

# NYA AFF

New York Attorneys for Adoption & Family Formation

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November 20, 2019

## TO INTERESTED PARTIES

**Re: Child Parent Security Act/Egg Donation**

**Dear Sir or Madam:**

We, the undersigned, are a group of adoption and assisted reproduction law attorneys and other child-welfare professionals from across New York State, who work with adoptive families, children, child welfare agencies and the court system to protect and advocate for the rights of adoptive children, children born through assisted reproduction and their families. We submit this letter in support of the Child Parent Security Act ("CPSA") and specifically to explain the positive effects it will have on egg donation in New York State.

The proposed language of the CPSA supports and would enhance the New York State Department of Health's requirements regarding obtaining the informed consent of egg donors in the context of assisted reproduction.<sup>1</sup>

CPSA at Article 25-B Section 2599-cc (4) states:

The commissioner, in consultation with the transplant council, shall promulgate regulations on the donation of ova. Such regulations shall include, but not be limited to: (a) guidelines and procedures for obtaining fully informed consent from potential donors, including but not limited to a full disclosure of any known health risks of the ova donation process; (b) the development and distribution, in printed form and on the department's website, of informational material relating to the donation of ova; ....

The New York State Department of Health is the Agency of the New York State Government responsible for public health. Public Health Law Article 43-B, enacted in 1990, established the Department of Health Commissioner's authority over tissue banks. Based on that delegation of authority, the Department of Health promulgates Rules and Regulations which have

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<sup>1</sup> There are different informed consent requirements for donor involved in stem cell research or other medical procedures and research.



the force of law. The Rules and Regulations are published in the New York Code of Rules and Regulations (NYCRR).

Section 4365 of the Public Health Law directs the Commissioner to establish standards for tissue banks and storage facilities. 10 NYCRR Part 52, Tissue Banks and Nontransplant Anatomic Banks, covers such tissues as skin, eye, semen, embryos, and stem cells. Licensure is required for all tissue banking activities in New York, including collection, processing, storage, and distribution. See 10 NYCRR 52-2.1, attached.

The regulations for *Reproductive Tissue Banks* are at Title 10 of the NYCRR Part 52-8 and became effective on November 1, 2000. Subpart 52-8.8 sets out the requirements for donor's informed consent.

The rules regarding egg donors' informed consent were published and became effective after the New York State Task Force on Life and the Law<sup>2</sup> engaged in an extensive study of the practice of egg donation.

In 1998 after its research on egg donation, the Task Force received a Ford Foundation grant to create a model process and a model form for obtaining informed consent from egg donors.

The NYS Guidebook on egg donation "Thinking of Becoming an Egg Donor" was published by the Task Force and can be found on the Department of Health website at <https://www.health.ny.gov/publications/1127/> . In addition, the Task Force created a Model Informed Consent Form (attached here) and a guide for practitioners to use the Model Form which can be found at: [https://www.health.ny.gov/regulations/task\\_force/docs/informed\\_consent\\_for\\_egg\\_donors\\_guide.pdf](https://www.health.ny.gov/regulations/task_force/docs/informed_consent_for_egg_donors_guide.pdf) ). The Model Form and the Guidebook were widely distributed to medical practitioners in the assisted reproduction field.

As mentioned above, Title 10 of the NYCRR Part 52-8 was promulgated after the Task Force investigation and recommendations on egg donation were published and includes in large measure the recommendations of the Task Force.

#### 52-8.8 Informed consent.

(a) Reproductive tissue banks shall obtain written informed consent from the donor for participation in the donation program, after the director or a designee has provided information to the donor on the procedures for collection, storage and use of semen, oocytes or embryos, and the risks of any drugs, surgical procedures and/or anesthesia administered. The informed consent shall include:

- (1) a statement that the donor has been informed that his or her name and address will be kept on file by the reproductive tissue bank, and advised of the

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<sup>2</sup> The New York State Task Force on Life and the Law was created by Gov Mario Cuomo in 1985 to develop public policy on issues arising from medical advances, including assisted reproduction.



- restrictions on release of donor-identifying information specified in section 52-8.9 of this Subpart;
- (2) authorization for performance of genetic and infectious disease marker testing, consistent with statutory requirements for genetic testing;
  - (3) notification of all currently known ways in which the donor's reproductive tissue and resulting embryos may be used. If the reproductive tissue bank accepts reproductive tissue with restrictions on the manner in which embryos created may be used, the consent also shall include a statement that the reproductive tissue bank has informed the donor that it will make a good faith effort to ensure that the donor's restrictions are respected, but that it cannot guarantee that the recipients of the reproductive tissue will abide by the donor's restrictions;
  - (4) authorization for disclosure of the donor's medical history information to potential recipients and their physicians, consistent with statutory requirements for the disclosure of genetic and other medical information;
  - (5) an explanation of the oocyte donor's extent of responsibility for any costs of any medical complications associated with oocyte donation; and
  - (6) a statement that the reproductive tissue donor has the right to withdraw his/her consent to donation up until such time that a specific recipient has begun an assisted reproduction cycle in reliance on the availability of tissue from that donor.
- (b) Reproductive tissue banks shall obtain written informed consent from the client-depositor for participation in the semen, oocyte or embryo storage program, after the director or a designee has provided information to the client-depositor on the procedures for collection/storage and retrieval of semen, oocytes or embryos, and the risks of any drugs, surgical procedures and/or anesthesia administered, as well as procedures for payment for semen, oocyte or embryo storage. The informed consent shall include the male client-depositor's specific instructions for disposition of frozen semen upon his death. The reproductive tissue bank shall maintain and adhere to written procedures for ensuring that the client-depositor's instructions are followed.
- (c) The insemination/implantation site shall obtain written informed consent from the recipient for receipt of donated reproductive tissue, after a physician has explained the risks and benefits of the procedure, made available details of the medical history of the donor or donors, and, if applicable, notified the recipient that reproductive tissue bank records are required to be kept for the periods of time specified in section 52-8.9(a) of this Subpart and that the outcome of the procedure is required to be reported to the reproductive tissue bank.

Despite its robust requirements on informed consent for egg donors, New York State does not have a registry for egg donors. A registry, along with longitudinal research on the impact of egg



donation on women's health and well-being, would provide women considering egg donation with information to help inform their decisions.

Section 2599-cc (4)(c) of Article 25-B of the CPSA continues with this requirement:

...(c) the establishment of a voluntary central tracking registry of ova donor information, as reported by banks and storage facilities licensed pursuant to this article upon the affirmative consent of an ova donor. Such registry shall provide a means for gathering and maintaining accurate information on the: (i) number of ova donated from a single donor; (ii) health information of the donor at the time of the donation; and (iii) other information deemed appropriate by the commissioner. In addition, all such regulations shall maintain the anonymity of the donor and any resulting offspring and govern access to information maintained by the registry.

The CPSA's requirement for the establishment of a voluntary central tracking registry of ova donor information would provide a useful database which would lead to more information and therefore improved informed consent for citizens of New York considering becoming an egg donor.

We respectfully urge you to vote in favor of the CPSA during the upcoming legislative session and if this organization can be of assistance in providing additional information about the CPSA in general or egg donation specifically, please do not hesitate to reach out to me by phone at 518-436-4170 or email at [kdipaola@theCDSLAWFirm.com](mailto:kdipaola@theCDSLAWFirm.com).



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