefit to the woman, or to the woman and fetus. If there is no participation benefit, the research must involve no greater than minimal risk and must be intended to generate important biomedical knowledge.¹⁶⁸ Particularly in RTT, because of the vulnerability of many of the infertile persons being enrolled in such trials, informed consent will need to make it clear that the research is not intended to benefit the individual, but rather to obtain generalized knowledge about the procedures.¹⁶⁹ Disclosures of risks must include the risks to the potential fetus and the individual—including risks of immunosuppression—as well as alternative treatment options that are available to the individual.¹⁷⁰ One considerable risk in cancer patients is the concern that the cancerous cells will be transplanted back into the patient with the reproductive tissue transplant, so histological evaluation of tissues is necessary.¹⁷¹ Participants must also be informed of the likelihood of success.¹⁷²

Some authors have suggested—in other areas of research related to gamete donation—that participants must be selected in a just manner so that only those who stand to benefit from the research can be selected for participation.¹⁷³ In their example, it is unethical to recruit infertile women as egg donors for stem cell research on general medical conditions.¹⁷⁴ Instead, these women should be recruited for studies regarding infertility, and women from the general public should be recruited for general medicine studies and treated as healthy volunteers.¹⁷⁵ In a discussion of these values to the case of oocyte preservation studies, “women whose cancer treatments are likely to adversely affect their fertility” are recommended as the best population to enroll in such trials because they stand to benefit the greatest from the developing procedures.¹⁷⁶ “Fertility patients, reproductive

167. 45 C.F.R. § 46.204 (2009).

168. *Id.*

169. Angela Ballantyne & Sheryl de Lacey, *Wanted—Egg Donors for Research: A Research Ethics Approach to Donor Recruitment and Compensation*, 1 INT’L J. FEMINIST APPROACHES TO BIOETHICS 145, 150 (2008).

170. See, e.g., Dianne B. McKay & Michelle A. Josephson, *Reproduction and Transplantation: Report on the AST Consensus Conference on Reproductive Issues and Transplantation*, 5 AM. J. OF TRANSPLANTATION 1592, 1593 (2005).

171. *Ovarian Tissue and Oocyte Cryopreservation*, *supra* note 10, at S243.

172. 45 C.F.R. § 46.116 (2003).

173. Ballantyne & de Lacey, *supra* note 169, at 150.

174. *Id.* at 151.

175. *Id.* at 145.

176. Michelle L. McGowan, *Participation in Investigational Fertility Preservation Research: A Feminist Research Ethics Approach*, in ONCOFERTILITY 209, 218 (T.K. Woodruff & K.A. Snyder eds., 2007).

oocyte donors, and healthy research volunteers may be suitable research subject populations for the basic research associated with investigational fertility preservation techniques . . . but the potential risks to their own reproductive health and the potential for commodification of their reproductive tissues” make them more vulnerable.¹⁷⁷ When applied more generally to RTT trials across all types of reproductive tissues, this will hold true as well. Persons who stand to benefit greatest from the technology are recommended as the primary audience for recruitment into clinical trials.

It is also important to note that the model of recruiting those most likely to benefit has been used in clinical trials of ART generally, “but one danger of this precedent has been that investigational techniques have often moved into clinical use in the private medical sector with professionally generated practice guidelines instead of using a model of controlled clinical trials.”¹⁷⁸ It will be important to avoid this and ensure clinical trial applications for RTTs to ensure safety and efficacy for generalized populations, and to ensure certain baseline protections for participants.

B. Informed Consent in Clinical Application

Informed consent derives from the basic principle of respect for persons and the right of individuals to make decisions about their bodies.¹⁷⁹ Informed consent can serve many functions: it protects individual autonomy as well as the patient’s status as a human being, it prevents fraud and duress, it encourages doctors to consider their decisions while fostering decision-making in patients, and it involves the public generally in medicine.¹⁸⁰ Informed consent has generally been thought of as the anecdote to an overly paternalistic system of medicine, allowing the patient’s voice to enter the equation as a true consideration, equal to or greater than medical considerations.¹⁸¹ The informed consent doctrine has developed in the courts over time, as malpractice cases have increasingly defined the obligation of physicians to ensure that patients are informed of the reasonably anticipated benefits, risks, and burdens of treatment.¹⁸²

Generally, informed consent in RTT in a clinical context should involve an explanation of risks, benefits, and burdens of treatment,

177. *Id.*

178. *Id.* at 213.

179. Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PENN. L. REV. 340, 366 (1974).

180. *Id.* at 364, 366, 369, 371, 374, 376.

181. *Id.* at 399.

182. *Id.* at 348.

including the effect of immunosuppression on the individual and the potential fetus, risks of surgical interventions generally, the statistical likelihood of viable pregnancy (as derived from research and clinical data) and any other treatment options for the individual. Special consent issues are raised with respect to RTTs that involve living or deceased donors.

1. *Informed Consent by Donors*

Informed consent for donors in the context of RTT will significantly differ depending on whether the donor is living or deceased. Traditionally, living organ donors are a protected group and many precautions are in place to ensure that a donor's decision is free of coercion and is fully informed and voluntary.¹⁸³ Provisions to protect living donors include a division of responsibility from donor and recipient teams and specially mandated living donor advocates who protect the living donor and ensure adequate informed consent.¹⁸⁴ The added precautions are in place because living donors expose themselves to significant medical risk without any anticipated clinical benefit for themselves, but rather for the benefit of the recipient.¹⁸⁵ Special informed consent provisions for living donors apply. OPTN requires informed consent for donors according to applicable legal authority, as a condition of approving the transplant center.¹⁸⁶ It does not currently provide specific rules for deceased donors.¹⁸⁷ DHHS's Advisory Committee on Organ Transplantation does provide a lengthy list of recommendations related to living donation.¹⁸⁸ Within informed consent, the donor must have decision-making capacity and must be willing to donate. The donor should be free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits to the donor, and fully informed of the risks, benefits, and alternative treatment options for recipients.¹⁸⁹ The Center for Medicare and Medicaid

183. 42 C.F.R. § 482.98(d) (2007).

184. *Id.*

185. U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, POLICIES: LIVING DONATION 12.2 (Dec. 13, 2012), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_172.pdf [hereinafter OPTN, LIVING DONATION] (noting the importance of informed consent for living kidney donors).

186. U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, POLICIES: MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO) (Sept. 1, 2012), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_2.pdf [hereinafter OPTN, MINIMUM PROCUREMENT STANDARDS].

187. *Id.*

188. *Summary Recommendations to the Secretary*, DEP'T OF HEALTH & HUM. SERVS., ADVISORY COMM. ON ORGAN TRANSPLANTATION, <http://organdonor.gov/legislation/acotsummaryrec.html> (last visited Jan. 18, 2013).

189. *Id.*

requires that consent include an understanding of the following: the confidentiality of the communication between donor and transplant center; the evaluation process and surgical procedure; the medical and psychosocial risks; the alternatives to donation; data on medical outcomes; the possibility of future health problems; insurance coverage concerns; and a right to opt out at any time.¹⁹⁰

Informed consent for living donors of uteruses, ovaries, and testicles will be unique.¹⁹¹ For example, in donating a kidney, the donor risks the need for transplant or death if his other kidney fails him, and he may experience other medical issues from having only one kidney, in addition to the risk of general surgery.¹⁹² Donors of reproductive organs may experience some harms from donation that are non-life-threatening, such as early menopause or hormonal difficulties after removal of ovaries or uteruses, or experience risks of general surgery, though surgeries in ovary and uterus transplant may be less invasive if done vaginally.¹⁹³ Akin to living organ donors more broadly, however, all of these risks are at the clinical benefit of the recipient, not the donor.¹⁹⁴

Most importantly, however, the current living donor informed consent standards fail to address reproductive concerns, i.e., the fact that the donation is intended to create the donor's genetically related offspring for the upbringing of the recipient.¹⁹⁵ ASRM clinical guidelines spell out the proper mechanisms for preventing communicable disease transmission by the donor to the recipient of egg or sperm, as well as proper screening to prevent genetic disease transmission to the offspring.¹⁹⁶ Similar guidelines will need to apply in the context of RTT—specifically egg and testes transplants—when genetic materials are involved.

Though the Fertility Clinic Success Rate Act does not provide specific guidance regarding donors and thus is not a useful model, general guidance from consenting gamete donors in ART may prove

190. 42 C.F.R. § 482.102(b) (2007) (noting that these regulations only exist with respect to CMS certifications, approval, and reimbursement of a transplant center. At this stage in RTT it is difficult to tell if RTT will be performed in traditional transplant programs and whether it would be covered under insurance, though these regulations provide a useful model.).

191. Blake & Shah, *supra* note 147, at 232.

192. He also may have risked insurance discrimination prior to the onset of the ban on insurance refusal for pre-existing conditions.

193. See, e.g., Gosden, *supra* note 133, at 671.

194. OPTN, LIVING DONATION, *supra* note 185, at 12.2.

195. Blake & Shah, *supra* note 147, at 234.

196. Practice Comm. Of the Am. Soc'y for Reprod. Med. & the Practice Comm. of the Soc'y for Assisted Reprod. Tech., *2008 Guidelines for Gamete and Embryo Donation: A Practice Committee Report*, 9 FERTILITY & STERILITY S30 (2008) [hereinafter *2008 Guidelines*].

useful.¹⁹⁷ Like living organ donation, donors of gametes experience some level of risk—the risk is much smaller in sperm donation than in egg donation—for the benefit of a recipient rather than the donor.¹⁹⁸

The American Society for Reproductive Medicine (ASRM) Ethics Committee published guidelines in 2009 to protect the interests and rights of gamete donors, including informed consent considerations.¹⁹⁹ ASRM recommends that gamete donors “be fully informed of the risks of the process, including, but not limited to, the medical risks.”²⁰⁰ Donors should also be informed that genetic tests may be carried out and whether they will be informed of results.²⁰¹ They should be informed that donation will sever their legal rights to have contact with any resulting child, that there might be a level of compensation, and that they can seek independent legal counsel.²⁰² They should be informed of the emotional benefits and risks of donation and of the emotional implications their donation may have on children they have or will have in the future, as well as the possibility that the resulting offspring may someday have the ability to find and contact them.²⁰³ These provisions surrounding consent and risks, benefits, and burdens of donation are unique to donation of reproductive material, and are simply not addressed by current guidelines or literature of other types of organ donations.²⁰⁴ The ASRM provide some level of guidance regarding risks of procedures not intended to benefit the donor—as particularly gamete donors undergo some measure of clinically invasive procedure to donate.²⁰⁵ The OPTN guidelines provide a greater level of protection for informed consent, including understanding the consequences for both donor and recipient, which is also important and valid to RTT, like other transplants.²⁰⁶ Though it is premature to speculate at what the ideal requirements of informed consent for RTT will be, it will need to involve an amalgamation of both gamete donor and organ donor guidelines to address the broad spectrum of issues raised by RTT donation.

197. The reproductive aspect of gamete donation is somewhat inapplicable to uterus transplant because it does not involve the transplant of genetic material. However, gestational surrogacy informed consent is somewhat inapplicable to uterus transplant because, although both involve donation of a womb, gestational surrogacy involves much more risk to the woman than uterus transplant, as the pregnancy and birthing occur in the donors body.

198. Ethics Comm. of the Am. Soc’y for Reprod. Med., *Interests, Obligations, and Rights of the Donor in Gamete Donation*, 91 FERTILITY & STERILITY 22, 25 (2009).

199. *Id.* at 24.

200. *Id.*

201. *Id.*

202. *Id.*

203. *Id.* at 24–25.

204. See, e.g., OPTN, LIVING DONATION, *supra* note 185.

205. 2008 Guidelines, *supra* note 196, at S36, S40.

206. OPTN, LIVING DONATION, *supra* note 185, at 12.2.

RTT could also implicate deceased donors, which present distinct issues from informed consent by the living. Whereas some attempts at uterus transplant involve living donors, others have involved cadaver uteruses. Moreover, cryopreservation techniques of testicle and ovarian tissue could lead to an eventual consideration of cadaver donation. Again, the FDA and the FCSRCA provide little guidance here.²⁰⁷ OPTN requires consent from the donor according to applicable legal authority, whether living or deceased.²⁰⁸

With cadaver donation, UAGA would apply because deceased donation places it in the realm of an anatomical gift.²⁰⁹ In deceased donations, currently the UAGA applies for any type of organ or tissue donation, whether of a reproductive nature or not.²¹⁰ This measure was set in place to increase the availability of life-saving organs and to respect the presumed wishes of the deceased.²¹¹ This presents unique and unusual results in the context of RTT when the anatomical gift has reproductive potential (ovary and testicle transplants) for two main reasons: 1) it essentially allows family members like parents or siblings to make reproductive decisions on behalf of the deceased and 2) it provides for the possibility of reproduction posthumously.²¹² With respect to the first issue, traditionally, reproductive decisions have been confined to the individual or the couple.²¹³ The only major area in which reproductive decision-making is broadened beyond the scope of the individual or the couple is in abortion by a minor, as some states may require parental consent.²¹⁴ The right to reproduce is seen in the courts as a fundamental one, central to an individual's identity, and traditionally left up to the individual or the couple's choice.²¹⁵ Without

207. Pub. L. No. 102-493, 106 Stat. 3146 (1992).

208. OPTN, MINIMUM PROCUREMENT STANDARDS, *supra* note 186, at 2.4.

209. UAGA § 2(3).

210. *Id.* § 2(18).

211. *Id.* at Brief description of act.

212. *Id.* §§ 5, 9.

213. Blake & Shah, *supra* note 147, at 233 (noting that reproductive decisions are ones that we do not traditionally leave up to our next of kin).

214. *State Policies in Brief: An Overview of Minors' Consent Law*, GUTTMACHER INST. (Jan. 1, 2013), available at http://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf.

215. *Planned Parenthood v. Casey*, 505 U.S. 833, 896 (1992) (citing *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976) (ruling that “‘when the wife and the husband disagree on this decision, the view of only one of the two marriage partners can prevail. Inasmuch as it is the woman who physically bears the child and who is the more directly and immediately affected by the pregnancy, as between the two, the balance weighs in her favor.’ This conclusion rests upon the basic nature of marriage and the nature of our Constitution: ‘[T]he marital couple is not an independent entity with a mind and heart of its own, but an association of two individuals each with a separate intellectual and emotional makeup.’”)); *Roe v. Wade*, 410 U.S. 113, 169 (1973) (affirming the individual's right to choose); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) (arguing that “the right of the individual, married or single, to be free from unwarranted governmental intrusion into

the express wishes of the decedent being known with respect to posthumous use of gametes, it seems inappropriate to permit family members to donate eggs or testicles. Such an act touches upon broader fundamental interests than other organ donations and, additionally, does not have such a countervailing interest in preserving life to justify greater infringement on the deceased's rights or interests.

Second, the context of reproductive tissue gifted posthumously by family allows for posthumous reproduction.²¹⁶ This concern is not unique to RTT; ART in general has created this possibility with the development of techniques to cryopreserve embryos and sperm.²¹⁷ Generally, posthumous reproduction cases have dealt with spousal requests to use a preserved embryo or sperm sample.²¹⁸ The request by other family members is much more controversial and also much less common. It would require more caution, and may never be permissible in the context of RTT, unless the wishes of the donor are known.²¹⁹ With spousal posthumous reproduction, ASRM is generally viewed as permissible if the wishes of the deceased have previously been known.²²⁰ At the initiation of storage of gametes and embryos, individuals are encouraged to express their disposition wishes if they may die.²²¹ Though heavy philosophical debates might center on whether and to what extent an individual has a reproductive interest or right

matters so fundamentally affecting a person as the decision whether to bear or beget a child" is inherent in this nation's understanding of privacy).

216. Am. Soc'y for Reprod. Med. Ethics Comm., *Posthumous Reproduction*, 67 FERTILITY & STERILITY 8S, 8S (1997) [hereinafter *Posthumous Reproduction*].

217. Posthumous reproduction is not to be confused with posthumous birthing, when the child is born without both parents living. The latter is a common occurrence that can occur without the use of technology, but the ability to conceive a child when already deceased requires modern and special technology.

218. See *Posthumous Reproduction*, *supra* note 216, at 8S.

219. *Hecht v. Superior Court*, 20 Cal. Rptr. 2d 275 (Cal. Ct. App. 1993) (showing that posthumous reproduction legal cases have centered around issues of who is the parent, property rights of decedent's gametes, and inheritance rights of resulting children. In this notable case, William Kane bequeathed his sperm to girlfriend Deborah Hecht for use at his death. The court held that the sperm was a type of property which could be bequeathed in Kane's estate. Additionally, the court found that postmortem insemination was not against public policy, nor that public policy forbid artificial insemination of Hecht because she was unmarried. Resultantly, Hecht was granted access to Kane's sperm posthumously.); see also Lisa M. Burkdall, Note, *A Dead Man's Tale: Regulating the Right to Bequeath Sperm in California*, 46 HASTINGS L.J. 875, 880–81 (1995); Sheri Gilbert, Note, *Fatherhood from the Grave: An Analysis of Postmortem Insemination*, 22 HOFSTRA L. REV. 521, 558 (1993) (comparing a French court case in which a wife of a deceased husband who had banked his sperm prior to chemotherapy asked for use of the sperm after his death, and the court focused instead on "whether it was the decedent's intent for his sperm to be used to father a child after his death." The court ordered the sperm bank to return the sperm to the wife, focusing on compelling evidence that the husband would have wanted his wife to have a child and the wife's sacred right to birth.).

220. *Posthumous Reproduction*, *supra* note 216, at 9S.

221. *Id.*

to control their reproductive potential after death, it is generally viewed to be on more ethically solid ground to only perform posthumous reproduction when the wishes of the donor are known and, when applicable, the gestational surrogate and other relevant parties are informed.²²² Likewise in RTT, UAGA currently can be read as permitting a wide range of close relatives and agents to donate reproductive tissue on behalf of the deceased.²²³ As RTT develops, the UAGA will need to address this unique aspect of anatomical gifts and should not permit donation of reproductive materials, with a possible exception of personal use by the spouse, and with similar protections in place as other cases of posthumous reproduction require.

2. *Informed Consent by Recipients*

Recipients of RTT are also going to require a hybrid of some of the considerations raised by other reproductive procedures, as well as organ transplantation consideration, because of the dual nature of the procedure. OPTN requires that recipients also provide informed consent when receiving an organ, and particularly spells out documented informed consent requirements from the patient or the patient's representative when there is a risk of HIV transmission.²²⁴ Apart from these basic requirements, there is very little regulatory guidance or guidance in the literature on obtaining consent for organ transplant.²²⁵ This is presumably because, up until very recently, organ recipients have been in life-or-death situations.²²⁶ With the advent of quality of life organ transplants like hand, face, or RTT, greater measures will need to be in place to aid potential recipients in weighing the benefits and burdens of the transplant to make a quality of life evaluation that reflects their own personal wishes and values. An individual will need to understand the medical risks at stake as well as the likelihood of success in choosing to undergo surgery and receive anti-rejection medications in order to reproduce. Again, guidance on consent for other high-tech reproductive interventions like IVF may prove useful. Additionally, however, the unique issues raised by receiving the organs of another individual, deceased or living, may require additional requirements or considerations outside those raised by ART.

222. *Id.*

223. UAGA § 9a(1)–(9).

224. OPTN, MINIMUM PROCUREMENT STANDARDS, *supra* note 186, at 2.2; U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, POLICIES: IDENTIFICATION OF TRANSMISSIBLE DISEASES IN ORGAN RECIPIENTS 4.2 (Dec. 13, 2012), available at http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_16.pdf.

225. JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., HEALTH CARE AT THE CROSSROADS 16 (2004).

226. Persad et al., *supra* note 127, at 424 (describing the "sickest first" ethical principle of organ allocation).

C. Allocation Decisions

Another key regulatory issue relates to allocation of medical resources, an issue with distinct outcomes depending on which regulations apply. OPTN provides the greater measure of guidance on this issue, as it was built to deal with the allocation of a scarce and life-saving medical resources to those in need.²²⁷ OPTN provides different guidance depending on the type of transplant in question, but mainly the question of allocation revolves around medical urgency and distance criteria.²²⁸ Persons who are the best match and the most likely to achieve the greatest benefit from the organ are the likeliest to get it, because the system is based on gleaning the greatest use out of the scarce resource.²²⁹ The use of psychosocial criteria likewise is applied to ensure that individuals who will receive the greatest benefit and longevity from the organ receive it.²³⁰ Apart from geographic criteria, the system has great limits when applied to RTT. The UNOS criteria have limited use when applied to uterine transplant.

First, it is unclear how medical prognosis or urgency criteria would apply here, given that RTT intends to treat infertility, a disease which does not have a scale.²³¹ Persons who are seeking out RTT to reproduce will be likely more or less equally infertile. Certainly, some individuals may be more likely to achieve pregnancy than others (and we can likely measure some of these outcomes from previous experience with ART—for example, age decreases likelihood of successful pregnancy). Prognosis (the extent to which the recipient would match the donor uterus) could be quantified similarly to other organ transplants.²³² Additionally, some individuals may not be able to be recipients of uterine transplant for medical reasons. If they have significant other health issues that would contraindicate organ transplant or pregnancy generally, or if they are lacking or have scarred vascular

227. U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, CHARTER, art. II (June 24, 2004), *available at* http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_CHARTER_II_-_NOV_04.pdf.

228. U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, POLICIES: ALLOCATION SYSTEM FOR ORGANS NOT SPECIFICALLY ADDRESSED, 3.9 (Nov. 9, 2010), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_11.pdf.

229. *Id.*; U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, POLICIES: ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION (Sept. 1, 2012), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_6.pdf.

230. *Facts About Living Donation*, U.S. DEP'T OF HEALTH & HUM. SERVS., ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/about/donation/livingDonation.asp> (last visited Jan. 18, 2013).

231. Blake, *supra* note 9, at 29.

232. *Id.*

connections due to cancer or congenital anomalies, then uterine transplant may not be medically appropriate for them.²³³ However, with a large number of candidates, these factors will not likely provide an efficient or complete way to sort candidates. Additionally, if the organ should go to the person with the likeliest chance to benefit, this may mean something entirely different, like an individual who is nearing the end of her reproductive years or who has tried the greatest number of attempts at commercial surrogacy. For this reason, a first-come, first-served allocation system seems more feasible, though this raises its own issues of equity and fairness.²³⁴ Some ethicists strongly critique the first-come, first-served method of distribution, because it can be manipulated by wealthy individuals who place themselves on multiple transplant lists or by transplant centers that manipulate their patients' healthcare state in order to improve their chances of receiving organs.²³⁵

A special mention of the unique consequences of psychosocial criteria in the context of RTT should also be mentioned. Psychosocial measures should have been developed based on measures of predictable medical outcome.²³⁶ They are social factors that impact how well a person will recover from transplant, how likely they are to follow through on a challenging and continuous medical regime, etc.²³⁷ Because these measures have been based on long-term maintenance of the organ, they have limited application to RTT.²³⁸ The case of RTT, after all, only requires short-term maintenance until reproduction can be achieved.²³⁹ Within a pool of candidates who are all likely to maintain the organ for the period of reproduction, then, other non-psychosocial criteria should be applied, like first-come, first-served. Moreover, the measures previously only considered successful maintenance of the organ itself; in other words, did the candidate keep the organ and survive? In RTT for uteruses and ovaries, success will be measured not just by healthy maintenance of the organ but also by achievement of pregnancy, as that is the intended goal of the organ transplant.

Committees making decisions about transplant distribution are used to weighing the interests of many stakeholders.²⁴⁰ Stakeholders

233. Caplan et al., *supra* note 48, at 20.

234. Persad et al., *supra* note 127, at 424.

235. Arthur L. Caplan, IF I WERE A RICH MAN COULD I BUY A PANCREAS? AND OTHER ESSAYS ON THE ETHICS OF HEALTH CARE 146–47, 169–70 (1992).

236. Flamme et al., *supra* note 129.

237. *Id.*

238. *Id.*; Nair, *supra* note 37, at 85.

239. Nair, *supra* note 37, at 85.

240. Flamme et al., *supra* note 129.

in traditional organ transplant would include the patient, the living or deceased donor, the donor and recipient's family and support system, the transplant team, etc.²⁴¹ However, in the case of uterine transplant, where the goal is to produce a viable pregnancy, some may argue that there is another stakeholder involved: the potential child whose birth is enabled by the transplant.²⁴² In fact, scholars have already assumed that the well-being of the child should be considered, at least with regards to whether we should permit reproductive tissue transplants to occur at all given the use of anti-rejection medications during pregnancy.²⁴³

It is unclear to what extent psychosocial criteria could or should be used to determine the well-being of a potential child, but it certainly could lead to a slippery slope of considering the quality of the individual as a potential parent, rather than simply a recipient of an organ. Debates have already formed around whether to provide ART to persons with questionable child rearing abilities.²⁴⁴ Although there is no systematic attempt—nor practical ability—to screen everyone who reproduces coitally, the question has been raised whether ART candidates should be screened like adoption candidates.²⁴⁵ As ASRM points out in a relevant ethics statement, home visits are inappropriate because there is no current child to protect, yet providers of ART are not removed from the psychosocial and other aspects of the infertility patient and may occasionally see behaviors that they fear would compromise any resulting offspring. The ASRM ethics statement recommends that providers may screen patients on the basis of offspring welfare but are not morally obligated to withhold services.²⁴⁶

Other guidance on allocation in this context is rather slim. The FCSRCA does not deal with the issue of allocation, and ART generally is allocated as to who is willing and able to pay for the procedure.²⁴⁷

241. Persad et. al., *supra* note 127.

242. Caplan et al., *supra* note 48, at 19.

243. *Id.*

244. The Ethics Comm. of the Am. Soc'y for Reprod. Med., *Child-Rearing Ability and the Provision of Fertility Services*, 92 FERTILITY & STERILITY 864, 865 (2009) [hereinafter *Child-Rearing Ability*].

245. *Id.* at 864.

246. *See id.* at 867 (noting the fear that providers will potentially discriminate against disabled individuals for fear of potential offspring and recommending that such refusals only occur when the provider has a well-substantiated basis for thinking the individual could not provide, or find others to provide, for the offspring. In cases of substance abuse, child abuse history, etc., physicians are recommended to make their decisions based on empirical evidence and not stereotype or prejudice, and involvement of psychologists or mental health workers may be appropriate.).

247. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (1992); *Child-Rearing Ability*, *supra* note 244, at 864.

D. Payment of Donors

Payment of donors is another significant disparity between organ policies and reproductive medicine policies. For deceased organ donation, the UAGA forbids payment—“[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”²⁴⁸ “[V]aluable consideration” does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.”²⁴⁹ Organ donation draws a distinction between remuneration to make a donor “whole again” after donations versus a commercial market where individuals can knowingly sell their organs for personal profit.²⁵⁰

A number of ethical arguments are advanced against payment. Mainly, there is a concern that allowing for payment will lead to exploitation of the poor, with a two-tier system being created when the poor donate the organs and the rich receive them.²⁵¹ Critics also fear that sale of human organs will devalue human life, place a price on human life, and create a vision of human beings as a means rather than an end in themselves.²⁵² However, the 1997 Bellagio Task Force on Transplantation, Bodily Integrity, and the International Traffic in Organs found no single ethical argument to support a universal payment on organs at all times, and this view has been echoed by many prominent ethics scholars.²⁵³ Living organ donors are also prohibited from receiving valuable consideration, and are left to cover their own lost wages and other expenses incurred by their donation.²⁵⁴

248. 42 U.S.C. § 274e(a) (2006).

249. 42 U.S.C. § 274e(c)(2) (2006).

250. *Id.*

251. Jessica Cynowiec et al., *Incentivizing Living Organ Donation*, 14 CURRENT OPINION IN ORGAN TRANSPLANTATION 201, 202 (2009).

252. See L.D. de Castro, *Commodification and Exploitation: Arguments in Favour of Compensated Organ Donation*, 29 J. MED. ETHICS 142, 142 (2003); *Opinion 2.15—Transplantation of Organs from Living Donors*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion215.page?> (last updated June 2011) (“Living donors should not receive payment for any of their solid organs. However, donors should be treated fairly; reimbursement for travel, lodging, meals, lost wages, and the medical care associated with donation is ethically appropriate”).

253. D.J. Rothman et al., *The Bellagio Task Force Report on Transplantation, Bodily Integrity, and the International Traffic in Organs*, 29 TRANSPLANTATION PROCEEDINGS 2739 (1997); A.S. Daar, *Paid Organ Donation: The Grey Basket Concept*, 24 J. MED. ETHICS 365, 365 (1998).

254. Amy L. Friedman, *Payment for Living Organ Donation Should Be Legalised*, 333 BMJ 746, 746 (2006).

Organs are unique because payment is permitted in many other bodily donations.²⁵⁵ Hair, blood, semen, ova, and plasma are all saleable for profit.²⁵⁶ Payment for gametes is, in fact, a burgeoning market in the United States. Sperm donors receive smaller sums, around \$100 for their less-invasive donations, but egg donors can conservatively receive upwards of \$3,000–\$5,000 for one IVF cycle.²⁵⁷ Colloquially known “Ivy League” eggs, or eggs from a donor who is attributed with certain physical or intellectual features desirable to the recipient(s), can garner up to \$25,000–\$50,000.²⁵⁸ ASRM has proposed a cap on payment of egg donation, with payments of greater than \$5,000 requiring “justification” and sums above \$10,000 being “not appropriate.”²⁵⁹ In this sense, ASRM is suggesting the payment correlate to the level of harm and inconvenience that the donor undergoes, but not for payment of the egg itself.²⁶⁰ Whereas there certainly have been critics in opposition of payment for gametes, as well, the status quo is a commercial market when personal profit is permissible. Similar concerns of commodification and exploitation apply here as in organ donation.²⁶¹ However, ASRM has supported payment of gamete donation for a number of reasons. Mainly it provides fair compensation for the burdens placed on the donor, without dampening the altruistic reasons why a woman would donate.²⁶² A true comparison of the ethics of payment for organs versus reproductive tissues would be expansive and outside of the scope of this article. However, one major distinction is that organ donation, up until the advent of RTT, will involve organs which are necessary for life, like kidneys and livers.²⁶³ Though kidney donors can live off of a single kidney, it has some medical impact and there is always a risk that they will need a transplant if their second kidney is compromised. Donation of a uterus or ovary will not present the same concern.²⁶⁴ Though women may go through premature menopause, just as they would with premature ovarian failure or hysterectomy, reproductive organs are not necessary for life. If a woman donated one ovary and the other ovary later failed, she would not need a transplant to survive. There may be something ethically salient

255. *Id.* at 747.

256. *Id.*

257. Spar & Harrington, *supra* note 65, at 46–47.

258. *Id.* at 47.

259. Ethics Comm. of the Am. Soc’y for Reprod. Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305, 308 (2007) [hereinafter *Financial Compensation of Oocyte Donors*].

260. *Id.* at 306.

261. *Id.*

262. *Id.* at 307.

263. Nair, *supra* note 37, at 85; Rothman, *supra* note 253.

264. Rothman, *supra* note 253.

about the fact that the egg is not a full bodily organ, although the ovary is. It seems more likely that the concern is around the harm to the donor and the fear of coercing them, through payment, into too great a personal harm. Although more normative considerations are necessary to address this key distinction between reproductive tissue transplants and other types of organ transplant, there is a strong argument that RTT should be treated more like gamete donation in this context, and thus valuable consideration may be permissible.²⁶⁵

E. Parental Rights

The issue of parental rights has certainly never been addressed in transplantation decisions. However, because the end goal of RTT is to produce a child, RTT will raise all the same issues that gestational surrogacy and gamete donation raised with respect to parental rights.²⁶⁶

Parental rights of gamete donors come under a number of arguments including genetic-identity argument (that genetic relation takes precedence) as well as property rights over gametes.²⁶⁷ For surrogates, arguments surround maternal bonds created through gestation and birthing, and the best interests of the child.²⁶⁸ For intended parents, their intent to have brought the child forth in the first place is often a major focus for why they should have exclusive parental rights.²⁶⁹ Courts have split on custody rights for gamete donors and surrogates, leading to some uncertainty for persons seeking the use of ART.

For surrogacy, state laws vary on whether surrogacy contracts will be recognized and many cases turn on three factors: “whether the surrogacy is traditional or gestational, whether the surrogate is compensated beyond expenses, and the marital status and sexual orientation of the intended parents.”²⁷⁰ In states where surrogacy is illegal or contractually unenforceable, states tend to split custody between the genetic father and the surrogate mother.²⁷¹ Two famous cases of

265. *Financial Compensation of Oocyte Donors*, *supra* note 259, at 307.

266. See John Lawrence Hill, *What Does It Mean to Be a “Parent”? The Claims of Biology as the Basis for Parental Rights*, 66 N.Y.U. L. REV. 353, 355 (1991).

267. *Id.* at 388–89.

268. *Id.* at 389–90.

269. *Id.* at 415 (extending arguments in favor of the intended parents include the argument that “but for” the intended parents, the child would never have been conceived. Additionally, contractual arrangements often weigh in favor of intended parents, and making intended parents the default custody ensures parentage for the child because not all gestational surrogates will change their mind and want custody.).

270. Darra L. Hofman, *“Mama’s Baby, Daddy’s Maybe”: A State-by-State Survey of Surrogacy Laws and Their Disparate Gender Impact*, 35 WM. MITCHELL L. REV. 449, 460 (2009).

271. *Id.*

surrogacy custody were *Johnson v. Calvert*²⁷² and *In the Matter of Baby M*.²⁷³ In *Johnson*, a couple donated their eggs and sperm and a surrogate agreed to carry the child in exchange for \$10,000 and life insurance. When relationships between the couple and surrogate soured, the surrogate fought for custody of the resulting child. The California court held that “she who intended to procreate the child—that is, she who intended to bring about the birth of a child that she intended to raise as her own—is the natural mother.”²⁷⁴ In the case of *Baby M*, Mary Beth Whitehead was artificially inseminated by William Stern’s sperm, making her both the surrogate as well as the egg donor in the arrangement.²⁷⁵ The Supreme Court of New Jersey rejected surrogacy arrangements as against public policy, but accepted a lower court’s “best interests” notion of determining parental rights.²⁷⁶ When remanded to the lower court, Stern was awarded custody, but Whitehead was given visitation rights.²⁷⁷

With respect to gamete donors, courts continue to battle over whether a donor does or should have parental rights.²⁷⁸ The issue touches on complex state statutory and case law in fields of property, family law, and inheritance law, and deals with matters of best interests of the child, parental responsibility and neglect, and public policy promotion in the use of ART and gamete donors.²⁷⁹ In a recent Kansas Supreme Court case, the court held that a sperm donor who wanted custody needed a prior written contract with the mother.²⁸⁰ In another case, a sperm donor has won an appeal for parental rights.²⁸¹

272. *Johnson v. Calvert*, 851 P.2d 776 (Cal. 1993).

273. *Matter of Baby M*, 537 A.2d 1227 (N.J. 1988).

274. *Johnson*, 851 P.2d at 782.

275. *Matter of Baby M*, 537 A.2d at 1234.

276. *Id.*

277. Editorial, *Justice for All in the Baby M Case*, N.Y. TIMES, Feb. 4, 1988, <http://www.nytimes.com/1988/02/04/opinion/justice-for-all-in-the-baby-m-case.html>.

278. See Michael J. Yarworsky, *Rights and Obligations Resulting from Human Artificial Insemination*, 83 A.L.R. 4th 295 (1991).

279. See, e.g., *id.* (showing that “[i]n the absence of a governing statute, courts have generally resorted to common-law principles, such as equitable and promissory estoppel and effectuation of the intent of the parties, to decide contested issues involving parental rights and obligations of donors and unmarried donees in connection with artificial insemination.”); Elizabeth E. McDonald, *Sperm Donor or Thwarted Father? How Written Agreement Statutes Are Changing the Way Courts Resolve Legal Parentage Issues in Assisted Reproduction Cases*, 47 FAM. CT. REV. 340 (2009).

280. See *In re K.M.H.*, 169 P.3d 1025, 1028–29 (Kan. 2007); see also Jonathan Turley, *Sperm Donor Takes Case to Supreme Court Seeking Parental Rights* (Mar. 19, 2008), <http://jonathanturley.org/2008/03/19/sperm-donors-takes-case-to-supreme-court-seeking-parental-rights/>.

281. See, e.g., Seymour Family Law, *Father Wins Appeal for Parental Rights as Sperm Donor* (Jan. 21, 2012), http://www.lakevillefamilylawattorney.com/mt-bin/mt-search.cgi?blog_id=11629&tag=Paternity&limit=20. There are now services available which assist those born via sperm donation in finding their donor or their half-siblings. THE DONOR

In another case, a sperm donor was given parental rights because the pair did not use a physician, and instead performed the procedure at home.²⁸²

The Uniform Parentage Act (UPA) provides some guidance. The UPA of 2000 (and amended in 2002) specifically addresses reproductive technologies. It states that donors are “not a parent of a child conceived by means of assisted reproduction.”²⁸³ Likewise, for posthumous reproduction, the deceased spouse is not the parent of the child unless the decedent “consented in a record that if assisted reproduction were to occur after death, the deceased spouse would be a parent of the child.”²⁸⁴ Additionally, in the case of gestational surrogacy when there is a validated contract, the intended parents will be the parents of the child with several procedural steps in place.²⁸⁵ Combined, these new provisions of the 2000 UPA suggest that after the raging battle at the state level of the courts, the UPA wishes to recognize intended parents as the controlling norm where ART is used. Donors and surrogates thus are not, in the usual case, going to have parental rights claims over the offspring produced by their volunteering/donation. However, the application of UPA to RTT as currently framed is not inclusive. First, for donors of eggs and sperm, the UPA defines donor as “an individual who produces eggs or sperm used for assisted reproduction, whether or not for consideration.”²⁸⁶ In RTT the donor arguably produces whole reproductive organs or slivers for transplant, and not assisted reproduction, so language would need to be altered to encompass RTT donors. Likewise, with gestational surrogacy, the gestational mother is defined as the woman who gives birth under a gestational agreement.²⁸⁷ This will not control uterus donors, who will not give birth to the child resulting from RTT.

The general intent of the UPA, however, does seem fitting to RTT. For donors of ovaries and testicles (if it ever comes to stranger donation), they present little unique issue beyond that of gamete donors. The only significant difference is that the recipient of a whole ovary or testicle can, if transplant is successful, continue to have multiple

SIBLING REGISTRY, <https://www.donorsiblingregistry.com/>; Amy Harmon, *Getting to Know a Sperm-Donor Dad*, N.Y. TIMES (Oct. 20, 2011, 5:25 PM), <http://well.blogs.nytimes.com/2011/10/20/getting-to-know-a-sperm-donor-dad/>; Rachel Lehmann-Haupt, *Are Sperm Donors Really Anonymous Anymore?*, SLATE (Mar. 1, 2010, 9:36 AM), http://www.slate.com/articles/double_x/doublex/2010/02/are_sperm_donors_really_anonymous_anymore.html.

282. *Jhordan C. v. Mary K.*, 179 Cal. App. 3d 386, 398 (Cal. Ct. App. 1986); McDonald, *supra* note 279, at 345.

283. UNIF. PARENTAGE ACT § 702 (2000).

284. *Id.* § 707.

285. *Id.* §§ 801–802.

286. *Id.* § 102(8).

287. *Id.* § 102(11).

children with a single donation, whereas gamete donation is a one-shot deal.²⁸⁸ For egg donors, women must match their ovulation cycles with the recipient, and thus donation is a one-to-one mapping.²⁸⁹ However, egg donors often do not have dispositive control over resulting embryos, which may be again used for reproduction, or disposed of, or donated to research. Sperm donors often have even less involvement because of cryopreservation.²⁹⁰ They bank amounts of sperm and individuals or couples choose these samples, without knowledge of the donor, so a donor conceivably may not know how many times his sperm samples are used for reproductive purposes.²⁹¹ As such, it seems likely that, if it came to the courts, they would view the claims of RTT donors to be similar to other gamete donors, as the usual standard will be for custodial rights to go to intended parents, not donors.

For uterus donors, the claims to parenthood seem less than a gestational surrogate, and thus the standard almost certainly become standard custody for the intended parents, not the donor. Whereas the uterus donor provides the necessary womb for pregnancy, not unlike a gestational surrogate, the pregnancy does not occur within the donor's body. Thus the greater claim surrogates have over the resulting child because of emotional attachment and labor is not present here.²⁹² However, only nine of the fifty states have enacted the most recent iteration of the UPA, suggesting that parental rights of RTT donors may be a significant issue in the future.²⁹³

Testicle and ovarian tissue transplant will involve, in many instances, cryopreservation of these materials.²⁹⁴ Storage of cryopreserved reproductive materials, as well as dispositional authority of the materials, was a complex question when embryo cryopreservation techniques first became viable.²⁹⁵ What should be done with a

288. Westphal, *supra* note 81.

289. *How the Egg Donor Process Works*, CTR. FOR HUM. REPROD., http://www.centerforhumanreprod.com/egg_donor.htm (last visited Jan. 18, 2013).

290. Jacqueline Mroz, *In Choosing a Sperm Donor, a Roll of the Genetic Dice*, N.Y. TIMES (May 14, 2012), http://www.nytimes.com/2012/05/15/health/in-sperm-banks-a-matrix-of-untested-genetic-diseases.html?pagewanted=all&_r=0.

291. Lehmann-Haupt, *supra* note 281.

292. See, e.g., *Traditional or Gestational Surrogate?*, SURROGACY911.COM, <http://www.surrogacy911.com/surrogacy/motherhood/traditional-gestational.htm> (last visited Jan. 18, 2013).

293. *Legislative Fact Sheet—Parentage Act*, UNIF. LAW COMM'N, <http://www.uniformlaws.org/LegislativeFactSheet.aspx?title=Parentage%20Act> (last visited Jan. 18, 2013) (including Alabama, Delaware, New Mexico, North Dakota, Oklahoma, Texas, Utah, Washington, Wyoming).

294. See Westphal, *supra* note 81.

295. See *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992) (showing that divorce battles over frozen embryos were prevalent. The Tennessee Supreme Court held that an embryo occupies neither the rights of a legal person nor should be treated like property, but instead occupies a special category where their potential for human life is respected. The court

frozen ovary or testicle when someone dies or divorces? This issue is fortunately not likely applicable to the case of RTT because it does not involve combined gametic material, as an embryo does. However, as in cases of posthumous reproduction, sometimes a partner wishes to make use of the decedent's reproductive tissue to procreate.²⁹⁶ Again, this is usually contingent upon some showing, during life, that the decedent not only wished to procreate with the person requesting use, but also that they anticipated procreating posthumously. As RTT becomes a viable clinical procedure and individuals begin to bank their reproductive tissues, the issue will almost certainly play out in the courts as frozen embryo and posthumous conception cases have, with these former cases likely playing strong models for the courts.

CONCLUSION

An analysis of the regulatory and ethical challenges raised by RTT suggests that it is a two-headed creature that does not perfectly fit in either an assisted reproduction or an organ transplantation model. Determining what types of rules should apply to which feature of RTT greatly depends on whether the salient features of that particular area, whether consent, allocation, etc. more closely mirrors salient issues in reproduction or transplant.

With respect to a general body of rules, DHHS regulations are more appropriate than FDA tissue regulations, because they open a door for regulating complex allocation, consent, and disposition issues which tissue regulation simply does not. However, traditional DHHS/NOTA rules fall short with respect to addressing the unique reproductive challenges raised by RTT, as well as issues of paying donors. Moreover, to the extent that UAGA applies to deceased donation, it will cause significant new dilemmas for RTT related to family donation which were never present in traditional organ transplantation. Whereas RTT is still only in research phases it is imperative that scholars and policy makers begin to think about how this two-headed creature can be regulated in a way that properly respects the unique reproductive and transplant issues it creates. However, many issues of regulation are premature until we have a better notion of what RTT would look like in clinical practice.

balanced the husband's right not to produce against the wife's right to produce, and favored an avoidance of procreation trumping the right to produce. The case was more simple because the wife did not wish to use the embryos for herself, but rather to donate); *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998) (upholding the original disposition agreement of a couple which called for donation to research if the couple no longer wished to produce when the divorced wife wanted to use the frozen embryos for herself).

296. UNIF. PARENTAGE ACT § 707 (2000).

As RTT continues to develop, a number of key regulatory questions should be considered, including foremost how to ensure protection of research participants in RTT trials. Additionally, once RTT becomes clinically applicable, how do we ensure informed consent of both donors and recipients in RTT, how do we properly allocate RTT resources, how do we reconcile payment models for ART with transplant, and who has custodial rights over the resulting offspring of RTT? Although it is too early to predict all of the legal and ethical issues raised by RTT or to anticipate regulatory solutions, it is imperative that researchers begin to consider how to address these issues before they become clinical practice without any form of guidance.