The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY
SECRETARY

PAUL J. COTE, JR.
COMMISSIONER

July 2006

MEMORANDUM

To: Massachusetts Providers of In Vitro Fertilization Therapy
Massachusetts Biomedical Research Advisory Council
Massachusetts Board of Registration in Medicine
Massachusetts Medical Society
Massachusetts Chapter of American College of Obstetricians and Gynecology

From: Paul J. Cote, Jr.
Commissioner

Re: Informational Pamphlet and Informed Consent Form for Patients Undergoing Egg Retrieval During In Vitro Fertilization Therapy

I. Overview

The attached Informational Pamphlet and Informed Consent Form have been developed by the Massachusetts Department of Public Health (MDPH) in accordance with the requirements of Massachusetts General Law c.111L, Biotechnology (Biotechnology Law) enacted in June 2005. The content of both the pamphlet and the consent form has been informed by the expertise of members of the Massachusetts Biomedical Research Advisory Council and providers of in vitro fertilization therapy.

Section 4 (a) of the Biotechnology Law requires a physician or other health care provider who provides a patient with in vitro fertilization therapy to provide the patient with timely, relevant and appropriate

information sufficient to allow that patient to make an informed and voluntary choice regarding the disposition of any pre-implantation embryos or gametes remaining following treatment.

The law specifically requires MDPH to prescribe, and provide for use by physicians and other health care providers who treat patients for infertility through in vitro or any other process where an egg is retrieved from a woman, the following materials:

(1) An informational pamphlet concerning the procedure by which an egg is retrieved from the patient; and
(2) An informed consent form as described in the law that includes an acknowledgement by the patient that she has been given, and has reviewed and understands, the informational pamphlet.

II. Informational Pamphlet (see attached)

As required by section 4(a)(1) of the Biotechnology Law, the Informational Pamphlet (Attachment I) describes the procedure by which egg retrieval is conducted, including:

- All short and long-term potential health impacts of the procedure on the patient;
- Any drugs or devices to be used, including whether they have received approval from the United States Food and Drug administration;
- The risks involved;
- Any discomfort and side effects that may be experienced;
- Any alternatives which the patient may have, and their attendant risks and benefits;
- Medical treatment available to the patient should complications arise; and
- A statement that the particular treatment may involve unforeseeable risks to the patient, embryo or fetus.

A physician or other health care provider treating a woman with a procedure by which an egg is intended to be retrieved is required to provide the patient with this pamphlet or a legible copy of the pamphlet, and provide any other treatment information which may be specific to the patient's treatment.

The requirement to provide the woman with this pamphlet does not restrict the provision of other informational materials by the physician or other health care provider.

III. Informed Consent Form for Infertility Treatment Involving Egg Retrieval (see attached)

As required by section 4(a)(2) of the Biotechnology Law, the Informed Consent Form (Attachment II) must state that the patient:

- Has been given, has reviewed, and understands the informational pamphlet;
- Has consulted with her physician or health care provider concerning the general procedures and her specific medical situation; and
- Consents to proceed with the procedure or process, understanding the procedure, process and risks.

The Law also requires that the Informed Consent Form contain a "Notes" section to be completed by the physician or health care provider. The "Notes" section must contain any medical information, alternative procedures, medicines, devices, considerations or risks relevant to the specific patient's informed consent to proceed. In each case, the "Notes" section must be completed by the physician or health care provider.

A physician or other health care provider treating a woman by a procedure by which an egg is intended to be retrieved from the patient must provide her with the Informed Consent Form (a legible copy), and must keep a signed copy of the form in the patient's medical file.

Please note that MDPH recognizes that physicians and other health care providers routinely provide patients with comprehensive, up-to-date informed consent forms for egg retrieval as issued by their own practice or facility. Therefore, the MDPH Form simply:

- Requires a copy of the physician or health care provider's own consent to treatment /informed consent form be attached to the MDPH Form;
- Requires that the patient acknowledge she has received and read the health care provider's informed consent form that explains the procedure and process and any risks involved with egg retrieval;
- Requires that the patient acknowledge she understands the procedure, process and risks as explained in the Egg Retrieval pamphlet and the health care provider's informed consent form; and
- States that the patient consents to proceed with the procedure or process as described in the health care provider's informed consent form.

IV. Reproduction and Distribution of Brochure and Informed Consent Form

Both the informational brochure and the informed consent form may be copied without permission or downloaded from the MDPH Website at http://www.mass.gov/dph/fch/dpech.htm
Any questions about the brochure or consent form may be addressed to:

Karin Downs, RN, MPH
Assistant Director for Clinical Affairs
Division of Perinatal, Early Childhood and Children with Special Health Care Needs
Massachusetts Department of Public Health
250 Washington St. 4th Floor
Boston, MA 02108 - 4619
(617) 624-5967
(617) 624-5927 (fax)
karin.downs@state.ma.us

Attachments
Consent form – English, Spanish, and Portuguese
Egg Retrieval brochure – English, Spanish, and Portuguese