



Informed Consent

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Disclosure

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The Law Office of Margaret E. Swain

- No Commercial or Financial Relationships
to Disclose



Patients' Rights

- Beneficence-actually contribute to patient's well being
- Nonmaleficence-no harm
- Respect and dignity
- Autonomy
- Honest information
- Privacy
- Refuse treatment


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- Inherent tension in doctor/patient relationship and the decision making process
 - Informed consent allows for mitigation of the potential conflict, while respecting patient's autonomy and doctor's expertise


Purpose

- Full information allows patient to make reasonable, informed decision about his own care, based on likely outcomes balanced with risk of harm
- Engages doctor and patient in meaningful, respectful dialogue

Doctrine of Informed Consent

- Provider must give patient detailed information about treatment
 - Type of treatment
 - Alternatives, including no treatment
 - Likelihood of success
 - Risks
 - Including the fact that some may currently be unidentified

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- Verbal & written explanation, in plain language
 - Sufficient time to consider
 - Voluntariness of decision
 - Patient competent to understand

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- Joint decision-making process
 - Doctor
 - Patient
 - Information provided in a form understandable by a lay person
 - Patient given the opportunity to digest and consider the information

ART & Informed Consent

- Different from many medical procedures
 - Arguably elective
 - Risks pertain not just to primary patient, but to potential offspring
 - May involve third-party collaborators, whose behavior is outside control of primary patient
 - For certain patient populations, chance of success less than 50%



ART and Informed Consent

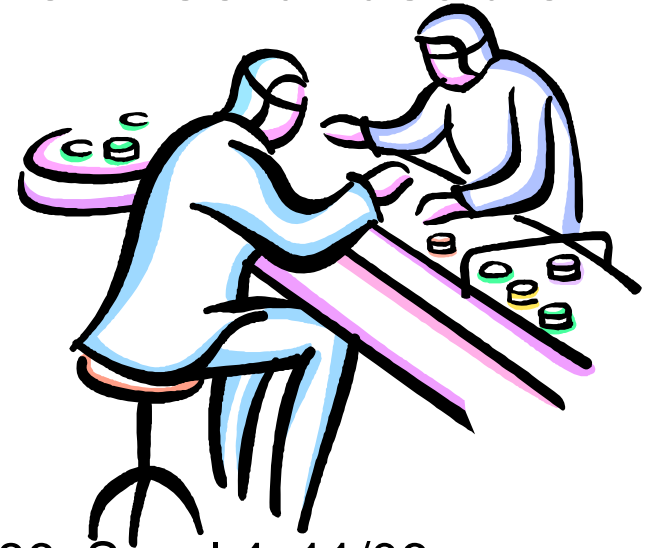
- Also discuss financial obligation and specific costs
- Information regarding treatment options not available at current provider's center
- Federal reporting requirements
- Information about non-medical options
 - Adoption
 - Foster care
 - Living without children

IVF

- Multiple factors to consider
 - Medications, monitoring, surgeries
 - Lab procedures
 - Risk factors for cycle failure
 - Pregnancy complications
 - Success rates
 - Health risks for pt/child

IVF

- Disposition of eggs
 - Discarding if unused
 - Discarding if abnormal or otherwise unusable
- Disposition of embryos
 - Option of freezing unused:
process, risks, benefits
 - Dispositional choices



Cryopreservation of Embryos

■ Potential risks:

- Loss of embryos
- Theoretic risks of congenital malformations/long term storage
- Failure to survive storage/thaw
- Lab handling of embryos
- Psychological effects

Fertility & Sterility Vol 86, Suppl 4, 11/06

Cryopreservation of Embryos

■ Disposition


- Facility's time limit on storage
- Charges
- What happens if:
 - One/both partners die
 - Nonpayment of storage fees
 - Loss of contact w/ gamete providers
 - Divorce/dissolution of partnership



When It Gets Ugly

- Disputes in this area arise when couples separate or divorce, and have jointly created embryos.



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- Majority of cases involve one spouse who wishes to reproduce, and the other who does not
 - Courts thus far have not forced the unwilling spouse to parent
 - However, at least two courts have viewed the cryo agreement as contract



Donation of Embryos for Scientific Research

Consent Guidelines

NAS Guidelines (2005)

- No donation w/o specific consent
 - Recognize conflict issues
 - May not ask RE to create > E/os than needed for Rx
 - Possible that identity will become known
- Offer to provide info derived from study
- Disclose that E/o will be destroyed in study
- Inform that resulting lines are retained indefinitely
- Reveal genetic manipulation/chimeric research
- Acknowledge donor may withdraw only until cells are used
 - <http://www.national-academies.org> 9/8/08

ISSCR Guidelines for Conduct of hESCR (2006)

- Voluntariness not undermined by improper inducements
- Consent at time of transfer of materials to researchers
- Consent must be obtained from all gamete donors
- No receipt of future commercial benefit
- May be financial benefit to researchers
- Donation won't affect donors' medical care
- Alternatives to donation for hESCR
- DE/os not used for reproduction nor kept *in vitro* > 14d

□ <http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf> 9/8/08

ASRM (2002)

- Decision to donate E/os should only be made after couple decides to no longer store them
- Disclose specific research project & source of funding
- No donation of fresh E/os, only frozen
- Abandoned E/os may not be used for research
- No reimbursement for E/os: payment for direct, out-of-pocket expenses appropriate (lab processing, handling, storage, transport)
 - Fertility & Sterility, Vol. 78, No. 5, 11/02

Donating Supernumerary Embryos

- Donate to someone else for reproduction
- Donate for scientific research
 - Treating physicians seldom recommend a dispositional choice
 - Clinics should not donate embryos if “owners” cannot be located, even if donation was choice in cryo agreement-lack of informed consent



Why Donation for hESCR is Scant

- Lack of information
- Logistical problems
- Emotionally unable to donate
- Procrastination based on indecision
- Moral/religious restrictions
- Fear

Choosing Donation for hESCR

■ Scenario #1

- IP's own gametes used to create embryos
- Choose scientific donation on cryo form
- Family complete, couple still married
- Still wish to donate
- Contact clinic, which refers couple to scientific research facility
- Researchers facilitate donation with patient education, consent forms and pick-up.



■ Scenario #2

- IPs originally chose donation for hESCR
- Couple divorced
- One spouse wants to donate, one wishes to destroy



■ Scenario #3

- Single woman, anonymous sperm donor from large sperm bank
- Woman chooses donation option on cryo form
- Family complete, still wishes to donate
- Sperm donor waived all rights to participate in the decision making



■ Scenario #4

- IPs need egg donor
- IPs sign agreement with egg donor, which outlines dispositional choices
- At time of egg donation, egg donor agrees to allow donation for scientific purposes
 - Does ceding dispositional authority to IPs trump donor's right for IC at time of E/o donation?



Prevalence of Donor Egg

- 134,260 ART cycles
- 12% of these involved donor eggs
 - Approximately 16,111 DE cycles
 - Most cycles produce an average of 8-12 eggs, 4-8 embryos

- 2005 ART Success Rates, CDC Report

Choice Restricted

- Choices outlined, but donor does not agree to scientific donation-no donation permissible
- Regardless of dispositional choices in agreement with egg donor, current best practice is to disallow donation unless donor can be contacted for IC discussion and agreement at time of E/o donation



Inadequate/Absent Informed Consent

- Allegation of negligent care may apply
- May be included as part of a medical malpractice cause of action, but rarely, standing alone, is the basis of a lawsuit
- Taken together with other negligence, can lead to an award of damages

Failure to Obtain Informed Consent

■ Plaintiff must show:

- Lack of informed consent
- Decision to proceed would have been different if patient had accurate facts that would have been presented in full informed consent discussion
- Extremely difficult to demonstrate plaintiff thought & decision making process in retrospect

“Taken as a Whole”

- If plaintiff can show negligence in other actions of defendant, then lack of informed consent/inadequate informed consent goes toward the establishment of a pattern of negligence.

Informed Consent for hESCR

- In this highly controversial field, the greater harm is disregarding rights and personal beliefs of potential donors and imposing society's needs over those of the individual. Informed consent addresses this issue and helps to prevent moral injustice and societal condemnation of the scientific process.

Moving Forward

- Patient education & public awareness
- Discussion of logistics/practicalities of donation
- Full and careful informed consent
 - Consider when, who and how
- Facilitation of the process
- Enlist support of fertility clinics
- Parameters for acceptance of donation
 - Donor gametes an issue



OBSERVATION:

Reproductive Endocrinologists have no uniform informational procedure pertaining to dispositional options for patients with excess embryos. Since 2001, the DHHS has spent over \$10MM to raise public awareness about embryo adoption/donation. This information has reached professionals in the field, but widespread knowledge among the patient community is still lacking. Conversely, there is scant public awareness about donating for research. The research community must recognize that accurate, accessible information about donation of embryos to research does not exist nor do patients have the logistical information to make a donation possible.

RECOMMENDATION:

The research community must fund awareness building campaigns targeted at patients.



OBSERVATION:

RE's not affiliated with a research facility do not provide patients with information about donation to research. The logistical hurdles for patients make donation very difficult and thereby encourage alternate dispositional choices.

RECOMMENDATION:

The research community must develop procedures and chain-of-custody plans for patients interested in embryo donation for hESCR and be willing to offer a frank discussion about the entire process, including monetary issues.



OBSERVATION:

Patients need help in understanding consent forms when they donate to research and need to understand what type of research is done.

RECOMMENDATION:

Research facilities should have a uniform consent form to ease the burden on the patient community. Research facilities must clearly state their research goals, methods and categories of research.



OBSERVATION:

General patient awareness regarding Human Embryonic Stem Cell research is lacking in both the purpose and application.

RECOMMENDATION:

The research community must explain in clear terms the therapeutic potential of hESCR and the role embryo donors play in this process.



OBSERVATION:

Patients may need/want to confer with an “industry” representative regarding hESCR and the consent forms.

RECOMMENDATION:

Provide resources in a patient package that not only includes a draft consent form, research facility information and logistical details (including financial), but also contact information for a research coordinator who can answer questions.

OBSERVATION:

Patients do not have easy access to information about research facilities' locations and the type of research they target.

RECOMMENDATION:

If this information exists, greater awareness within the patient community is needed. If a “clearinghouse” type website does not exist, it needs to be created so that patients anywhere can easily locate a facility that accepts donated embryos.

Special Attention

■ Third Party Participant

- How document describes participant is important

- KM v. EG, CA (2005)

- Same-sex partners, donor sperm, IVF, eggs from one partner, gestation by other partner
- Child born
- Couple splits
- Custody battle
- Egg provider termed “donor” by clinic’s IC, despite intention to parent-lost custody (court later over

A.Z. v. B.Z.

- Informed consent signed on 7 occasions
- So ambiguous cannot be used to determine fate of embryos
- IC may be relied upon only to determine relationship between couple and clinic
- Will not force parenthood
 - 2000

J.B. v. M.B.

- Consider changed circumstances and competing interests of parties
- Wish to not reproduce more compelling than hope to procreate
 - 2001

Litowitz v. Litowitz

- Cryopreservation agreement with clinic is controlling
- Strict contract analysis, neither party given embryos: clinic allowed to thaw, which was option chosen in original contract
 - 2002

Roman v. Roman

- Found “meeting of minds” in validating consent to allow embryos to be destroyed in event of divorce
- Follows trend of not forcing procreation
 - 2006