

## STEM CELL LEGISLATION (Connecticut General Statutes §§19a-32d-32g)

- Signed into law on June 15, 2005
- CT just 3<sup>rd</sup> State to permit and publicly fund embryonic & human adult stem cell research
- Bans the cloning of human beings, allows for nuclear transfer, prohibits direct and indirect payment for donations of embryos, embryonic stem cells, unfertilized eggs or human sperm for stem cell research; criminal penalties provided for violations
- Makes \$100 million available over 10 years to fund research performed in CT; \$10 million annually through 2015 from Tobacco Settlement Funds
- Freedom of Information and open meeting rules ensure transparency of the process (applicants should be sure to clearly indicate any confidential information in any materials submitted in response to the request for proposals)

## ADVISORY COMMITTEE

- Commissioner of Department of Public Health (DPH)(Chair) and 16 political appointees
- Experts in stem cell research, ethics, business and finance
- Develops application process
- Evaluates the applications after peer review
- The criteria employed in the Advisory Committee's evaluation include, but not are not limited to, the following:
  - Scientific merit of the proposed research
  - Conformance to high ethical standards

- Ability to perform the proposed research
- Commitment of host institution, hospital or company and (where applicable) collaborators to the proposed project, including cost sharing
- Potential for collaboration across disciplines and institutions, hospitals or companies
- Benefits (including financial benefits) to the State of Connecticut
- Alignment with funding priorities as determined by the Connecticut Stem Cell Research Advisory Committee

- Monitors on-going research

#### PEER REVIEW PROCESS

- 15 members, appointed by DPH Commissioner
- Members selection is based on training and expertise in human and animal SCR research
- Members recruited from out of state to avoid conflicts of interest
- Peer review committee reviews and evaluates applications for scientific and ethical merit
- Makes recommendation to SCR Advisory Committee and Commissioner of Public Health
- Uses scoring system of the National Institutes of Health and utilizes the National Academies' Guidelines for Human Embryonic Stem Cell research to evaluate each application

#### EMBRYONIC STEM CELL RESEARCH OVERSIGHT COMMITTEE APPROVAL

- Law requires hESC research to be overseen by an Embryonic Stem Cell Research Oversight Committee (ESCRO) as provided

in the National Academies' (NAS) Guidelines for hESC Research (<http://dels.nas.edu/bls/stemcells/guidelines.shtml>)

- Applicants must also receive approval from any other applicable institutional review board (e.g., IRB or IACUC)

#### VERIFICATION FORM

- Scientists must provide verification to DPH that donations of eggs, embryos, etc., are voluntary, with informed consent
- Consent for research donations for SCR must comply with NAS Guidelines
- Verification Forms are available on the DPH Stem Cell website

#### INTELLECTUAL PROPERTY

- CT law requires applicants to submit "proposed arrangements concerning financial benefits to the state of Connecticut as a result of any patent, royalty payment or similar rights developing from any stem cell research made possible by the awarding of such grants-in-aid"
- A minimum 5% royalty is expected to the State of CT from funded research on revenues generated (See RFP and Assistance/Royalty Agreement Templates for details).

#### ASSISTANCE AGREEMENT and ROYALTY AGREEMENT

- Applicants selected to receive funding will be required to execute an Assistance Agreement and Royalty Agreement in forms approved by the Advisory Committee