

**Interstate Alliance on Stem Cell Research
(IASCR)
New York State Policy Overview
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Empire State Stem Cell Board (ESSCB)

- Public Health Law, Article 2, Title V-A (April 2007)
- Mission: To foster a strong stem cell research community in New York State and to accelerate the growth of scientific knowledge about stem cell biology and the development of therapies and diagnostic methods under the highest ethical, scientific, and medical standards for the purpose of alleviating disease and improving human health.
- \$ 600 Million in New York State Funds over 11 Years

Strategic Plan of ESSCB

- Five categories for funding:
 - Research
 - Scientific training
 - Infrastructure development
 - Ethical, legal, social issues and education (ELSIE)
 - Administration
- In 2008-09, 413 applications were submitted and 125 applications were funded for a total of \$103.9 million.
- To date, ESSCB has made awards and approved the issuance of RFAs totaling \$175.5 million.

Strategic Plan of ESSCB

Current RFAs:

- Support for undergraduate summer internships and curriculum involving stem cells
- Support for the derivation of new human embryonic stem cell lines and for research on a broad range of stem cell research
- Support for promising stem cell researchers in their transition from fellows to faculty members
- Support for fellowships and pre- and post-doctoral training

Future RFAs:

- Support for medical, dental, and veterinary student training programs
- Support for public education on stem cell research

ESSCB Funding Goals: Ethical, Legal, Social Issues and Education

- Engage diverse communities to enhance public understanding of critical ethical, legal and social issues and provide opportunities for education on stem cell research and its impact on society.
- Evaluate ELSIE issues related to stem cell research and establish ethical standards for NYSTEM-funded research
- Support research and scholarship on ELSIE issues to advance stem cell research itself and inform public policy.

5 - Year Expenditure Plan

Category	Percent	Target Expenditures (5 Years)
Research	65 - 80%	\$ 195 M - \$ 240 M
Science training	4 - 10%	\$ 12 M - \$ 30 M
Infrastructure	10 - 15%	\$ 30 M - \$ 45 M
ELSIE	3 - 5%	\$ 9 M - \$ 15 M
Administration	3 - 5 %	\$ 9 M - \$ 15 M
Total	100%	\$ 300 M

The Empire State Stem Cell Board

- Comprised of a Funding Committee and an Ethics Committee
- Each Committee has 13 members
 - Appointed by the Legislature and the Governor
 - Chaired by the Commissioner of Health
- Several Advisory Working Groups

Meetings of the Committees and ESSCB

- Funding Committee: 12 meetings
- Ethics Committee: 15 meetings
- Full Board: 4 meetings
- All meetings are open to the public, webcast, and available on-line for 30 days after a meeting.

Funding Committee Responsibilities

- Provide for independent, scientific peer-review
- Develop criteria and standards for funding applications, and for the scientific and medical oversight of awards
- Solicit and review grant applications
- Make funding recommendations to the Commissioner of Health

Ethics Committee Responsibilities

Make recommendations to the Funding Committee on:

- Scientific, medical, and ethical standards for funded research
- Standards for the medical, socioeconomic and financial aspects of clinical trials and therapy delivery to patients
- Relevant ethical and regulatory issues

ESSCB Ethics Policy Development

- **Issues identified by Funding Committee, Ethics Committee, and NYSTEM Staff**

- **Deliberations informed by:**
 - **Expert presentations at meetings**

 - **Peer-reviewed literature**

 - **Guidelines issued by expert bodies, e.g., the National Academies of Science (NAS), the International Society for Stem Cell Researchers (ISSCR) and the Institutes of Medicine (IOM)**

 - **Laws and regulations of other states and countries**

 - **Staff presentations of relevant law and background; data gathered by survey or otherwise**

 - **Formation of Work Groups**

Ethics Committee Issues

The Ethics Committee has engaged in robust public discussions of a wide range of issues, including:

- ESCRO Membership and Duties
- Use of Embryos in Stem Cell Research
- Informed Consent
- NIH Guidelines
- Payments to gamete donors (particularly oocyte donors)
- Educational Initiatives

Use of Embryos in NYSTEM-Funded Research

- Statute is silent as to funding for hESC research
- Complex issue: pluralistic society; usage of public/taxpayer funds
- Is there a moral or ethical difference between embryos that are created for research and those that are leftover from IVF treatments (and which will likely be destroyed)?
- Is there a way to conduct hESC research that shows respect for the embryo? Does “respectful destruction” exist?

Respect for the Embryo

Possible points of consensus:

- Do not use embryos that have developed for more than 14 days or that have formed a primitive streak
- Protocols must have requisite scientific merit and/ or cannot be done without use of embryos
- Use only the number of embryos necessary to carry out the goals of the research

Donor Payment

- **Issue: Should we compensate donors of biological materials for their donation? If so, in what amount?**
- Donated biological materials may include oocytes, sperm, embryos and somatic cells.
- How do we evaluate the ethicality of donor payment?
- Should practical implications and other real-world factors impact the analysis?

Donor Payment

- Three types of payments:
 - Out-of-pocket reimbursement – direct expenses
 - Reimbursement for “time and burden”
 - Payment for the actual biological materials
- Last category widely-viewed as impermissible: commoditization of the body
- Accordingly, most consensus bodies prohibit payments for embryos that were created, and gametes that were harvested, for IVF purposes.

Oocyte Donor Payment: Ethical Arguments

Pros

- Fairness/ No Exploitation
- Avoids Paternalism/
Promotes Autonomy
- Justice/ Equity:
 - Society allows payments in other similar circumstances
 - IVF recruitment heavily favors caucasian women of higher economic brackets

Cons

- Coercion / Undue inducement to engage in risky behavior
- Commoditization
- Disproportionate Recruitment of Socioeconomically Disadvantaged Women

Oocyte Donor Payment: Other Considerations

- States that do not provide payment to oocyte donors have garnered virtually no donations
- Problems with interstate and international collaboration
- If payment is allowed, how should the amount be determined?
 - IRB/ ESCRO review for coerciveness?
 - Parallel with IVF payments?
 - Ceilings?
 - Wage-payment?
 - Token Appreciation?

Oocyte Donor Payment Vote

- Issue deliberated at numerous meetings for a year
- Presentations and literature on: legal and ethical issues; medical risks to women undergoing; scientific need for fresh oocytes
- **Resolution: Allow NYSTEM-funded researchers to compensate women who donate their oocytes directly and solely to research for the time, risk and burden involved in donating, in an amount parallel to what women in NYS are compensated for similar donations for reproductive purposes.**
- NYS permits compensation in line with ASRM
- 1 dissenting vote, on Ethics Committee

Factors Supporting Compensation for Oocyte Donors

- Finding that donations of oocytes are necessary to further important stem cell research
- Acknowledgement that the risks can be very detrimental, but do not occur frequently
 - Risks involved in donating to research are no greater than those involved in donating for reproductive purposes
- A woman is capable of adequately weighing these risks when disclosures are comprehensive

Factors Supporting Compensation for Oocyte Donors (Con't)

- Permissible and ethical to compensate women who donate oocytes for reproductive purposes for time, burden and risk
 - Donations to research arguable benefit more of society than private reproductive donations
 - IVF donations rarely come from minority or socio-economically-challenged women
- Permissible and ethical to compensate participants in other forms of human subjects research

Board Factors Supporting Compensation for Oocyte Donors (Con't)

- Appropriate oversight by IRBs and SCROs:
 - Ensure that the amounts, even if within guidelines, are still not coercive in individual circumstances
 - No compensation for number or quality of egg – just time and burden
- Importantly, tied to fully-informed, voluntarily-provided consent
 - Main argument against compensation: coercion to donor to consent despite risks, or to otherwise minimize risks
 - ESSCB: Women are able to properly weigh risks and benefits so long as compensation was not coercively high (in the individual scenario) and all risks are fully disclosed

Oocyte Donor Payment Vote Aftermath

- Statement posted NYSTEM website
- Positive response from policymakers in other states, the private sector, and researcher
- Media attention – mixed; very favorable editorial in the NY Times
 - Possible article in the works by Ethics Committee members to put the ethics rationales supporting their decision in peer-reviewed literature
- Confusion by some members of the public who thought they could donate at any clinic and receive NYSTEM compensation

Other Donor Payment Issues

- ESSCB has not addressed payment for sperm or somatic cell donors who donated solely to research
- ESSCB voted in initial meetings to adhere to the NAS and ISSCR recommendation of not allowing any payment for donations of excess embryos to stem cell research
 - Commoditizes the embryo
- Vague provision allowing ESCRO review of payment history of gamete donors who donated for reproductive purposes where available

Informed Consent

- Principles and Standards to be embodied in Contract Provisions
 - No ability to pass regulations or other widely-applicable guidelines
- Model Informed Consent Forms
 - Using ISSCR Forms as a base
 - Large undertaking – conform to NYSTEM standards, as well as NYS and Federal Law

Informed Consent

- Default is NAS or ISSCR, except where Board explicitly indicates, or otherwise alters, provisions
- Informed consent must result from a dynamic interaction
- Re-consent unless prohibitively difficult
- Disclosure of all long- and short-term risks
- Clear disclosure of financial issues

Informed Consent (Con't)

- Restrictions on Initial Use
 - Encourage to provide materials free of restrictions
 - Allowed to attach initial restrictions
 - Disclosure that long-term restrictions may not be adhered to
- Grantees must make counseling services available to donors, preferably at no charge
- NYSTEM's version of "acceptably derived"
 - Adhere to either NAS or ISSCR
 - Grandfather Presidential Lines

NIH Guidelines

- ESSCB submitted a letter commenting on the NIH Draft Guidelines
- In midst of considering whether and how to change NYSTEM provisions aid grantees
- Ethics Committee voted; presenting recommendations at Oct. 24 Funding Committee Meeting
- Discussion approach: Compare NIH contract language with NAS, ISSCR, and NYSTEM

NIH Guidelines & NYSTEM Requirements

- Certain provision of NYSTEM Contracts could be changed with little substantive impact
 - Research participation will have no affect on medical treatment
- Other provisions would impact principles that the Board deliberated and voted decisively upon:
 - ESCRO Review
 - Types of fundable research:
 - Creation of embryos solely for research
 - SCNT
 - Parthenogenesis

Ethics Committee Vote on New Language

- Altered language to insert:
 - Disposition options, in line with ISSCR
 - Unique clause: embryo adoption
 - Separation of decision to create embryo for reproduction and decision to donate
 - Withdrawal of consent up until time that identifiers are removed

- Did NOT alter:
 - Grandfathering of Presidential Lines
 - Re-consent
 - Obtaining informed consent from all gamete donors

NIH Registry Lines

- ESSCB has showed a willingness to relax its unique requirements for lines derived without NYSTEM funds
 - Default to NAS and ISSCR
- Many Ethics Committee members willing to allow usage of registry lines with no further review
- Some discomfort in allowing usage without any mechanism to review on the state level
- Recommended language still under Departmental review and subject to Funding Committee vote
 - Current draft allows usage of NIH cell lines, subject to ESCRO review of procurement and derivation for compliance with ethical standards

Conclusion

- www.stemcell.ny.gov
- Comments and Questions