



## **OVARIAN STIMULATION AND EGG RETRIEVAL: OVERVIEW & ISSUES TO CONSIDER**

Women are major players in the assisted reproductive health industry—both supplying and demanding eggs. Of the approximately 62 million women of reproductive age in 2002, about 1.2 million, or 2%, had an infertility-related medical appointment<sup>1</sup> in what has become a \$3 billion industry<sup>2</sup>. Some infertile women and men, as well as many researchers, are willing to pay other women exorbitant prices for their eggs. Women's eggs are also in high demand from researchers for use in embryonic stem cell research. With little to no US government oversight and regulation,<sup>3</sup> many doctors, patients, scientists, advocates and policymakers have had to make up the rules as they go.

This briefing paper provides an overview of the science and ethics of ovarian stimulation and egg retrieval and the related issues currently under debate including compensation of donors, informed consent, regulation and oversight. The Reproductive Health Technologies Project (RHTP) has developed questions around each of these topics (see Appendix A) to provide a starting point for advocates from the reproductive rights and justice communities to come together to develop and advocate for policies that put women's health and well-being center stage. RHTP views technology not as an end in itself but as an essential component for all women and men to control their own health and fertility. We believe each technology requires careful analysis of its safety, effectiveness, acceptability, and appropriateness, recognizing that all of these vary from person to person and community to community.

### **Ovarian Stimulation and Egg Retrieval: What is Involved?**

A woman may undergo ovarian stimulation and egg retrieval for:

- (1) her own assisted reproductive use;
- (2) to donate her eggs or be compensated for providing them to another woman or couple for their reproductive use; or
- (3) to donate her eggs or be compensated for providing them for use in embryonic stem cell research for the development of stem cell lines or for somatic cell nuclear transfer (SCNT).

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<sup>1</sup> Centers for Disease Control and Prevention. Fertility, Family Planning, and Reproductive Health of U.S. Women: Data from the 2002 National Survey of Family Growth. Available at: [www.cdc.gov/nchs/data/series/sr\\_23/sr23\\_025.pdf](http://www.cdc.gov/nchs/data/series/sr_23/sr23_025.pdf)

<sup>2</sup> Spar, Debora. *The Baby Business: How Money, Science and Politics Drive the Commerce of Conception*. Harvard Business School Press. 2006: pg 3.

<sup>3</sup>The U.S. restricts funding for stem cells harvested from unused embryos created during fertility treatments and therefore has not led the efforts at regulating the field and/or developing standards and guidelines for fertility clinics to follow.

SCNT, or therapeutic cloning, is a laboratory technique that involves removing the nucleus of an unfertilized egg cell, replacing it with the material from the nucleus of a "somatic cell" (a skin, heart, or nerve cell, for example), and stimulating this cell to begin dividing.<sup>4</sup>

During a typical menstrual cycle, one egg matures and is released during ovulation. In order to increase the chances of creating a viable embryo and a successful pregnancy, many women opt to stimulate their ovaries to obtain multiple mature eggs. To do this, a woman may undergo “controlled hyperstimulation” – the administration of a series of three hormones. The table below outlines the steps, the hormones, and the mechanisms of action to obtain multiple mature eggs.

		<b>Generic Drug Name/Hormone</b>	<b>Brand Name</b>	<b>Mechanism of Action</b>	
<b>STEP 1</b>	⇒	<b>Achieve baseline hormone levels</b>	Synthetic gonadotropin-releasing hormones (GnRH)	Lupron, Synarel	Temporarily suppresses normal ovarian function
<b>STEP 2</b>	⇒	<b>Stimulate ovaries to mature &amp; release multiple follicles</b>	Clomiphene citrate or Gonadotropins (injected directly)	Clomid, Serophene, Gonal-F, Follistim	Stimulates the pituitary gland to produce gonadotropins <sup>5</sup>
<b>STEP 3</b>	⇒	<b>Trigger ovulation &amp; prepare uterus for implantation of the embryo</b>	Human gonadotropin (hCG)	Pregnyl, Profasi, Novarel, Ovidrel	Similar in structure to luteinizing hormone (LH), it acts on the ovary to simulate final maturation of the egg. It also stimulates progesterone after egg retrieval to prepare uterus.

**Table 1: Controlled Ovarian Hyperstimulation**

Which hormones and drugs a woman uses is determined by her health care provider and is based on various factors, including age, ovarian responsiveness and the purpose of the egg retrieval. Typically, egg retrieval requires a commitment to a three week regimen of hormone therapy involving daily injections and frequent visits to the doctor’s office to undergo blood testing and ultrasounds.

<sup>4</sup> Association of American Medical Colleges. Available at: <http://www.aamc.org/advocacy/library/research/res0003.htm>; accessed January 10, 2008.

<sup>5</sup> Clomiphene citrate works by suppressing the amount of naturally-circulating estrogen in the body, thereby tricking the hypothalamus to send a signal to the pituitary gland to release more follicle stimulating hormone (FSH) and luteinizing hormone (LH) into the bloodstream. These hormones then stimulate the ovary to mature and release multiple follicles. Clomiphene citrate is also administered off-label in IVF procedures, following evidence-based regimens.

A woman may also undergo egg retrieval without ovarian stimulation. The egg yield, obviously, would be smaller: a woman typically releases one egg per cycle.

### **Ovarian Stimulation and Egg Retrieval: A Glossary**

**Follicle:** An egg surrounded by one or more layers of cells.

**Oocyte or Ova:** A human egg

**Gamete:** Human egg and sperm

**Zygote:** a one-celled fertilized egg.

**Blastocyst:** A thin-walled hollow structure in early embryonic development that contains a cluster of cells. It is preceded by a zygote, the fertilized egg cell, and succeeded by an embryo.

**Embryo:** A multi-celled fertilized egg, up to 8 weeks of development.

**Gonadotropin:** Protein hormone secreted by the pituitary gland to stimulate the follicles.

**Antibodies:** Proteins that are found in blood and are used by the immune system to identify and neutralize foreign objects, such as bacteria and viruses.

**Stem Cell:** Cells with the potential to develop into many different cell types in the body.

The egg retrieval procedure removes the matured eggs from the ovarian follicle using an ultrasound-guide needle. The out-patient procedure is usually conducted within 24-36 hours of the administration of the third series of hormones. The American Society for Reproductive Medicine (ASRM), a multidisciplinary membership organization committed to the advancement of reproductive medicine, estimates that a woman undergoing the process of controlled hyperstimulation will spend approximately 56 hours in the clinic, undergoing interviews, counseling and medical procedures.

### **Assessing Risks and Benefits**

As with any medical procedure, risks and benefits vary for each person. In

the case of ovarian stimulation and egg retrieval, the potential benefits are obvious for women seeking to have children of their own through assisted reproductive techniques.<sup>6</sup> The benefits may be less obvious to those women who donate or provide their eggs for someone else's reproductive benefit or for research purposes.

Surprisingly little is known about the short and long-term safety of the egg retrieval process on a women's health, the quality of the resulting eggs or the health of the resulting baby. Even less is known about the risks for a woman who undergoes multiple cycles of ovarian stimulation and egg retrieval in her lifetime. Currently, the ASRM recommends that women undergo no more than six retrieval cycles.

One potential, often discussed risk is ovarian hyperstimulation syndrome (OHSS) – a condition following the administration of human chorionic gonadotropin (hGC) to trigger ovulation. OHSS occurs when the ovaries become swollen and painful due to the development of an excessive number of follicles, the incomplete removal of follicles, or an excessive level of estrogen present in the bloodstream. OHSS may cause nausea and vomiting, abdominal discomfort, shortness of breath and labored breathing and can rapidly progress to a serious life-threatening condition, even resulting in death. In addition, OHSS carries an increased risk of clotting disorders, renal failure and ovarian twisting.

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<sup>6</sup> Although data on ART is limited, according to the CDC, in the US alone there were about 128,000 ART procedures resulting in 49,458 infants born in 2004.

While there is no formal data on the occurrence of OHSS, a recent assessment carried out by the Institute of Medicine and the National Research Council reported that most women who undergo ovarian stimulation will have some mild symptoms of hyperstimulation. In fact, ten percent of women undergoing ovarian stimulation feel lower abdominal or pelvic pain. Serious cases of OHSS occur at a rate of 100 to 200 cases per 100,000 stimulated cycles (a rate of about 1%) and in rare cases may cause kidney failure or blood clots.<sup>7</sup> It is also difficult to estimate a mortality rate, but, conservatively speaking, death appears to occur at a frequency between once every 450,000 and once every 500,000 egg donation cycles (among women with severe OHSS). The numbers are misleading, however, because they include patients who become pregnant with the eggs retrieved from their ovaries and later form blood clots during the pregnancy.<sup>8</sup>

Women who undergo egg retrieval may be at risk for early or late OHSS. Early OHSS occurs two to seven days after administration of hCG and late OHSS occurs 12-17 days after hCG administration. Late OHSS is more severe than that of early OHSS. One hypothesized explanation is that embryo transfer and pregnancy may exacerbate OHSS,<sup>9</sup> and recent studies suggest that women who donate their eggs have lower rates of OHSS than do women undergoing the procedure for their own reproductive goals.<sup>10</sup>

Information about risks associated with the actual procedure of retrieval is sparse. In one study, there were rare instances of vaginal bleeding, intra-abdominal bleeding, intestinal injuries, and peritonitis (inflammation of the lining of the abdominal cavity) but only 0.002% had complications requiring surgery.<sup>11</sup> The procedure requires use of anesthesia which may carry its own risks.

There is some known data on the potential links between the egg retrieval process and the risks of breast, ovarian and endometrial cancers, as well as the risk of future infertility:

- It is known that the three cancers are affected by hormones, but it is not known whether the interaction causes higher rates of cancer, or even perhaps lower rates.
- Data suggests that infertility, not ovulation induction drugs, increases a woman's risk of all three cancers.
- There is no current evidence that fertility drugs increase a woman's risk of breast or ovarian cancer.
- There is some evidence that the hormones increase the risk of endometrial cancers.
- Additionally, there is no compelling data proving an increased risk of infertility due to ovulation induction and egg retrieval.
- Nor does the evidence show an increased risk for early menopause, the depletion of the follicle pool, or significant instances of infection.

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<sup>7</sup> Delvigne, A. & Rozenberg S. (2002) Epidemiology and prevention of ovarian hyperstimulation syndrome: A review. *Human Reproduction Update*. 8(6): 559-77.

<sup>8</sup> Linda Giudice, Eileen Santa, and Robert Pool, eds. *Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research: Workshop Report*. Washington: National Academies Press, 2007.

<sup>9</sup> Sauer MV, Paulson RJ, Lobo RA. Rare Occurrence of Ovarian Hyperstimulation Syndrome in Oocyte Donors. *Int J Gynaecol Obstet* 1996;52: 259-62.

<sup>10</sup> Linda Giudice, Eileen Santa, and Robert Pool, eds. *Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research: Workshop Report*. Washington: National Academies Press, 2007.

<sup>11</sup> Ibid

- There is some risk of anti-ovarian antibodies being produced because of the trauma to the ovary from being pierced by a needle. It is unclear whether these antigens play any role in future IVF procedures or infertility.<sup>12</sup>

### Oversight and Regulation

The Food and Drug Administration (FDA) has authority over the approval and marketing of fertility drugs; like with many other medications, however, post-marketing surveillance and monitoring of drugs used in the egg retrieval process are weak and rely on voluntary reporting of serious adverse events by providers. Further, some of the drugs used in ovarian stimulation and retrieval have not been approved by the FDA for use in assisted reproductive techniques. Thus, there have not been prospective case controlled studies about efficacy and safety of these drugs for this purpose.

ASRM and the Society for Assisted Reproductive Technology (SART) provide guidelines and oversight of egg retrieval for reproductive purposes. In terms of protecting the egg donor, the guidelines recommend psychological evaluation and counseling as well as monetary compensation for the act of donating and all inconveniences involved. The compensation should not, however, reach an amount that would suggest payment for the oocytes themselves. However, as is true of every professional society, ASRM and SART cannot force fertility clinicians to abide by these guidelines. ASRM has also developed practice guidelines for informed consent for assisted reproductive technology services, repetitive egg donation, use of specific fertility drugs and egg transfer in clinical assisted reproduction.<sup>13</sup>

The prohibition of federal funding for human embryonic stem cell research<sup>14</sup> means there are no federal guidelines or oversight of research. In the absence of federal funding, several states – including California, Connecticut, Illinois, Indiana, Iowa, Maryland, Massachusetts, New Jersey, New York and New York – have permitted and/or funded embryonic stem cell research.<sup>15</sup> These states have or are in the process of developing regulations and guidelines for how hESC research

### Selected National/Governmental Stakeholders: A Glossary

**American Society for Reproductive Medicine (ASRM):** A multidisciplinary membership organization committed to the advancement of reproductive medicine.

**National Academies of Science (NAS):** a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare

**Institute of Medicine (IOM):** A nonprofit organization as well as an honorific membership organization established by the NAS that serves as adviser to the nation to improve health.

**National Research Council:** A nonprofit organization organized by the NAS to serve as advisor to the nation on science and engineering.

**Food and Drug Administration (FDA):** The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, including fertility drugs and devices.

**Society for Assisted Reproductive Technology (SART):** The primary membership organization of professionals dedicated to the practice of assisted reproductive technologies (ART) in the United States.

**International Society for Stem Cell Research (ISSCR):** An independent, non-profit entity formed in 2002 to encourage the field of stem cell research.

<sup>12</sup> Ibid

<sup>13</sup> These practice guidelines can be accessed via the “Members Only” section of the ASRM website, [www.asrm.org](http://www.asrm.org).

<sup>14</sup> Except for the stem cell lines created on or before August 9, 2001, as per President Bush’s executive order.

<sup>15</sup> <http://www.ncsl.org/programs/health/genetics/embfet.htm>, accessed 12/17/07

is conducted and how the eggs necessary for research are obtained yielding a patchwork of approaches. England and Canada have comprehensive laws regulating the use of all eggs, sperm, and embryos.<sup>16</sup>

## **Issues for Consideration**

### ***Compensation of Donors***

The growth in numbers of assisted fertility clinics yielded a similar increase in enterprises seeking woman willing to “donate” their eggs at prices that average \$3,000 - \$8,000. Some “baby brokers” have offered as much as \$50,000 for specific egg donors – women who are in college, 5’10” or taller, SAT scores of 1,250 or higher, no family medical problems, blue eyes, athletic build, etc. ASRM’s guidelines discourage such exorbitant rates but allow that women who donate their eggs for use in assisted reproduction can be compensated for their time and risk up to \$5000, or \$10,000 in rare cases. Compensation is not regulated or prohibited by either state or federal law.<sup>17</sup>

As interest in human embryonic stem cells (hESC) grows, and oocytes are needed for hESC research, the debate over compensation has spilled into the research arena.<sup>18</sup> Opponents of compensation cite fears of undue inducement, the potential exploitation or coercion of socially and economically disadvantaged women, undermining the voluntary nature of choice, and introduction of elements of commodification in human reproduction. Proponents argue that without compensation, women will be less likely to donate their eggs, thereby limiting the availability of eggs with which to conduct research. Proponents also argue that women will be better able to protect their interests in a market system because their control of a scarce resource will give them bargaining power. Finally, they also point out that men who donate sperm also receive compensation.<sup>19</sup>

In 2005, the National Academies of Science (NAS) issued guidelines prohibiting the payment of eggs for hESC research, including compensating women for providing eggs. Many states, including California, Connecticut, Indiana, Iowa, Maryland, Massachusetts, and nations, including Canada, the United Kingdom and South Korea, have passed similar legislation barring compensation for egg donation, some of them allowing reimbursement for direct expenses, usually the costs associated with the procedure. Our Bodies Ourselves; Center for Genetics and Society and Pro-Choice Alliance for Responsible Research have taken a similar position. In 2006, ASRM’s Ethics Committee concluded it is permissible to compensate women for research donation as these women undergo the same risks as women who donate for reproductive purposes.

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<sup>16</sup> Galpern E. Beyond embryo politics: women's health and dignity in stem cell research. Women's Health Activist. May/June 2006. (Washington, DC: National Women's Health Network.)

<sup>17</sup> In 2006, the Arizona state legislature passed a bill prohibiting compensation for both research and reproductive purposes. This bill was not signed into law.

<sup>18</sup> Most recently, in a pair of landmark studies announced in December 2007, scientists have been able to reprogram human skin cells to act like stem cells. This new advancement may allow researchers to bypass the need to retrieve oocytes for embryo creation and reduce and/or eliminate the exploitation of women in this arena.

<sup>19</sup> ASRM recommends that egg donors receive no more than \$5,000 per cycle based on a calculation multiplying the average number of hours an egg donor spends in a medical setting by the average payment to sperm donors.

The International Society for Stem Cell Research (ISSCR), an independent, non-profit entity formed in 2002 to encourage the field of stem cell research, recently convened a task force to formulate guidelines for embryonic stem cell research. The guidelines prohibit research without compelling scientific rationale and call for researchers to obtain explicit consent from donors for their somatic cells to be used in embryonic stem cell research. The task force could not come to a consensus about compensation, but did agree that donors should at least be reimbursed for direct expenses. Although the ISSCR has no way to enforce its findings, it is asking editors of peer review journals and agencies which provide research funds to require that the guidelines be followed.<sup>20</sup>

### ***Informed Consent***

As discussed above, although ovarian stimulation and egg retrieval procedures have been conducted for many years as a fertility treatment, surprisingly little is known about the short and long-term safety of the hormones and drugs used in the process. There are hundreds of anecdotal reports of complications resulting from the use of fertility drugs; however, there is an absence of quality, standardized data on the safety of these drugs. Some women's health advocates have expressed concern about the extent to which women can give informed consent when the risks and benefits of these procedures are so unknown. Additionally, advocates have called for better informed consent guidelines that realistically depict the potential impacts of research in the larger world and in the foreseeable future.

As federal funding of hESC research is prohibited, state and private hESC research and funding institutions have developed their own guidelines for informed consent. The California Institute for Regenerative Medicine (CIRM) and the state of Massachusetts both have adopted policies that draw upon the guidelines established by NAS. The major components of the various guidelines include:

- Requiring an institutional review board (IRB) review of the procurement of gametes, blastocysts and somatic cells to ensure they were obtained with informed consent from donors;
- Providing donors with a description of 'foreseeable medical risks' associated with egg donation, including risks of ovarian hyperstimulation syndrome, bleeding, infection and pregnancy;
- Notifying donors that donated eggs will not be used for reproductive purposes;
- Notifying donors that the research conducted with the donated eggs will not benefit the donor nor any other individual directly at this time;
- Notifying donors that they will not receive payment beyond reimbursement for permissible expenses;
- Notifying donors that embryos will be destroyed in the process of deriving embryonic stem cell; and
- Notifying donors that they have the right to withdraw consent of their donation until the donated materials are actually used to derive cell lines.

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<sup>20</sup> Daley, George Q. et al. "The ISSCR Guidelines for Human Embryonic Stem Cell Research." *Science* 2 February 2007: 603-604.

### ***Conflict of Interest***

The potential for a conflict of interest arises when someone in a position of trust (e.g., a health care provider or clinical researcher) has competing personal or professional interests. A clinician who is also conducting research may be in a position of conflict of interest and encourage a woman to take more risks with ovarian stimulation in order to retrieve the largest number of eggs. In California, women's health advocates have pointed out that the chair of the state task force which is supposed to create and enforce ethical guidelines also has a financial interest in firms which may benefit from the public resources available for stem cell research.

Unlike compensation and informed consent, there is a general consensus among researchers, professional societies, policymakers and advocates on the importance of preventing conflict of interest and the standards to ensure it. The basic components of standards to protect against conflict of interest, as established by NAS, include:

- Physicians performing the egg extraction must disclose his/her relationship to the research or researcher(s) to the egg donation, and shall not have a financial interest in the outcome of the research;
- Physicians attending to any donor and principal investigators shall not be the same persons, unless exceptional circumstances exist; and
- Researchers may not ask members of the infertility treatment team to generate more eggs than necessary. Any party responsible for obtaining consent and/or collecting materials should not be paid for the materials they obtain.

### ***Conclusion***

The issues surrounding ovarian stimulation and egg retrieval are complex and potentially contentious. This briefing paper provides an overview of the current science and practices of these procedures and should be used by advocates to actively engage in a more informed discourse on the various policies related to these procedures. Additionally, in an effort to start a dialogue and reach consensus on how to move forward, Appendix A of this document raises various questions under the categories of compensation, informed consent, and regulation and oversight. These questions can be used to define progressive goals and values and move the reproductive rights and justice communities forward in the development of concrete policies and procedures. As the Center for American Progress elegantly states in their publication on ART and the law, "If we are to ensure a balanced and just approach to the use of these technologies, progressives must enter the fray as soon as possible."<sup>21</sup> RHTP hopes to add to this fray and convene interested stakeholders to create a vision and a policy agenda for assisted reproductive technologies that prioritizes women's health and well-being.

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<sup>21</sup> Arons, J. *Future Choices: Assisted Reproductive Technologies and the Law*. Center for American Progress. December 2007.

## Appendix A: Questions for Discussion

### *Oversight and Regulation*

- How do we address the general lack of oversight and/or drug approval for use in assisted reproductive techniques by the FDA?
- Post-marketing surveillance and monitoring of drugs used in egg retrieval are weak and rely on voluntary reporting. How can we improve this system to capture accurate and adequate data?
- Should physicians take a strong ethical position on this issue? Should we insist that physicians create a “medical threshold”—diseases and conditions—and stay away from “designing babies?” And what do we consider a disease/condition?
- How can we create policies and/or guidelines on ovarian stimulation and egg retrieval that respect individuals’ sexual orientation and marital status?

### *Compensation of Donors*

- Should women receive compensation for the time, medical expenses and potential health risks associated with egg donation? If yes, should the compensation policy differ for donations for reproduction versus for research?
- There have been reports of couples from specific racial and ethnic backgrounds seeking eggs from women of similar backgrounds and offering larger sums of money for them. Should we address the issue of paying premiums for certain eggs, e.g. African-American or Jewish eggs? If so, how?
- How can donation policies for other organs and human material inform our development of egg donation policy recommendations?

### *Informed Consent & Conflict of Interest*

- It is widely assumed that the egg retrieval process should be the same for reproductive and research purposes, although the potential benefits to the women who provide the eggs are different. Given this, should we evaluate the risks associated with donation differently? If so, why?
- Should we adopt informed consent standards that require disclosure that the uses of Lupron, etc. are off-label and, as a result, there are no prospective safety data?
- What are the critical components of informed consent for egg retrieval procedures? Should these standards differ for the clinical and research settings? If so, how?

### *Next Steps*

- What should our priorities be moving forward?
- What are the outstanding questions regarding stimulation and egg retrieval which would be priorities for a research/policy agenda?

## **APPENDIX B: Proposed and enacted federal and state legislation related to egg donation.<sup>22</sup>**

### **FEDERAL BILLS**

Note: None passed

#### **HOPE Act**

To provide increased Federal funding for stem cell research, to expand the number of embryonic stem cell lines available for Federally funded research, to provide ethical guidelines for stem cell research, to derive human pluripotent stem cell lines using techniques that do not create an embryo or embryos for research or knowingly harm human embryo or embryos, and for other purposes.

S 363

110<sup>th</sup> Congress

Introduced by Senator Norm Coleman

**Relevant language:** ...No Valuable Consideration... [for] human ovum, human blastocyst, human embryo, or stem cell derived from a human embryo.

#### **Human Cloning Ban and Stem Cell Research Protection Act of 2003**

To prohibit human cloning and protect stem cell research.

S 303

108<sup>th</sup> Congress (version in 109<sup>th</sup> Congress additionally)

Introduced by Mr. Hatch (for himself, Mrs. Feinstein, Mr. Specter, Mr. Kennedy, Mr. Harkin, and Mr. Miller)

**Relevant language:** (1) Informed consent- In accordance with subsection (b), an oocyte may not be used in nuclear transplantation research unless such oocyte shall have been donated voluntarily by and with the informed consent of the woman donating the oocyte. (2) Prohibition on purchase or sale- No human oocyte or unfertilized blastocyst may be acquired, received, or otherwise transferred for valuable consideration if the transfer affects interstate commerce.

#### **Human Cloning Ban and Stem Cell Research Protection Act of 2007**

A bill to prohibit human cloning and protect stem cell research.

S.812

110<sup>th</sup> Congress

Introduced by Mr. Hatch and Mr. Orrin (for themselves, Mrs. Feinstein, Mr. Harkin, Mr. Kennedy, Mr. Rockefeller, and Mr. Specter)

**Relevant language:** Prohibits: (1) a somatic cell nucleus from being transplanted into a human oocyte (egg) that has undergone or will undergo fertilization; (2) an unfertilized blastocyst from being maintained after more than 14 days from its first cell division, not counting storage times at temperatures less than zero degrees centigrade; (3) an oocyte from

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<sup>22</sup> Federal bills were found on [www.thomas.gov](http://www.thomas.gov) with a search using the term, "stem cell." State laws were found on <http://www.ncsl.org/programs/health/genetics/embfet.htm>. All bills were searched for language regarding eggs, oocytes etc. State laws pertaining to egg donation informed consent and compensation are included in this paper. For a complete list of laws pertaining to embryo disposition, go to: [www.ncsl.org/programs/health/embryodisposition.htm](http://www.ncsl.org/programs/health/embryodisposition.htm).

being used in nuclear transplantation research unless donated voluntarily with the donor's informed consent; (4) a human oocyte or unfertilized blastocyst from being acquired, received, or transferred for valuable consideration in interstate commerce; and (5) nuclear transplantation in a laboratory in which human oocytes are subject to assisted reproductive technology treatments or procedures.

### **Stem Cell Research Act of 2000**

To amend the Public Health Service Act to provide for research with respect to human embryonic stem cells.

S 2015

106<sup>th</sup> Congress (version in 107<sup>th</sup> Congress additionally)

Introduced by Mr. Specter (for himself and Mr. Harkin)

**Relevant language:** It shall be unlawful for any person receiving Federal funds to knowingly acquire, receive, or otherwise transfer any human gametes or human embryos for valuable consideration if the acquisition, receipt, or transfer affects interstate commerce.

### **Stem Cell Research Investment Act of 2005**

To amend the Internal Revenue Code of 1986 to allow tax credits to holders of stem cell research bonds.

HR 1650

109<sup>th</sup> Congress

Introduced by Mrs. Johnson of Connecticut (for herself, Mr. Castle, Mr. Boswell, Mrs. Christensen, Ms. Lee, Mr. Ramstad, Ms. Loretta Sanchez of California, Mr. Shays, and Mr. Simmons)

**Relevant language:** Neither the individuals for whom the embryo was created nor any other person or entity which participated in the fertility treatment through which the embryo was created received, directly or indirectly, any monetary incentive or other compensation with respect to the donation of the embryo.

### **Stem Cell Research Enhancement Act of 2007**

A bill to amend the Public Health Service Act to provide for human embryonic stem cell research.

S.997

110<sup>th</sup> Congress

Introduced by Mr. Harkin (for himself, Mrs. Feinstein, Mr. Hatch, Mr. Kennedy, Mr. Reid, Mr. Smith and Mr. Specter)

**Relevant language:** Limits such research to stem cells that meet the following ethical requirements: (1) the stem cells were derived from human embryos donated from in vitro fertilization clinics for the purpose of fertility treatment and were in excess of the needs of the individuals seeking such treatment; (2) the embryos would never be implanted in a woman and would otherwise be discarded; and (3) such individuals donate the embryos with written informed consent and receive no financial or other inducements.

## **STATE LAWS**

### **California**

California Penal Code § 367g

California prohibits the use of sperm, ova, or embryos in assisted reproduction technology, for any purpose other than that indicated by the sperm, ova, or embryo provider's signature on a written consent form. It also requires signed written consent to implant gametes or embryos. However, men who donate their sperm to a licensed tissue bank are excluded from this statute.

California Health and Safety Codes § 125315

California requires health care providers to give infertility patients the necessary information to make an informed and voluntary choice regarding the disposition of embryos following fertility treatments including: storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. The health care provider must also provide a form to the individual that sets forth advanced written directives regarding the disposition of embryos. The State Department of Health Services must also establish and maintain a registry of embryos that would provide researchers access for research purposes. The law specifies specific requirements for obtaining informed consent for individuals donating embryos for research.

Cal. Stats., Chap. 483 (2006)

California requires that a health care provider obtain written and oral informed consent from a patient for any ovarian egg retrieval method after providing the patient with a standardized written summary of health and consumer issues. It also prohibits human oocytes or embryos from being acquired, sold or transferred for valuable consideration for medical research or therapies.

### **Connecticut**

Connecticut General Statutes § 19a-32d-32g

Connecticut requires healthcare providers to give infertility patients the information to make an informed choice regarding the disposition of embryos following fertility treatments including: storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. The law also requires written consent to donate embryos, embryonic stem cells, eggs or sperm for research.

### **Maryland**

Md. Ann. Code Business and Economic Development §5-2B-10

Maryland requires a health care provider delivering fertility treatment to provide patients with the option to store, discard, donate the embryos to research or for adoption, or donate embryos to the fertility clinic for clinical purposes. The law also requires written consent to donate for research purposes and unused eggs may not be donated to state-funded research.

## **Massachusetts**

Mass. Gen. Laws Chapter 111L

Massachusetts requires physicians to provide patients with information sufficient to allow that patient to make an informed and voluntary choice regarding the disposition of any embryos or gametes remaining after in vitro fertilization therapy. The physician must present the patient with the options of storing, donating to another person or to research, or other wise disposing or destroying any unused pre-implantation embryos.

## **New Jersey**

N.J. Stat. Ann. §26:2 Z-2

New Jersey requires that individuals be presented with the option of storing any unused embryos, donating them to another person or to research, or other means of disposition.

## **New York**

NYCRR 52-8.7

New York prohibits the creation of embryos for donation by fertilizing donor eggs with donor semen, except at the request of a specific patient who intends to use the embryos for her own treatment.

NYCRR 52-8.8

New York requires that reproductive tissue banks obtain written informed consent from the donor for participation in the donation program, after the director/designee has provided information to the donor on the procedures, storage and use of semen, oocytes or embryos, and the risks of any drugs, surgical procedures and/or anesthesia administration. The rules include criteria for informed consent.

## **Oklahoma**

Okla. Stat. tit. 10, §556

Oklahoma authorizes human embryo donations and transfers and requires that certain techniques be used by physicians with written consent and confidentiality.