

## Providing Embryo Placement Services



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- **What is a *Donation***
- **What do patients really do when they have decided their families are complete or otherwise decided to cease treatments?**
- **What are the responsibilities and with whom do they lie?**
- **What do the FDA, AATB, and ASRM say about Embryo Donation?**
- **What are the intricacies of embryo donation for research?**

## **What is a Donation?**

**Donation refers to:**

- Gift
- Contribution
- Bequest

## **What is a *Donation*?**

**Anonymous donation of embryos is really the only common “true “ anonymous “donation” we work with in reproductive medicine.**

**Embryo donors are not paid to “donate”, as are sperm and egg (oocyte) “donors”.**

## **Donation Statistics**

**Our most recent five years of data from more than 800 clients requesting termination of storage whose embryos were created in more than 100 different IVF clinics from 25 different states shows that:**

- **73% chose to have their embryos thawed and discarded**
- **18% chose to donate to research (>90% of this is stem cell research)**
- **9% chose to donate to other recipients**

## **Donation Statistics**

**These statistics varied slightly between our 3 facilities (FL, MN, \*NV), with a lower percentage of individuals selecting thawing and discarding in our MN office than our other two offices. Anecdotally, this may be attributed to the service area of our MN office. While these trends are real, they don't appear to be statistically significant.**

**\*NV has only been in operation for 2 of the 5 years of this data.**

**What are the responsibilities and with whom do they lie?**

**First, we are charged with properly informing the owners of the embryos**

- Of all of their options
- Of the implications of donation.

**Embryo Donation is a very generous act, however, it is an involved process, the clients need to understand that.**

**Steps Involved in donation to other recipients:**

**Proper consenting of both the donors and the recipients.**

**This is a step, in our opinion at ReproTech, where costs can be controlled by using standardized donation and recipient agreements.**

## **Steps involved in donation to other recipients:**

### **Embryo evaluation by laboratory which created the embryos**

**Are there a sufficient number of embryos of adequate quality to provide the recipients with a reasonable chance of a transfer..... or a pregnancy.....or a baby? If not, why go any further?**

## **FDA vs. AATB vs. ASRM requirements**

### **What are the FDA requirements?**

**Wait 6 months from retrieval**

**Proper labeling of the embryos while suitability is being determined.**

**Proper notification of the treating physicians and recipients of communicable disease risk.**

## **FDA vs. AATB requirements**

### **What are the AATB requirements?**

**Previously mentioned FDA requirements,  
plus FDA requirements for egg and  
sperm donors,**

**Plus a six month quarantine and follow-  
up testing,**

**Plus genetic screening**

## **Steps involved per AATB**

### **Donor Screening**

**Completion of the same screening  
questionnaires used for an egg donor  
AND a sperm donor.**

## **Steps involved per AATB**

**Communicable disease testing of both gamete providers.**

**Genetic disease screening and testing of both gamete providers, followed by genetic evaluation by qualified personnel**

**Physical Examinations of both gamete providers is suggested by FDA but not required by FDA or AATB**

## **Steps involved per ASRM**

**Most of above, plus Psychological Evaluation and counseling by trained professional**

**Three month “cooling” period between signing donation paper work and the donation.**

## **Donor Suitability**

**In truth, you can't complete a Donor Eligibility Determination (DED) on two individuals at the point in time when a decision to donate the embryos is made. The FDA required testing windows are closed.**

## **Donor Suitability**

**After completing the above steps, we complete what we call donor suitability.**

**It is essentially a Donor Eligibility Determination but by strict definition does not meet the DED criteria.**

## **Donor Suitability**

**Once suitability is completed, how do we act on it? i.e. can embryos from an “unsuitable” or “ineligible” donor or donors be used?**

**In directed donations:**

**YES**

**In anonymous donations:**

**YES**

## **Working with Third Party entities, what are the requirements?**

**Unless AATB standards are met, we label the embryos as:**

- **Quarantined Tissue**
- **The tissue must not be:**
  - implanted,
  - transplanted,
  - infused,
  - or transferred until completion of the donor-eligibility determination.

## **Steps Involved in donation to research**

- **Selection of research program alternatives which have all of the proper elements in place.**
- **Enrollment of your facility in the research facility's IRB is sometimes required.**
- **Training of your staff in proper human subject consenting.**

## **Steps Involved in donation to research**

### **Proper consenting of both donors**

**This is often complicated by:**

- Divorce
- Use of gamete donors
- Regulations/Laws in effect in the State
  - Where the embryos were created
  - Where the donors currently reside
  - Where the embryos currently reside

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**Questions??**

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