



REPRODUCTIVE SPECIALTY CENTRE
Invitro Fertilization GIFT Advanced Laparoscopic and Laser Surgery Microsurgery

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July 5, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

This letter is to express our concerns about the proposed testing of egg donors prior to the IVF cycle and freezing the embryos for six months until the egg donor is tested again. This proposal would be detrimental to everyone involved in the donor oocyte process and would make it even more difficult to meet the needs of our patients.

Our current success rate with fresh IVF cycles is 40 to 45%. Being required to use frozen embryos would decrease the success rate by approximately 15%. This makes a huge difference to potential oocyte donors and oocyte recipients who base a large part of their decision to participate on the success rate. Why should either party participate when the chance for a successful pregnancy is so low?

Finding suitable donors is already a challenge in our area, and this would be made even more difficult with the above requirements. Decreasing the rate of success so drastically will discourage many donors and even more will be discouraged by the prospect of having to return six months after completing their cycle. The mobility of today's society makes having to contact all donors to return after six months a daunting and investigative task. What is to become of the frozen embryos? Would they have to be destroyed after collecting and storing them for over six months?

The oocyte donor program carefully screens all potential egg donors socially, physically, and psychologically. This extensive process was created to prevent anyone that may risk the welfare of the potential embryo or recipient from being able to participate. To our knowledge, there has been no documented transmission of disease using donated eggs.

Thank you for this opportunity to voice our concerns. Hopefully, you will reconsider the proposed requirements. If you would like to discuss this matter further, please feel free to contact our office.

Sincerely,

Mary Reardon RN

Mary Reardon, R.N.
Oocyte Donor Program Coordinator

MR/taj

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