A Labor of Love Part II: Representing Clinics

Friday, May 3, 2019

Moderator:
Lila Newberry Bradley

Speakers:
Said T. Daneshmand
Joyce Murty
Lila Newberry Bradley, Esq.
Atlanta, GA

Lila Newberry Bradley is a partner in the law firm of Claiborne|Fox|Bradley, which focuses its practice on family building through adoption and assisted reproduction. Lila is a Fellow in the Academy of Adoption & Assisted Reproduction Attorneys and the Georgia Council of Adoption Lawyers.

Lila is the former director of the Atlanta Volunteer Lawyers Foundation’s Children’s Law Programs where she worked with volunteer lawyers to provide pro bono legal representation for children who were in foster care or were the subject of high-conflict custody disputes. Lila continues to have a special interest in the legal issues surrounding children in foster care, and she provides training to foster parents on how the law and the court process can ensure that children’s rights and interests are protected.

Said T. Daneshmand, MD, F.A.C.O.G.
San Diego, CA

Dr. Said Daneshmand has expertise in complex IVF cases, and his research and publications have featured work on endometrial receptivity as a way to maximize the probability of success during IVF. He is internationally recognized for his expertise in egg donation and surrogacy, and is one of the main providers of third-party care in the United States, with patients traveling from more than 40 countries in 2017 alone. He is known for developing and implementing cutting-edge technologies, including NGS (next generation sequencing), the latest and most precise technique for assessing embryonic genetic health.

Dr. Daneshmand completed his fellowship and residency at UCLA. He is double board certified in Obstetrics and Gynecology as well as in Reproductive Endocrinology.

Among his achievements, Dr. Daneshmand is the recipient of numerous awards including the Eileen Pike Medical School Valedictorian Award, the PCRS Fellowship and Practicing Physician Research Award, as well as the recipient of the prestigious ASRM STAR Award in 2017 and 2018. He has served as the President of the Alpha Omega Alpha Honor Society (Iota Chapter) and is a member of the Decherney Society, the American Society for Reproductive Medicine (ASRM) and the European Society of Human Reproduction and Embryology (ESHRE).

Dr. Daneshmand speaks English, French, Spanish and Farsi.

Joyce Murty, Esq.
Sandy Hook, CT

Joyce Murty has been associated with IntegraMed America, Inc. for over 10 years. Her initial focus was general corporate and SEC advice, but given the small size of the legal department (initially, 2 attorneys), she developed a strong partnership with the Risk Management and clinical operations groups, and expanded her role to include healthcare and artificial reproductive law. In 2016, Joyce decided to “semi-retire” and become a dedicated consultant, responsible for the task of revising IntegraMed’s library of over 35 informed consents and providing advice to the Director of Risk Management. Before IntegraMed, Joyce was Assistant General Counsel and Director of Corporate Ethics & Compliance at a medium-sized publicly held company in Dayton OH (The Reynolds and Reynolds Company) and Senior Counsel at Georgia-Pacific Corporation in Atlanta, GA. Earlier in her career, she was a corporate associate at Simpson Thacher & Bartlett in New York. Joyce graduated from the University of Dayton and received her J.D. from Catholic University of America, The Columbus School of Law where she was Editor-in-Chief of the Law Review.
Vignette #1

**Patient A and Patient B (male/female) present as a couple using donor eggs. Clinic’s protocol requires that gamete providers undergo genetic screening (and receive results) before beginning fertility treatment. Frozen donor eggs were obtained through egg bank and treating Provider has test results. Patient B (contributing sperm) undergoes genetic screening and is determined to be a carrier for a recessive mutation. Donor had not been tested for this mutation as she had donated some years earlier and this mutation was only recently added to the panel of testing.**

**a. Should Patient A and Patient B be allowed to proceed with chosen donor?**

**b. Should Clinic require genetic counseling session and Waiver and Consent to be signed prior to Day 1?**

**c. Should Clinic require Patients A and B to agree to PGT – A testing (pre-implantation testing of embryo prior to transfer)?**

**d. Would it make a difference if the genetic disorder was potentially life threatening or of serious health consequences to resulting child?**

Slight variation of the facts: What if Patient A and Patient B move forward and 5 years later Clinic is notified by the egg bank that the Donor has earned that she is a carrier of a serious genetic disorder (her own child was born with a serious genetic disorder). Should the Clinic notify Patient A and B? What if the Donor has notified the egg bank that she has recently been diagnosed with depression and as bi-polar – a disorder that may be genetically linked but not conclusively or exclusively so. Should the Clinic notify Patient A and B?

Genetic carrier screening has become the standard of care in the treatment of infertility. In carrier screening, the DNA of the gamete provider is tested for mutations for a number of diseases. Genetic recessive screening cannot and will not identify all genetic diseases, but will identify diseases whose mutations have been identified, researched, and published. Approximately 30-50% of patients who are screened will be found to be a carrier of at least one genetic mutation while only 1-3% of these mutations will be present in both the sperm and egg provider. If the Intended Parents/gamete providers are found to be carriers of the same recessive mutation, then there is a 25% chance of this genetic disease being present in the child that is conceived. Testing for these mutations prior to conception allows infertility physicians the opportunity to prevent the genetic transmission of these diseases for future generations.
The American College of Obstetrics and Gynecology (ACOG) and the American College of Medical Genetics (ACMG) recommend offering patients carrier screening for only a limited number of genetic conditions based on their ethnic background. However, with the passage of time, more and more fertility centers, sperm banks, and egg banks have been offering an expanded array of mutation screening for their patients, increasing the pressure on the rest of the fertility community to adopt similar standards and measures. Gamete donors who may have initially donated gametes at a time when a more limited number of mutation screenings were offered, now face the option of more expanded screening. However, if they are experienced donors who have donated in the past, this presents a clinical conundrum. Do we retest and expand the mutation carrier screening for these donors and if positive for these new mutations, do we inform every Intended Parent/Parents of these newly found results, or do we ask the Intended Parents to sign a waiver to exclude expanded carrier screening?

Vignette #2

Patient A and Patient B present as a couple using their own gametes. Both have non-syndromic hearing loss— an inherited genetic mutation. Should Clinic allow the patients to decline genetic screening and proceed with fertility treatment? Should Clinic require Patients to see a disease specialist and genetic counselor before proceeding? What are the Clinic’s obligations to the resulting child who may be born with the same disorder? Would the Clinic be discriminating against someone with disabilities if it refused to treat Patient A and Patient B?

Parents may go to some lengths to ensure that their children stay in their world, by intentionally choosing to have children who will carry genetic mutations that produce disabilities such as deafness or dwarfism. Through the use of Preimplantation Genetic Diagnoses or PGD, the DNA can be analyzed for such mutations and in this way, embryos that are destined to have a particular disease, could be excluded from embryo transfer. A fascinating survey conducted at the Genetics and Public Policy Center at Johns Hopkins University surveyed 190 American IVF clinics and found that 3% had intentionally used PGD to select an embryo for the purpose of a disability.

In other words, some parents underwent fertility treatment and IVF for the express purpose of having children with a genetic mutation. From their perspective, these parents don’t view these genetic conditions as disabilities but as a way to enter into a rich shared culture. Some fertility specialists find requests for the express purpose of selecting for genetic mutations unacceptable. Many such specialists deny requests to use the IVF process for selecting for genetic mutations such as deafness and dwarfism. From their point of view, the diagnostic tool of carrier screening must serve the purpose of trying to avoid a disease and not to select for it. As fertility experts, do we help Intended Parents select for their specific diseases in order for the children to share in their culture? Do we respect the family’s judgement? These parents share a resolute faith that having children similar to them will strengthen family and social bonds. Or do we use genetic screening tools only to avoid and eliminate genetic diseases and deny the requests of these Intended Parents because the genetic diseases are not the norm?
Vignette #3

Patient A and Patient B (same sex unmarried female couple) present and will be creating embryos with Patient A’s eggs and donor sperm; embryo transfer to Patient B. Patient A and Patient B are required to sign an In-Vitro Pre-Implantation Embryo Disposition and Storage Agreement as part of the consent package.

a. Should Patient A and Patient B seek independent legal advice? Should Clinic require as condition of treatment?
b. Should the Agreement be considered a legally binding agreement between Patient A and Patient B in the same way as a pre-nuptial agreement?
c. Should Patient A have a greater claim on the disposition authority of resulting embryos because the embryos were created with her eggs? What if Patient A and Patient B were married?
d. What if Patient A and Patient B agree to discard frozen embryos in the event their relationship is terminated. Five years later, per the Agreement, Patient A notifies the Clinic that the relationship is terminated and requests the Clinic to discard the frozen embryos. Patient B contacts the Clinic and confirms that the relationship is terminated, but states that she has changed her mind and she no longer agrees to discard and requests the Clinic to transfer the embryos to her. Patient B is infertile and unable to use her own eggs. What should the Clinic do? What if the situation was reversed and it is Patient A who wants the embryos and she is no longer able to produce eggs?

Gamete and embryo cryopreservation are relatively mainstream in the field of IVF; however, it is imperative to obtain legal consents and direction in the event of conditions such as death, incapacity, posthumous reproduction, divorce and separation.

Divorce and separation are particularly important as it relates to the disposition of gametes and embryos. These particular consents and agreements should be created under the direction of reproductive attorneys and legal scholars, so as to protect the rights of each particular parent, irrespective of the genetic link between that parent and the child. In this vignette, Patient A and B have presented to the clinic as partners and future parents and so if there were to be any deviations in each party’s parental rights, this needs to be addressed in a formal legal document and each party should have the right to seek independent legal counsel in regard to gamete and embryo disposition.

Vignette #4

Clinic has over 10 storage tanks of genetic material in its laboratory. The tanks are owned by the Clinic but maintained and serviced by Company X. The tanks are monitored by laboratory personnel and a warning signal is transmitted to their cellular phones in the event of a failure. The handling, maintenance and service are all per best practices and meet industry standards, including an emergency backup plan in the event of a natural disaster. A cataclysmic earthquake (7 on the Richter scale) creates power outages and flooding beyond a scale not seen before. The emergency backup plan fails after 5 days and the genetic material is lost.
a. Who should bear the risk of loss? What if the clinic was located in an area that had never seen an earthquake and its emergency plan was based on that location?
b. Can the Clinic obtain insurance coverage for this type of loss?
c. Should sperm, eggs and embryos be compensated for differently?
d. If the tank failure was caused by mechanical failure, should the Clinic bear the risk of loss? What if the storage agreement stated that the patients acknowledged and agreed that mechanical failure was a risk of storage and that the patient bore that risk. If patient bring a cause of action against the Clinic, would damages be limited to cost of an IVF cycle? Would be storage agreement be upheld as a binding agreement? What if the storage agreement contained a liquidated damages clause? Would that be enforced? Are embryos property and can they be valued as such? Or special status and property laws not applicable?

Failure of liquid nitrogen storage tanks that store gametes and embryos has sparked a review of procedures at many fertility centers and at the American Society for Reproductive Medicine. At least three lawsuits, one a Federal Class Action, have been filed by patients whose eggs or embryos may have been damaged or lost as a result of these tank failures. The first such incidence occurred on March 4, 2018, at University Hospitals Fertility Center in Cleveland. This center subsequently notified 700 patients that their eggs or embryos may had been damaged as a result of the tank failure. The ASRM has characterized these as two major failures (apparently of equipment, redundancy in warnings) which have led to some tissue loss, though the extent of that loss is not yet fully determined. The organization also noted that cryopreservation and subsequent use of reproductive tissue is a technology that has been used reliably for years around the world. In 2016, ASRM issued a committee opinion about emergency planning for IVF programs, making every effort to provide a stable environment for cryopreserved oocytes, embryos, sperm and other human tissue. After natural disasters hurricanes, floods, earthquakes, and severe storms, ASRM has recommended that every effort be made to replenish the nitrogen in the tanks containing the reproductive tissue. The document does not make mention of equipment malfunctions. In response to these latest developments, several companies are now offering liability insurance for fertility centers in order to cover the costs for a potential loss of gametes or embryos. These companies are requesting patients sign legally binding documents which assigns a monetary value to eggs, sperm and embryos in the event of loss. The key questions to be answered are the following:

1) In the case of nature disasters who should bear the risk of a loss? The answer lies in whether the clinic or cryo storage facility has emergency backup plans in case of natural disasters.
2) The clinic can obtain insurance coverage for these types of losses, but patients may be denied treatment coverage unless they sign these consent forms and legal documents. Sperm, eggs and embryos are valued and compensated differently with these types of insurance. Most clinics have consent forms which discuss the risks of cryo storage, including but not limited to mechanical failures, natural disasters, and human error. What recourse should patients have in case of clinic negligence and human error?
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Creating a “Library” of Informed Consents, by Joyce Murty, Esq.

1) Creating or revising a “library” of informed consents for an ART physician practice
   a) Develop a work plan by identifying the groups of informed consents and/or waivers needed
   i) **Treatment informed consents:**
      
      (1) In Vitro Fertilization (IVF): Process, Risks and Consent
      (2) Ovarian Stimulation and/or Intrauterine Insemination (IUI) Consent (with or without medication)
      (3) Frozen Embryo Transfer Consent
      (4) Consent for Ovarian Stimulation and Egg Retrieval for Cryopreservation (Planned Oocyte Preservation)
      (5) IVF Shared Maternity: Process, Risks and Consent

   **Important Considerations/Concepts**:

   - ensure that consents are universal and can be used for same sex female or same sex male couples or for single sex individuals; consider how you will accommodate gender neutral or transgender individuals
   - establish, in advance, processes and policies for handling unusual requests or situations (i.e., ethics committee, shareholder v. physician employee approval)
   - conform to state laws and any tissue bank regulations
   - develop a definition of “embryo” that accurately reflects its status as pre-implantation; then use the defined term “embryo” throughout
   - consider whether you will adopt “long-form” consent with a detailed discussion of all possible medical treatments that may be needed over the course of the cycle (i.e., ICSI, Assisted Hatching) or a short-form consent with an accompanying acknowledgement of receipt and review of the ART booklet
   - ensure that your consents conform to all recommended American Society for Reproductive Medicine guidelines
   - Establish process for regularly updating consents based on changes in law, technology, treatment plans
   - Have a clear definition of “spouse/partner” in the consents so there is no confusion later as to whether a “partner” was a donor
   - Have a clear policy on terminated or changed relationships and the impact on the cycle or the beginning of another cycle (i.e., will you allow a patient who is in the midst of a divorce to re – present with another partner?)
   - Specify documentation that will be required to evidence a divorce or termination of a relationship
   - Have a new treatment consent signed for each cycle
   - Consider electronic signatures and how the authentication of signatures will then be accomplished
   - Consider the use of educational tools to help streamline the informed consent process and identify areas of concern or misunderstandings of your patients
ii) Informed Consents/Waivers related to Genetic Screening and Testing

(1) For all patients:
   (a) Consent for Genetic Carrier Screening (for gamete providers and must be completed or declined prior to Day 1 (start of medications); The American College of Obstetricians and Gynecologists (‘ACOG’) and the American College of Medical Geneticists and Genomics (‘ACMG’) recommend screening for certain genetic diseases for all men and women prior to conceiving, and additional screening when indicated due to ethnicity, family history, or other known risk factors. See www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Genetics/Carrier-Screening-for-Genetic-Conditions
   (b) Option to Accept or Decline PGT-A Testing (for aneuploidy, i.e., missing or additional chromosomes whether or not medically indicated);
   (c) Zika Waiver and Acknowledgement

(2) For patients who want to proceed after positive genetic screening test:
   (a) Waiver when both gamete providers are carriers;
   (b) Waiver for proceeding when one gamete provider has tested positive and the other declines testing;
   (c) Waiver for proceeding when one gamete provider has tested positive and the chosen donor has either not been tested or has tested positive (slightly different exposure than (c) above since the Intended Parents could choose a different donor)

(3) Pre-Implantation Genetic Testing (PGT) of in vitro pre-implantation embryos for patients choosing biopsy and genetic testing of embryos:
   (a) Consent for biopsy for genetic testing of embryos
   (b) Once results of (a) received, then patient must make decision about disposition of PGT tested embryos in a separate consent
   (c) Clinic should establish informed, deliberative and collaborative policies for the transfer of embryos that have either (i) tested positive for a single-gene defect or (ii) whose test results indicate have a high probability of being abnormal or (iii) whose test results cannot determine with a high degree of probability that an embryo is normal in accordance with the recommendations and guidelines set forth by the American Society of Reproductive Medicine (ASRM). If Clinic decides to permit the transfer of these types of embryos, patients should also sign either:
      (i) Consent for Transfer of an Embryo with a Single Gene Defect or
      (ii) Consent for Transfer of Embryo with Indeterminable PGT Chromosomal Abnormality

iii) Agreements/Informed Consents relating to the Management/Administration of Cryopreserved Embryos, Eggs or Sperm

(1) Agreement for Disposition and Storage of Cryopreserved Embryos (review your State statutes to see if/how disposition choices may be affected)
(2) Agreement for Disposition and Storage of Cryopreserved Eggs (unless eggs are donor eggs, only the egg provider needs to sign)
(3) Agreement for Disposition and Storage of Cryopreserved Sperm (unless sperm is donor sperm, only the sperm provider needs to sign)
(4) Consent for the Transfer of Cryopreserved Embryos, Eggs and Sperm
(5) Consent for the Receipt of Cryopreserved Embryos, Eggs and Sperm
(6) Consent to Discard Cryopreserved Embryos, Eggs and Sperm

**Important Considerations/Concepts**

- Consider how to help ensure that “agreements” will be binding
- Consider how long Clinic will store embryos, eggs and sperm
- Consider whether Clinic will offer disposition options in the event of a divorce or termination of a relationship or, instead, require a new contemporaneous consent to be signed or a final court order to be delivered
- Have a written policy outlining the process and steps to be followed in the event of an embryo dispute; also include a statement in the agreement describing the Clinic’s policy
- Add a default provision that patients initial that gives Clinic the authority to discard embryos if unable to fulfill disposition choices after a specified period of time
- Add a provision that gives the Clinic the right to discard embryos if patient fails to pay storage fees or fails to be in contact for a specified period of time
- Unless Clinic is aware of a current program, ensure that patient is responsible for costs of storing the embryos until a research program is found; consider shifting all responsibility to the patient for research donation option, including compliance with federal and state regulations
- Encourage patients to seek legal advice, especially with regard to choices in the event of divorce or death
- Be very clear as to what documentation will be required to be submitted to the Clinic to evidence a death, divorce or termination of a relationship
- Inform patient that any disposition choice must be consistent with any donor agreement, if applicable
- Establish a policy for the administration of embryos the purpose of which is to (i) help Clinics ensure that they are appropriately following patient instructions regarding the disposition of cryopreserved embryos subject to evolving legal and ethical guidelines, (ii) determine whether cryopreserved embryos held in storage are “abandoned,” and (iii) provide guidelines for the disposition of embryos, including abandoned embryos. Make sure the Clinic has made the patients aware of this policy and that the Clinic follows the policy to help protect the Clinic in the event of discard
- Consider whether electronic signatures will be accepted, particularly if the consent or agreement deals with embryos (i.e., will you accept an electronic signature to discard embryos?)
- Consider provisions that limit the liability of the Clinic in the event of the loss of embryos, sperm and egg for mechanical failure or natural disaster (binding arbitration, liquidated damages, etc.)
- Explore potential insurance coverages for loss of embryos, sperm and egg, including for potential cause of action if embryos are discarded (i.e., because abandoned) and patient later comes forward and sues
  - Malpractice/Medical Professional Liability
iv) Third Party Arrangements

(1) For all patients:
   (a) PHI Disclosure in Third Party Reproductive Cycles

(2) For Egg Donation Cycles:
   (a) If Clinic has its own in-house egg donor program, then will need Egg Donor Screening Consent before donor is accepted into program
   (b) Egg Donation: Process, Risks and Consent (create one document that can be used for anonymous or a directed (known) donor); this should mirror the IVF Consent for the discussion of ovulation induction and egg retrieval
   (c) Egg Donation Consent and Agreement re Disclosure of Identity (for anonymous egg donors only)
   (d) Recipient(s) of Donor Eggs (should include a full discussion of the medical treatment of the egg donor as well as mirror the IVF Consent for the preparation of the embryo and embryo transfer)
   (e) Use of Known or Suspected Infectious Tissue from Directed Donor (if applicable)

(3) For Sperm Donation Cycles:
   (a) Consent and Agreement of Donor to Donate Sperm to Directed Recipient
   (b) Consent for Recipient of Donor Sperm (unlikely that a Clinic will have its own sperm donation program; recipients will either have directed donor or obtain sperm from approved sperm bank); draft this Consent for both anonymous and directed donation
   (c) Use of Known or Suspected Infectious Tissue from Directed Donor (if applicable)
   (d) Consent and Waiver for Six Month Quarantine and Retesting of Directed Sperm Donor

(4) For IVF Cycles using a Gestational Carrier:
   (a) Gestational Carrier Cycle – Gestational Carrier
   (b) Gestational Carrier Cycle – Recipient(s)

**Important Considerations/Concepts**

- Consider whether Clinic will have an internal embryo donation program or refer patients who wish to donate or receive embryos to third party matching program
- Ensure that patients understand that Clinic does not provide legal advice; require a legal confirmation letter from the patients’ attorney stating that a legal agreement has been entered into rather than requesting (or accepting) a copy of the donor legal agreement
- Develop policies and protocols for legal considerations of third party arrangements; will Clinic require confirmation letter of legal agreement for all donations (whether internal, third party matching, anonymous or directed?)
- Ensure that both egg donor and recipient acknowledge and agree that there is no guarantee of anonymity given donor photos, ancestry DNA programs, facial recognition tools and the internet search groups and tools
- Egg donor should specifically agree to re-donation of her eggs in the egg donation consent, including re-donation to create a pregnancy
• Consider whether Clinic will permit traditional surrogacy; confirm legality in your state
• Have clear language regarding the obligations of the egg donor to update important medical information; recipients should understand that Clinic cannot guarantee that egg donor will, in fact, update the Clinic or remain in contact
• Create and follow document retention policies based upon ASRM and State guidelines
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ABA Spring 2019
Dominican Republic

Joyce Murty, J.D.
Sandy Hook, CT

Said Daneshmand, M.D.
San Diego Fertility Center
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Vignette One

Donor Egg Genetic Screening
Patient A and Patient B (male/female) present as a couple using donor eggs. Clinic’s protocol requires that gamete providers undergo genetic screening (and receive results) before beginning fertility treatment. Frozen donor eggs were obtained through egg bank and treating Provider has test results. Patient B (contributing sperm) undergoes genetic screening and is determined to be a carrier for X mutation. Donor had not been tested for this mutation as she had donated some years earlier and this mutation was only recently added to the panel of testing.

A. Should Patient A and Patient B be allowed to proceed with chosen donor?

B. Should Clinic require genetic counseling session and Waiver and Consent to be signed prior to Day 1?

C. Should Clinic require Patients A and B to agree to PGT – A testing (pre-implantation testing of embryo prior to transfer)?

D. Would it make a difference if the genetic disorder was potentially life threatening or of serious health consequences to resulting child?
Vignette Two

Selecting for a Genetic Mutation
Patient A and Patient B present as a couple using their own gametes. Both have non-syndromic hearing loss—an inherited genetic mutation. Should Clinic allow the patients to decline genetic screening and proceed with fertility treatment?

Would the Clinic be discriminating against someone with disabilities if it refused to treat Patient A and Patient B?

Should Clinic require Patients to see a disease specialist and genetic counselor before proceeding?

What are the Clinic’s obligation to the resulting child who may be born with the same disorder?
Vignette
Three

In-Vitro Pre-Implantation
Embryo Disposition and
Storage Agreement
Patient A and Patient B (same sex unmarried female couple) present and will be creating embryos with Patient A’s eggs and donor sperm; embryo transfer to Patient B. Patient A and Patient B are required to sign an In-Vitro Pre-Implantation Embryo Disposition and Storage Agreement as part of the consent package.

A

Should Patient A and Patient B seek independent legal advice? Should Clinic require as condition of treatment?

B

Should the Agreement be considered a legally binding agreement between Patient A and Patient B in the same way as a pre-nuptial agreement?
Patient A and Patient B (same sex unmarried female couple) present and will be creating embryos with Patient A’s eggs and donor sperm; embryo transfer to Patient B. Patient A and Patient B are required to sign an In-Vitro Pre-Implantation Embryo Disposition and Storage Agreement as part of the consent package.

Should Patient A have a greater claim on the disposition authority of resulting embryos because the embryos were created with her eggs? What if Patient A and Patient B were married?

What if Patient A and Patient B agree to discard frozen embryos in the event their relationship is terminated. Five years later, per the Agreement, Patient A notifies the Clinic that the relationship is terminated and requests the Clinic to discard the frozen embryos. Patient B contacts the Clinic and confirms that the relationship is terminated, but states that she has changed her mind and she no longer agrees to discard and requests the Clinic to transfer the embryos to her. Patient B is infertile and unable to use her own eggs. What should the Clinic do? What if the situation was reversed and it is Patient A who wants the embryos and she is no longer able to produce eggs?
Vignette
Four

Storage Tank Failure
Clinic has over 10 storage tanks of genetic material in its laboratory. The tanks are owned by the Clinic but maintained and serviced by Company X. The tanks are monitored by laboratory personnel and a warning signal is transmitted to their cellular phones in the event of a failure. The handling, maintenance and service are all per best practices and meet industry standards, including an emergency backup plan in the event of a natural disaster. A cataclysmic earthquake (7 on the Richter scale) creates power outages and flooding beyond a scale not seen before. The emergency backup plan fails after 5 days and the genetic material is lost.

Who should bear the risk of loss? What if the clinic was located in an area that had never seen an earthquake and its emergency plan was based on that location?

Can the Clinic obtain insurance coverage for this type of loss?
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Should sperm, eggs and embryos be compensated for differently?

If the tank failure was caused by mechanical failure, should the Clinic bear the risk of loss? What if the storage agreement stated that the patients acknowledged and agreed that mechanical failure was a risk of storage and that the patient bore that risk. If patient bring a cause of action against the Clinic, would damages be limited to cost of an IVF cycle? Would be storage agreement be upheld as a binding agreement? What if the storage agreement contained a liquidated damages clause? Would that be enforced? Are embryos property and can they be valued as such? Or special status and property laws not applicable?
Thank you!