CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Keeping Connecticut Healthy

REPORT TO THE GENERAL ASSEMBLY

AN ACT PERMITTING STEM CELL RESEARCH AND BANNING THE CLONING OF HUMAN BEINGS

JUNE 30, 2007

Connecticut Stem Cell Research Advisory Committee
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Department of Public Health

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Public Act 05-149, "An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings" (the Act), was approved by the Connecticut General Assembly and signed by Governor M. Jodi Rell on June 15, 2005. The Act appropriated the sum of twenty million dollars to the newly established Stem Cell Research Fund for the purpose of grants-in-aid for conducting embryonic or human adult stem cell research. For each of the fiscal years ending June 30, 2008 to June 30, 2015, inclusive, the Act specified that an additional ten million dollars should be disbursed from the State's Tobacco Settlement Fund to the Stem Cell Research Fund to support additional grants-in aid.

In accordance with Section 3(g)(3) of the Act, the Stem Cell Research Advisory Committee shall report to the Governor and the General Assembly on (1) the amount of grants-in-aid awarded to eligible institutions from the Stem Cell Research Fund pursuant to section 2 of this act, (2) the recipients of such grants-in-aid, and (3) the current status of stem cell research in the state not later than June 30, 2007.

Passage of the Act positioned Connecticut as just the third state in the nation, behind only California and New Jersey, in providing public funding in support of embryonic and human adult stem cell research. It mandated the establishment of the Connecticut Stem Cell Research Advisory and Peer Review Committees by October 1, 2005, and required the Commissioner of Public Health, as Chair of the Advisory Committee, to convene the first meeting by December 1, 2005. Significant accomplishments to date include:

- Establishment of vibrant CT Stem Cell Research Advisory and Peer Review Committees;
- Design and implementation of interactive Stem Cell Research Web Page;
- Development and Issuance of a Request for Proposals on May 10, 2006;
- Receipt of 77 Letters of Intent by June 1, 2006 and receipt of 70 Applications by July 10, 2006;
- Marketing of CT Stem Cell Research Program at ISSCR Symposium in Toronto in June 2006;
- Successful implementation of PA 06-33 and PA 06-77;
- Successful Stem Cell Research Peer Review Committee review, rating and ranking of 70 grants-in-aid applications on scientific and ethical merit while maintaining transparency of process;
- Successful Stem Cell Research Advisory Committee review and rating of 70 grants-in-aid applications during a two day event while maintaining transparency of process;
- Successful awarding of twenty one grants-in-aid totaling $19.8 million, the largest amount of public support of embryonic stem cell research provided by any state in the country, to UCONN, Yale and Wesleyan University;
- Successful completion of a report by the Ad Hoc Committee on Umbilical Cord Blood Banking
- Successful design and roll out of **StemCONN 07**, Connecticut's first International Stem Cell Research Symposium, on March 27 and 28, 2007.
- Successful branding of Connecticut as an International Center of Excellence for Stem Cell Research.

I. INTRODUCTION AND BACKGROUND

Public Act 05-149, "An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings"[1] (the Act), was approved by the General Assembly of the State of Connecticut and signed into law by Governor M. Jodi Rell on June 15, 2005. The Act appropriated the sum of twenty million dollars to the newly established Stem Cell Research Fund for the purpose of grants-in-aid for conducting embryonic or human adult stem cell research. In addition, for each of the fiscal years ending June 30, 2008 to June 30, 2015, inclusive, the Act specified that an additional ten million dollars should be disbursed from the State's Tobacco Settlement Fund to the Stem Cell Research Fund to support additional grants-in aid.

Passage of the Act positioned Connecticut as just the third state in the nation, behind only California and New Jersey, in providing public funding in support of embryonic and human adult stem cell research. It mandated the establishment of the Connecticut Stem Cell Research (SCR) Advisory and Peer Review Committees[2] by October 1, 2005, and required the Commissioner of Public Health, as Chair of the Advisory Committee, to convene the first meeting by December 1, 2005. In accordance with Section 3(g)(3) of the Act, the Stem Cell Research Advisory Committee shall report, to the Governor and the General Assembly on (1) the amount of grants-in-aid awarded to eligible institutions from the Stem Cell Research Fund pursuant to section 2 of this act, (2) the recipients of such grants-in-aid, and (3) the current status of stem cell research in the state not later than June 30, 2007.

Within the Department of Public Health (DPH), the Office of Research and Development was tasked with implementation of the Act for the State of Connecticut, including identifying and recruiting members to the Connecticut Stem Cell Research Advisory and Peer Review Committees. Additionally, the Act designated Connecticut Innovations (CI) as administrative staff of the Advisory Committee, responsible for assisting in the development of the application for grants-in-aid, reviewing such applications and preparing and executing assistance agreements in connection with awarding the grants-in-aid.

All appointees to the Peer Review were completed by September 29, 2005, and on November 29, 2005, the Commissioner chaired the inaugural meeting of the Advisory Committee. Since then, both Committees have conducted multiple meetings, with all transcripts and minutes posted on the agency's website.

II. COMMITTEE AND SUBCOMMITEE ACTIVITIES

A critical focus of DPH and CI was supporting the work of the SCR Advisory Committee in the development of the Request for Proposals, inviting applicants for grants-in-aid to apply for the initial $20 million in public funding. While Public Act 05-149 required the issuance of the RFP no later than June 30, 2006, DPH, CI and the stem cell research community committed to releasing the RFP ahead of the statutory deadline. SCR Advisory Committee meetings were held on January 17, 2006, February 14, March 7, 2006 and March 22, 2006. The meetings focused primarily on the development of the draft guidelines and application. The January 17, 2006

[1] See Appendix A
[2] See Appendix B

meeting included an informational hearing for potential applicants for grants-in-aid. As part of the hearing, DPH staff presented a Power Point summarizing the work to date accomplished by the State of Connecticut and the SCR Advisory Committee. Multiple representatives of all the universities currently engaged in stem cell research presented to the Advisory Committee during the televised event.

CI staff managed the development of multiple versions of the guidelines and application, and as a result of their efforts, presented a final draft to the Advisory Committee at its meeting on March 22, 2006. Following these meetings, it was agreed that two members of the Advisory Committee, Dr. Willy Lensch and Dr. Charles Jennings, would present final draft language for review at the next Advisory Committee meeting, scheduled for May 9, 2006.

Some of the thorniest issues arising in drafting the application and guidelines included intellectual property and indirect costs. As of result of working out these issues, an Intellectual Property Workgroup was created to provide support to the SCR Advisory Committee. Other states and law firms throughout the country were solicited for input and advice on the issues of intellectual property, indirect costs and the commercialization of stem cell research. The pro bono services of the law firm of Foley&Lardner to assist in this effort were secured.

The most serious and time consuming legal efforts during this time period focused on the issues of conflict of interest and biological donations, issues which threatened the current and future progress of Connecticut's stem cell research community. Questions related to payment for biological donations raised by the workgroup and by other Advisory Committee members prompted DPH to request a formal opinion from the Office of the Attorney General.

On January 11, 2006, in response to concerns regarding the potential conflict of interest of some members of the Advisory Committee and potential applicants for grants-in-aid, DPH requested clarification from the newly reconstituted Citizen's Ethics Board concerning how the Code of Ethics for Public Officials of the General Statutes applied to members of the Boards employed by, or sitting on the boards of, institutions that submitted applications for grants-in-aid. On April 6, 2006, the Ethics Board ruled in part "…members of the stem cell research advisory committee should not also be employed by, or paid members of, institutions that submit applications for grant-in-aid…"

This breadth of this ruling raised the possibility of impacting five or more SCR Advisory Committee members, setting back the implementation efforts and raising possible options for legal challenges downstream of the release of public dollars. In response to this ruling, to insure a continuation of effort, and with bipartisan support in the executive and legislative branches, Public Act 06-33[3] was enacted. The bill clarified the conflict of interest requirements as they apply to SCR Advisory Committee members and added eight new members to the Advisory Committee.

With the ruling of the Ethics Board in hand and with final draft language completed by Advisory Committee members ready for discussion by the full Committee, the SCR Advisory Committee

[3] See Appendix C

reconvened on May 9, 2006. On that date, the Committee accepted the final draft application and guidance language, and authorized Connecticut Innovations to issue the Request for Proposals. On May 10, 2006, CI issued the attached RFP[4], requesting Letters of Intent from interested applicants by June 1, 2006, and requiring the submission of applications by July 10, 2006. Thanks to the coordinated efforts of CI, the Advisory Committee and DPH staff, the statutory deadline of June 30, 2006 was eclipsed by 51 days. In response to the RFP, a total of 77 Letters of Intent requesting nearly $63 million were submitted by public and private institutions in Connecticut by the administrative deadline of June 1, 2006.

While CI, DPH and the Advisory Committee were working to meet the deadline for issuance of the RFP, a number of concurrent efforts and initiatives were under development. Three of the most significant and time consuming initiatives included the design and roll out of the DPH Stem Cell Research web page, the development of a working SCR Peer Review Committee, and the branding of the State of Connecticut as an International Center of Excellence for Stem Cell Research.

Since day one, a guiding principle of the SCR program was transparency of effort. As directed by the Office of the Commissioner, DPH staff, CI staff, and the Advisory Committee committed to an open and inclusive process of deliberations leading to the allocation of public dollars in support of human embryonic stem cell research. The most critical tool in this transparent approach required the design, implementation and management of a consumer friendly web page dedicated to the State's SCR program. Staff benchmarked public and private stem cell research sites in developing the DPH stem cell research website, located at http://www.dph.state.ct.us/stemcell/

Since its roll out on February 14, 2006, more than seven thousand visitors have used the site to access transcripts and meetings of all SCR Advisory and Peer Review Committee meetings, to learn about upcoming meetings and events, to access the application for grants-in-aid, to learn more about stem cells and stem cell research, and to find out how to assist the State of Connecticut in the implementation of this critical effort.

With the issuance of the RFP imminent, it became critical to develop the five member Peer Review Committee into a working committee, ready to review seventy or more applications without compensation. Two original members of the Peer Review Committee, Dr. Haifin Lin and Dr. Douglas Melton, resigned from the Peer Review Committee during this time period. Dr. Lin, the first appointee to this body, resigned due to a potential job offer in Connecticut, while Dr. Melton resigned due to work load. Two outstanding replacements, Dr. Miodrag Stojkovic in Valencia, Spain and Dr. Michael Kyba from Texas, were recruited and agreed to join the Peer Review group. With the full complement of members, Commissioner Galvin convened the inaugural meeting of the Peer Review Committee on May 24, 2006. As two of the members of the body were located in Europe and one in California, the meeting was conducted telephonically. Dr. Leslie Weiner, a neurologist from USC, was elected chair of the Committee. The Peer Reviewers were briefed on the status of the RFP, and set a voluntary deadline of October 4, 2006 to complete their work.

[4] See Appendix D

Commissioner Galvin reconvened this body on June 30, 2006, during the 4th Annual Meeting of the International Society for Stem Cell Research. With four of the five members in Toronto at their own expense, DPH facilitated a face-to-face meeting of the four members with the Commissioner. In keeping with the policy of transparency, the meeting was open to the public, and was attended by members of the Connecticut media. The Committee was briefed on the Letters of Intent received, and reiterated their goal of completing their work by October 4, 2006. In addition, all members of the Peer Review Committee agreed to participate in Connecticut's International Stem Cell Research Symposium on March 27 and 28, 2007.

The rollout out of a user friendly Connecticut Stem Cell Research Website in February 2006 and the active participation of the Connecticut stem cell research community at the International Society of Stem Cell Research Symposium in Toronto in June 2006 were just part of a concerted effort to market Connecticut as an International Center of Excellence for Stem Cell Research. This is consistent with the language of Public Act 05-149 that calls for the development of specific methods to improve and promote for-profit and not-for profit embryonic and human adult stem cell and related research in Connecticut.

From June through October 2006, the five member Peer Review Committee completed the enormous effort of rating and ranking each of the seventy applications for grants-in-aid from Connecticut's research community. During a teleconferenced meeting on October 24, 2006, the Peer Review Committee agreed as a body on the ratings and rankings of each of the applications, and agreed to forward their findings and narrative descriptions of the applications to the Advisory Committee for determination of funding.

During a two-day meeting on November 20 and 21, 2006, the Advisory Committee reviewed and discussed each of the applications for grants-in-aid, including the findings of the Peer Review Committee. The Advisory Committee directed the allocation of $19.78 million in stem cell research funds to researchers from the University of Connecticut, Yale, and Wesleyan on November 21, 2006. The proceedings were open to the public and the media. Just seventeen months from enactment of the enabling legislation, the following researchers were funded as noted:

- An Integrated Approach to Neural Differentiation of Human Embryonic Stem Cells, Yale University, Michael P. Snyder, Principal Investigator, $3,815,476.72
- Directing hES Derived Progenitor Cells into Musculoskeletal Lineages, University of Connecticut Health Center and University of Connecticut, David W. Rowe, M. D., Principal Investigator, $3,520,000
- Human Embryonic Stem Cell Core Facility at Yale Stem Cell Center, Yale University, Haifan Lin, Principal Investigator, $2,500,000
- Human ES Cell Core At University of Connecticut and Wesleyan University, University of Connecticut Health Center, Ren-He Xu, Principal Investigator, $2,500,000
- DsRNA and Epigenetic Regulation in Embryonic Stem Cells, University of Connecticut Health Center, Gordon G. Carmichael, $880,000.
- Alternative Splicing in Human Embryonic Stem Cells, University of Connecticut Health Center, Brenton R. Graveley, Principal Investigator, $880,000

- SMAD4-based ChIP-chip Analysis to Screen Target Genes of BMP and TGF Signaling in Human ES Cells, University of Connecticut Health Center, Ren-He Xu, Principal Investigator, $880,000
- Directing Production and Functional Integration of Embryonic Stem Cell-Derived Neural Stem Cells, Wesleyan University, Laura B. Grabel, Principal Investigator, $878,348.24
- Role of the Leukemia Gene MKL in Developmental Hematopoiesis Using hES Cells, Yale University, Diane Krause, Principal Investigator, $856,653.72
- Migration and Integration of Embryonic Stem Cell Derived Neurons into Cerebral Cortex, University of Connecticut, Joseph LoTurco, Principal Investigator, $561,631.84
- Optimizing Axonal Regeneration Using a Polymer Implant Containing hESC-derived Glia, University of Connecticut, Akiko Nishiyama, $529,871.76
- Development of Efficient Methods for Reproducible and Inducible Transgene Expression in Human Embryonic Stem Cells, University of Connecticut Health Center, James Li, Principal Investigator, $200,000
- Pragmatic Assessment of Epigenetic Drift in Human ES Cell Lines, University of Connecticut, Theodore Rasmussen, Ph.D., Principal Investigator, $200,000
- Cell Cycle and Nuclear Reprogramming by Somatic Cell Fusion, University of Connecticut Health Center, Winfried Krueger, Principal Investigator, $200,000
- Function of the Fragile X Mental Retardation Protein in Early Human Neural Development, Yale University, Yingqun Joan Huang, Principal Investigator, $200,000
- Quantitative Analysis of Molecular Transport and Population Kinetics of Stem Cell Cultivation in a Microfluidic System, University of Connecticut, Tai-His Fan, Principal Investigator, $200,000
- Embryonic Stem Cell as a Universal Cancer Vaccine, University of Connecticut Health Center, Bei Liu, Zihai Li, M. D., Principal Investigators, $200,000
- Lineage Mapping of Early Human Embryonic Stem Cell Differentiation, University of Connecticut, Craig E. Nelson, $200,000
- Directed Isolation of Neuronal Stem Cells from hESC Lines, Yale University School of Medicine, Eleni A. Markakis, Principal Investigator, $184,407
- Magnetic Resonance Imaging of Directed Endogenous Neural Progenitor Cell Migration, Yale University School of Medicine, Erik Shapiro, Principal Investigator, $199,975
- Generation of Insulin Producing Cells from Human Embryonic Stem Cells, University of Connecticut, Gang Xu, Principal Investigator, $200,000

While the funds were allocated effective November 21, 2006, awarding the grants-in-aid required the development of a master agreement between DPH and CI, and the execution of assistance agreements with awardees. This required a coordinated effort by DPH and CI and significant guidance from the Office of the Attorney General. Thanks to these efforts, grants-in-aid were made to the eligible recipients by March 2007, just four months from the Notice of Awards.

A. Fundraising Subcommittee

This subcommittee was created to assist with the mandate of developing a donated funds program to encourage the development of funds other than state appropriations for embryonic and human adult stem cell research in Connecticut. The subcommittee consists of Milton

Wallack (Chair), Gerald Fishbone, Michael Genel, Charles Jennings, Nancy Rion, and Jerry Yang.

The subcommittee has not formally met to date; however, an informal discussion took place at StemConn 07. Members of the subcommittee have begun to develop plans for a donated funds program. The subcommittee decided that, in collaboration with the strategic planning subcommittee, a statement should be developed outlining the goals of the donated funds program and a recommendation of why donations should be made to this fund. In conjunction with this effort, the subcommittee will also continue to identify corporations, philanthropic funds, foundations, institutions, organizations and individuals who might be interested in supporting this work in Connecticut. Approximately 20 such prospects have been identified.

In addition, the subcommittee will be working to develop an organizational structure to help implement the program. This should consist of professional staff as well as a Leadership Council of interested participants. This will allow for appropriate expansion of a network of interested parties and appropriate resources to move this entire process forward. It will also allow for the development of a structure needed to receive funds.

B. Intellectual Property and Contracts Subcommittee

The contracts and IP subcommittee was created to formalize contractual provisions and the treatment of intellectual property generated from grant activity. The subcommittee initially focused on the treatment of intellectual property for insertion into the Request for Proposals and later on the detailed contract template for the disbursement of grants. The subcommittee worked closely with the Attorney General's office, Connecticut Innovations, Connecticut Innovations' external attorney and the Department of Public Health to ensure all parties provided input with regard to the key issues. The subcommittee also invited representatives of the major Connecticut universities' technology transfer offices to participate in the process and to review draft agreements and provide comments. Particular attention was paid to the ownership of intellectual property, responsibility for commercialization of intellectual property and to the economic interest due to the State in the form of royalties on any commercial activities resulting from intellectual property created through the stem cell initiative. Members of this subcommittee include Kevin Rakin (Chair), Robert Galvin, Stephen Latham, Willy Lensch, and Milton Wallack. Meetings were held on March 29, 2006, October 12, 2006, November 17, 2006, December 8, 2006, January 4, 2007 and January 26, 2007.

C. Law and Ethics Subcommittee

This subcommittee was created to offer guidance to the SCR Advisory Committee in its responsibility to monitor and evaluate proposals. In addition, the subcommittee may be a resource to DPH, which has authority to draft regulations regarding informed consent and the conduct of stem cell research. Ultimately, the work of the subcommittee should assure the public that stem cell research projects funded by the state are being conducted ethically. It also may help harmonize discussions between ESCRO committees and researchers in Connecticut. The subcommittee is role is information sharing and consultative, rather than formal monitoring and review.

The following are the members of the Legal and Ethics Subcommittee: Audrey Chapman, University of Connecticut; Lori Gruen , Wesleyan University; Anne Hiskes, University of Connecticut; Ann Kiessling, Harvard University; Julius Landwirth (Chair), Yale University; Stephen Latham, Quinnipiac University; Maurice Mahoney, Yale University; and Lisa Newton, Fairfield University. The subcommittee met on the following dates: November 9, 2006, December 13, 2006, January 8, 2007, February 5, 2007, March 7, 2007, April 11, 2007, and May 9, 2007.

Issues that the subcommittee have reviewed include: updates of activities and problems experienced by the ESCRO committees of the three universities receiving state stem cell funding, the November 2006 Attorney General opinion on payments to donors, the Certification for Voluntary Donation for Human Embryonic Stem Cell Research required by statute to be filled out by researchers. The subcommittee recommended that this requirement apply prospectively and that IRB-approved consent procedures be accepted for previously derived cell lines. The subcommittee reviewed information available with respect to cell lines offered by various sources and especially those to be used by grantees of the program. Although lines registered with the NIH are generally considered acceptable with respect to provenance, the subcommittee wished to conduct a good faith effort to ascertain the status of actual documentation. The subcommittee proposed to the SCR Advisory Committee that a program of public education on stem cell research be considered in the interest of promoting public awareness and providing a forum for discussion of complex issues. The SCR Advisory Committee agreed with the importance of public education in concept and suggested that further discussion about specific activities include DPH staff whose activities include public education.

D. Review Process Subcommittee

This subcommittee was created to develop a mechanism for making final selections on the stem cell research grants. Members included Willy Lensch, Chair, Charles Jennings, Ann Kiessling, and Robert Mandelkern. The subcommittee met on September 6, 2006.

Due to the challenges of determining funding awards for 70 applications in one day, it was important to define and agree upon a process that could be utilized. The substance of the subcommittee's discussions revolved around philosophical and practical issues. The philosophical issues were those that would help guide the committee when considering whether or not an application was funded. In addition to the scientific and ethical merits of a proposal, other issues were considered in making funding recommendations including: ability to perform the proposed research; commitment of host institution and (where applicable) collaborators to the proposed project, including cost sharing; potential for collaboration across disciplines and institutions; benefits (including financial benefits) to the State of Connecticut; and alignment with funding priorities as determined from time to time by the SCRAC. The subcommittee also recommended that conflicts of interest declared by individual members of the SCRAC be documented prior to the review of applications. The subcommittee also discussed practical issues including a proposed process for reviewing the applications, utilizing a blending of the category approach and merit approach.

E. Strategy Subcommittee

This subcommittee was created to help the SCR Advisory Committee identify long term strategic priorities and to plan accordingly. The subcommittee consists of Charles Jennings (Chair), Milt Wallack, Bob Mandelkern, Paul Huang, and Willy Lensch. The subcommittee met on February 15, 2007 and identified the following issues as priorities:

- Solicit feedback from external stakeholders on the research funding priorities for the SCR Program.
- Consider the administrative resources needed to maintain the stem cell program and budget accordingly for the expected costs.
- Explore ways to raise additional funds to support the activities of the SCR Program.

The subcommittee's key recommendation was to engage an external consultant to conduct a survey of representative stakeholders whose opinions can inform future strategic planning, particularly as it relates to research funding. This recommendation was endorsed by the SCR Advisory Committee at its February 20, 2007 meeting. It was decided to approach the Connecticut Academy of Science and Engineering (CASE) to help conduct the study.

With input from the subcommittee, CASE considered bids from three consulting firms and selected PricewaterhouseCoopers (PwC) to conduct the survey. PwC are highly qualified given that they had also produced a detailed strategic plan for the California Institute of Regenerative Medicine, and therefore, are conversant with most of the key issues.

The strategy subcommittee assisted CASE in identifying interviewees from each of the following key constituencies: university administrators and researchers, representatives of the private biotechnology industry, and patient advocates. PwC conducted thirty phone interviews and also obtained written comments and focus group input from additional experts and stakeholders.

CASE and the strategy subcommittee members met with PwC on April 26, 2007 to review the findings. CASE presented its draft report to the SCR Advisory Committee on May 15, 2007 and issued its final report on May 24, 2007. The SCR Advisory Committee will consider this report before it prepares its next call for proposals.

III. INTERNATIONAL CENTER OF EXCELLENCE FOR STEM CELL RESEARCH

Connecticut's efforts to position itself in the international research market reflect its commitment to and acknowledgment of the global hESC research community. Federal funding restrictions not only resulted in state specific efforts, but also led to a brain drain, where many of the country's best and brightest hESC researchers moved to those international locations where funding and public support were readily available. Some of the most influential of these markets included the United Kingdom and other members of the European Union, Australia, South Korea, Singapore and the People's Republic of China.

The entry of Connecticut into the international market for hESC research was met initially by indifference or tepid support in the international research community and in some sectors of the

State. DPH recognized the need to aggressively market the State to these potential partners. The DPH Commissioner first tapped into this international marketplace through the recruitment and appointment of the Peer Review Committee members. Two of the original five appointees represented Scotland and Belgium, respectively, and the sixth member, appointed as a replacement, is located in Spain. The three appointees each direct their own stem cell institutes and are recognized leaders in the international community. Their appointments to the Peer Review Committee provided Connecticut's program instant credibility.

Consistent with its vision of international prominence, the DPH, Connecticut United for Research Excellence (CURE) and the Connecticut Stem Cell Research Coalition committed to co-hosting an International Symposium on hESC research in Connecticut. As a founding planning partner and as co-chair of the planning committee, the ORD Chief created the opportunity for the three Peer Reviewers from Europe to come to Hartford as part of a scientific symposium held on March 27 and 28, 2007, providing the conference with an "international" credential and label.

The Commissioner of Public Health and two ORD staff also attended the International Society for Stem Cell Research's Scientific Symposium in Toronto in June 2006. The DPH and CURE staffed a booth at the event, and marketed Connecticut and the planned International Symposium in Connecticut to the thousands of attendees representing dozens of different countries. This effort led to partnerships and funding from both the Canadian and British Consulates. Both parties provided funding for StemCONN 07 conference in Hartford. More importantly, the relationship with the British Consulate led to an August 2006 visit from three members of the Parliament of the United Kingdom, including the Personal Secretary to Gordon Brown, Chancellor of the Exchequer. DPH and Yale also co-hosted an event with Dr. Glyn Stacy, Chair of the UK Stem Cell Bank, on February 15, 2007.

The centerpiece of this marketing effort was StemCONN 07, Connecticut's first Stem Cell Research International Symposium, held on March 27 and 28, 2007. Paul Pescatello of CURE, Milt Wallack of the Connecticut Stem Cell Research Coalition and Warren Wollschlager of DPH chaired the Symposium. Yale, UCONN and Wesleyan also sponsored the event, and planned the scientific portion of the symposium. The event was an overwhelming success, attracting more than 650 attendees to sold out sessions on both days of the symposium. Attendees from six countries and nine states attended scientific presentations by international and national experts in the field, including researchers from Connecticut's academic institutions. DPH convened a meeting of all states with supportive stem cell research language, leading to the establishment of an Interstate Alliance for Stem Cell Research (IASCR), under the direction of Connecticut. The State of Connecticut, its policy makers, researchers and elected officials, were successfully presented to and represented in the international stem cell community.

Next steps for the stem cell research program have already been initiated. On March 28, 2007, three members of the Peer Review Committee with terms expiring on October 1, 2007 agreed to accept reappointment from the Commissioner to serve the State of Connecticut for another term. The Advisory Committee has established active Subcommittees for Strategic Planning, Fundraising, and Legal and Ethics issues. CI, the Advisory Committee and DPH staff are planning to issue the next RFP for grants-in-aid applications on or after August 1, 2007.

Connecticut is also moving ahead with securing a leadership role among the national and international stem cell research communities. At a meeting in California on May 23 and 24, 2007, members voted to formalize the IASCR and named Warren Wollschlager as chair of the Alliance. In addition to participating states, members of the IASCR include representatives of the National Academies of Science, Canada, and the United Kingdom.

Connecticut DPH continues to position the state in the international stem cell research community as well. Two DPH staff marketed Connecticut at the International Society for Stem Cell Research's (ISSCR) Annual Symposium in Australia. In conjunction with the symposium, Attorney Marianne Horn provided two presentations to members of the ISSCR.

Finally, plans are well underway for Connecticut's next International Stem Cell Research Symposium, StemCONN 09, scheduled for March 23-24, 2009.

IV. CONNECTICUT'S RESEARCH COMMUNITY

As noted above, due to the administrative efforts of CI and the DPH, and most importantly, due to the outstanding efforts of our volunteer members of the Peer Review and Advisory Committees, statutory deadlines were met, guidelines were developed, applications were requested and reviewed, stem cell research funds were allocated, assistance agreements were executed, and grants-in-aid were awarded to twenty-one researchers at the University of Connecticut, Wesleyan University and Yale University in the two years since Governor Rell signed PA 05-149 on June 15, 2005. Additionally, Connecticut sponsored a booth at the International Society for Stem Cell Research Symposium in Toronto, DPH hosted a visit from three members of the Parliament of the United Kingdom, DPH hosted a visit from Dr. Glyn Stacy, Director of the UK Stem Cell Bank, and Connecticut established the Interstate Alliance for Stem Cell Research. Connecticut also convened StemCONN 07, Connecticut's first International Stem Cell Research Symposium. All of these efforts supported a common goal, to support, fund and market Connecticut's stem cell research community. The following describes the state of stem cell research efforts at Yale University, Wesleyan University and the University of Connecticut.

A. Yale University[5]

The funding from the State of Connecticut has provided Yale with an unprecedented opportunity to work together with the University of Connecticut, Wesleyan University, and industry to establish Connecticut as a world-class state for stem cell research.

The almost eight million dollars in funding that Yale is receiving from the State has generated a transforming impact on stem cell research at Yale—it for the first time allows Yale to launch a human embryonic stem cell research program. Specifically, this funding has allowed Yale to achieve the following important missions:

[5] The following progress report on Connecticut supported stem cell research was prepared by Haifin Lin, Ph.D., Director, Diane Krause, M.D., Ph.D., Associate Director, and Paula Wilson, M.B.A., Administrator

1. Building core research facilities as a technical platform essential for stem cell research at Yale and in the State of Connecticut. These core facilities, including a human embryonic stem cell core, a genomics/bioinformatics core, and a cell imaging core, will make it possible for more than 43 world-class stem cell labs at Yale, totaling over 400 stem cell researchers, to conduct human embryonic stem cell research. These core facilities, together with those at the University of Connecticut, should generate an unparalleled technical infrastructure that supports both academic and industrial stem cell research in the State of Connecticut.

2. Providing opportunities for new investigators in the early stages of their careers to develop projects that will position them to become independent investigators. These studies focus on the basic understanding of the function of stem cells and will lead to important findings. Three investigators received seed funding for the following projects: *1) Function of the Fragile X Mental Retardation Protein in Early Human Neural Development; 2) Directed Isolation of Neuronal Stem Cells from hESC Lines; and 3) Magnetic Resonance Imaging of Directed Endogenous Neural Progenitor Cell Migration.*

3. Recruiting leading stem cell researchers to Connecticut. The State Stem Cell funding has aided Yale's ability to recruit a Technical Director for the human embryonic stem cell core facility from the Albert Einstein for Human Embryonic Stem Cell Research. It has also aided in the recruitment of new faculty members to the Yale Stem Cell Center. In a faculty search announced in December 2006, Yale received over 76 applications from stem cell experts all over the country, including 32 outstanding applications from major stem cell research states such as California, Massachusetts, Maryland, and New Jersey. This is an exciting sign of a trend-reversing effect that is only possible because of the state funding and its implicated opportunities. Yale is in an excellent position to recruit some of the best stem cell researchers in the world to Connecticut. In addition, the current funding will provide the resources to recruit eight non-faculty level stem cell researchers. These recruitments will build the first human embryonic stem cell program at Yale as a part of the Connecticut stem cell effort.

4. Helping the biotech industry to initiate stem cell research and development in Connecticut. The Yale Stem Cell Center, a seven-month old entity established as a result of the State funding, has already become an academic partner of a local biotech company, RainDance Technologies, Inc., to help the company to apply for federal support to develop human embryonic stem cell-related technology. Without Yale's offer of the required technical capacity and regulatory compliance system, this company would not be eligible for this application. This partnership is the first of many future opportunities for Yale to help establish a stem cell industry in the State of Connecticut.

B. The University of Connecticut (UConn)[6]

UConn obtained more than $11 million in grants-in-aid from the state's stem cell research fund in the first round of funding, allowing the university to move forward with its training and research mission in support of stem cell researchers in Connecticut. The first round of funding is expected to create as many as twenty new jobs in the state.

[6] The following update was edited by Marc Lalande, Ph.D., Professor and Chair ……

1. Building core facilities. In anticipation of roll out of state funding for stem cell research, UConn invested over two million dollars establishing a Stem Cell Core in order to provide research support and training to scientists throughout the State of Connecticut. The UConn stem cell core is currently operational and providing several services including culture, quality control and banking of nine human embryonic stem cell lines obtained from WiCell and Harvard. As a result of the recent grants-in-aid, the space dedicated to the UConn core facility at the UConn Health Center will be doubled over the course of 2007.

UConn has also taken steps to establish a Stem Cell Institute through the purchase and renovation of a research facility in Farmington, CT. This initiative represents a $45 million investment by the UConn. It is anticipated that both the Stem Cell Institute and Core facility will move to the refurbished Farmington laboratories by the end on 2008.

2. Recruiting leading stem cell researchers to Connecticut. Like Yale, UConn responded to the passage of PA 05-149 by recruiting scientists with hands-on expertise on human embryonic stem cells to run its core facility. Dr. Ren-He Xu and Dr. Leann Crandall were recruited from WiCell, the world-renowned human embryonic stem cell research institute affiliated with the University of Wisconsin. The additional funds from the first round of grants-in-aid will allow UConn to recruit three additional scientists for the Core facility so that it can fulfill its training and research mission.

3. Funding new research at UConn. The first round of funding will allow nineteen UConn investigators to initiate new stem cell research programs. Some of these scientists, who have worked primarily in their areas of Biomedical research, will bring their unique expertise to advance human embryonic stem cell research. Funded programs will include a large program in bone biology that will focus on regenerative stem cell therapies to repair traumatic injuries. Three other established investigators will focus on the properties of stem cells such as the discovery of molecules that guide stem cells into becoming a particular type of tissue. The grants-in-aid will also fund a number of new investigators in the early stages of their careers to develop projects that will position them to become independent investigators.

C. Wesleyan University[7]

1. Core facilities. Wesleyan was a co-recipient with UCONN of the grant-in aid to establish a new core facility in Farmington. Dr. Laura Grabel, Professor of Biology, will serve as the new co-director of the facility and will oversee outreach programs.

2. Funding new research at Wesleyan. Dr. Grabel also received state funding for stem cell research related to epilepsy and to identifying signals that direct embryonic stem cells towards becoming neurons. While Dr. Grabel and her colleagues have used mouse embryonic stem cells to study how to generate neurons from embryonic stem cells and how to implant stem cells into the brain to generate new healthy neurons, they now will be able to use human embryonic stem cells to further their investigations. This project is a collaborative effort with Janice Naegele and Gloster Aaron, also in the Biology Department at Wesleyan and with Alex Lichtler and

[7] From an article entitled *Wesleyan Joins State Stem Cell Initiative*, Wesleyan Magazine, Issue 1 2007.

Leonardo Aguila from the University of Connecticut Health Center. They will assist with vector design and Flow Cytometry work, essential components of the proposal.

Collaboration Between the Universities

The external advisory committee for the hESC Core Facility at the UConn Health Center is composed of faculty from all of the universities supported by the State stem cell fund. Representatives of the three universities, Yale, UConn and Wesleyan, met during StemConn'07. Key outcomes of the meetings include: the UConn Health Center hESC Core Facility will provide training to staff of any of the three university laboratories. There will be no training fee charged for the first two representatives from each such laboratory. The advisory committee will meet again to decide on a list of DNA expression vectors that are likely to be useful to the wider stem cell research community. These will be generated in the UConn Health Center stem cell vector core and made available to investigators from all three universities.

V. Umbilical Cord Blood Banking

Public Act 06-77[8], "An Act Designating the Month of November as Lung Cancer Awareness Month and Concerning the Establishment of a Public Umbilical Cord Blood Bank," mandated the Commissioner of Public Health, in consultation with the Stem Cell Research Advisory Committee established pursuant to section 19a-32f of the 2006 supplement to the general statutes, to establish an ad hoc committee to examine and evaluate the feasibility of (1) establishing a public umbilical cord blood bank for the purpose of collecting and storing umbilical cord blood and placental tissue donated by maternity patients at hospitals licensed in this state, (2) entering into a multistate public umbilical cord collaboration, and (3) developing a public-private partnership with existing umbilical cord blood banks. The law required that on or before January 5, 2007, the Commissioner of Public Health shall submit, in accordance with section 11-4a of the general statutes, the results of the examination, along with any recommendations, to the Governor and the joint standing committee of the General Assembly having cognizance of matters relating to public health. The Advisory Committee appointed Dr. Willy Lensch to the ad hoc committee on umbilical cord banking. In its report to the General Assembly on January 5, 2007, the committee recommended that the State enter into a partnership with an existing cord blood bank for the purpose of establishing a public umbilical cord blood bank in the state.

VI. Summary

Passage of the Public Act 05-149 positioned Connecticut as just the third state in the nation, behind only California and New Jersey, in providing public funding in support of embryonic and human adult stem cell research. The Act appropriated the sum of $20 million to the newly established Stem Cell Research Fund for the purpose of grants-in-aid for conducting embryonic or human adult stem cell research.

The efforts of the Connecticut Stem Cell Research Advisory and Peer Review Committees and the support of the Department of Public Health and Connecticut Innovations resulted in the

[8] See Appendix E

allocation of $19.78 million in stem cell research funds for 21 projects from the University of Connecticut, Wesleyan University and Yale University on November 21, 2006. The allocation of funds will provide ongoing support to the development of two core stem cell research facilities, will allow for the recruitment and retention of world class researchers, and will support new research efforts from established and junior faculty members.

Connecticut has successfully positioned itself as a leader in both the national and international stem cell research communities. With vehicles such as StemCONN, the Interstate Alliance for Stem Cell Research and the International Society for Stem Cell Research, we will continue to promote Connecticut as an International Center of Excellence for stem cell research.

APPENDIX A
Public Act 05-149

Public Act No. 05-149

AN ACT PERMITTING STEM CELL RESEARCH AND BANNING THE CLONING OF HUMAN BEINGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective from passage*) (a) As used in sections 1 to 4, inclusive, of this act and section 4-28e of the general statutes, as amended by this act:

(1) "Institutional review committee" means the local institutional review committee specified in 21 USC 360j(g)(3)(A)(i), as amended from time to time, and, when applicable, an institutional review board established in accordance with the requirements of 45 CFR 46, Subpart A, as amended from time to time.

(2) "Cloning of a human being" means inducing or permitting a replicate of a living human being's complete set of genetic material to develop after gastrulation commences.

(3) "Gastrulation" means the process immediately following the blastula state when the hollow ball of cells representing the early embryo undergoes a complex and coordinated series of movements that results in the formation of the three primary germ layers, the ectoderm, mesoderm and endoderm.

(4) "Embryonic stem cells" means cells created through the joining of a human egg and sperm or through nuclear transfer that are sufficiently undifferentiated such that they cannot be identified as components of any specialized cell type.

(5) "Nuclear transfer" means the replacement of the nucleus of a human egg with a nucleus from another human cell.

(6) "Eligible institution" means (A) a nonprofit, tax-exempt academic institution of higher education, (B) a hospital that conducts biomedical research, or (C) any entity that conducts biomedical research or embryonic or human adult stem cell research.

(b) No person shall knowingly (1) engage or assist, directly or indirectly, in the cloning of a human being, (2) implant human embryos created by nuclear transfer into a uterus or a device similar to a uterus, or (3) facilitate human reproduction through clinical or other use of human embryos created by nuclear transfer. Any person who violates the provisions of this subsection shall be fined not more than one hundred thousand dollars or imprisoned not more than ten years, or both. Each violation of this subsection shall be a separate and distinct offense.

(c) (1) A physician or other health care provider who is treating a patient for infertility shall provide the patient with timely, relevant and appropriate information sufficient to allow that person to make an informed and voluntary choice regarding the disposition of any embryos or embryonic stem cells remaining following an infertility treatment.

(2) A patient to whom information is provided pursuant to subdivision (1) of this subsection shall be presented with the option of storing, donating to another person, donating for research purposes, or otherwise disposing of any unused embryos or embryonic stem cells.

(3) A person who elects to donate for stem cell research purposes any human embryos or embryonic stem cells remaining after receiving infertility treatment, or unfertilized human eggs or human sperm shall provide written consent for that donation and shall not receive direct or indirect payment for such human embryos, embryonic stem cells, unfertilized human eggs or human sperm.

(4) Any person who violates the provisions of this subsection shall be fined not more than fifty thousand dollars or imprisoned not more than five years, or both. Each violation of this subsection shall be a separate and distinct offense.

(d) A person may conduct research involving embryonic stem cells, provided (1) the research is conducted with full consideration for the ethical and medical implications of such research, (2) the research is conducted before gastrulation occurs, (3) prior to conducting such research, the person provides to the Commissioner of Public Health documentation verifying that any human embryos, embryonic stem cells, unfertilized human eggs or human sperm used in such research have been donated voluntarily in accordance with the provisions of subsection (c) of this section, on a form and in the manner prescribed by the Commissioner of Public Health, (4) the general research program under which such research is conducted is reviewed and approved by an institutional review committee, as required under federal law, and (5) the specific

protocol used to derive stem cells from an embryo is reviewed and approved by an institutional review committee.

(e) The Commissioner of Public Health shall enforce the provisions of this section and may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, relating to the administration and enforcement of this section. The commissioner may request the Attorney General to petition the Superior Court for such order as may be appropriate to enforce the provisions of this section.

Sec. 2. (NEW) (*Effective from passage*) (a) There is established the "Stem Cell Research Fund" which shall be a separate, nonlapsing account within the General Fund. The fund may contain any moneys required or permitted by law to be deposited in the fund and any funds received from any public or private contributions, gifts, grants, donations, bequests or devises to the fund. The Commissioner of Public Health may make grants-in-aid from the fund in accordance with the provisions of subsection (b) of this section.

(b) Not later than June 30, 2006, the Stem Cell Research Advisory Committee established pursuant to section 3 of this act shall develop an application for grants-in-aid under this section for the purpose of conducting embryonic or human adult stem cell research and may receive applications from eligible institutions for such grants-in-aid on and after said date. The Stem Cell Research Advisory Committee shall require any applicant for a grant-in-aid under this section to conduct stem cell research to submit (1) a complete description of the applicant's organization, (2) the applicant's plans for stem cell research and proposed funding for such research from sources other than the state of Connecticut, and (3) 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 grant-in-aid. Said committee shall direct the Commissioner of Public Health with respect to the awarding of such grants-in-aid after considering recommendations from the Stem Cell Research Peer Review Committee established pursuant to section 4 of this act.

(c) Commencing with the fiscal year ending June 30, 2006, and for each of the nine consecutive fiscal years thereafter, until the fiscal year ending June 30, 2015, not less than ten million dollars shall be available from the Stem Cell Research Fund for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research, as directed by the Stem Cell Research Advisory Committee established pursuant to section 3 of this act. Any balance of such amount not used for such grants-in-aid during a fiscal year shall be carried forward for the fiscal year next succeeding for such grants-in-aid.

Sec. 3. (NEW) (*Effective from passage*) (a) There is established a Stem Cell Research Advisory Committee. The committee shall consist of the Commissioner of Public Health

and eight members who shall be appointed as follows: Two by the Governor, one of whom shall be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of bioethics; one each by the president pro tempore of the Senate and the speaker of the House of Representative, who shall have background and experience in private sector stem cell research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in stem cell research; one by the minority leader of the Senate, who shall have background and experience in either private or public sector stem cell research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology; and one by the minority leader of the House of Representatives, who shall have background and experience in business or financial investments. Members shall serve for a term of four years commencing on October first, except that members first appointed by the Governor and the majority leaders of the Senate and House of Representatives shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the Stem Cell Research Peer Review Committee established pursuant to section 4 of this act. All initial appointments to the committee shall be made by October 1, 2005. Any vacancy shall be filled by the appointing authority.

(b) The Commissioner of Public Health shall serve as the chairperson of the committee and shall schedule the first meeting of the committee, which shall be held no later than December 1, 2005.

(c) All members appointed to the committee shall work to advance embryonic and human adult stem cell research. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from the committee.

(d) All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10 of the general statutes. No member shall participate in the affairs of the committee with respect to the review or consideration of any grant-in-aid application filed by such member or by any eligible institution in which such member has a financial interest, or with whom such member engages in any business, employment, transaction or professional activity.

(e) The Stem Cell Research Advisory Committee shall (1) develop, in consultation with the Commissioner of Public Health, a donated funds program to encourage the development of funds other than state appropriations for embryonic and human adult stem cell research in this state, (2) examine and identify specific ways to improve and promote for-profit and not-for-profit embryonic and human adult stem cell and related research in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing embryonic and human adult

stem cell related businesses, recruiting new embryonic and human adult stem cell related businesses to the state and recruiting scientists and researchers in such field to the state, (3) establish and administer, in consultation with the Commissioner of Public Health, a stem cell research grant program which shall provide grants-in-aid to eligible institutions for the advancement of embryonic or human adult stem cell research in this state pursuant to section 2 of this act, and (4) monitor the stem cell research conducted by eligible institutions that receive such grants-in-aid.

(f) Connecticut Innovations, Incorporated shall serve as administrative staff of the committee and shall assist the committee in (1) developing the application for the grants-in-aid authorized under subsection (e) of this section, (2) reviewing such applications, (3) preparing and executing any assistance agreements or other agreements in connection with the awarding of such grants-in-aid, and (4) performing such other administrative duties as the committee deems necessary.

(g) Not later than June 30, 2007, and annually thereafter until June 30, 2015, the Stem Cell Research Advisory Committee shall report, in accordance with section 11-4a of the general statutes, to the Governor and the General Assembly on (1) the amount of grants-in-aid awarded to eligible institutions from the Stem Cell Research Fund pursuant to section 2 of this act, (2) the recipients of such grants-in-aid, and (3) the current status of stem cell research in the state.

Sec. 4. (NEW) (*Effective from passage*) (a) There is established a Stem Cell Research Peer Review Committee. The committee shall consist of five members appointed by the Commissioner of Public Health. All members appointed to the committee shall (1) have demonstrated knowledge and understanding of the ethical and medical implications of embryonic and human adult stem cell research or related research fields, including, but not limited to, embryology, genetics or cellular biology, (2) have practical research experience in human adult or embryonic stem cell research or related research fields, including, but not limited to, embryology, genetics or cellular biology, and (3) work to advance embryonic and human adult stem cell research. Members shall serve for a term of four years commencing on October first, except that three members first appointed by the Commissioner of Public Health shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the Stem Cell Research Advisory Committee established pursuant to section 3 of this act. All initial appointments to the committee shall be made by October 1, 2005. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from the committee.

(b) All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10 of the general statutes. No member shall participate in the affairs of the committee with respect to the review or consideration of

any grant-in-aid application filed by such member or by any eligible institution with whom such member has a financial interest in, or engages in any business, employment, transaction or professional activity.

(c) Prior to the awarding of any grants-in-aid for embryonic or human adult stem cell research pursuant to section 2 of this act, the Stem Cell Research Peer Review Committee shall review all applications submitted by eligible institutions for such grants-in-aid and make recommendations to the Commissioner of Public Health and the Stem Cell Research Advisory Committee established pursuant to section 3 of this act with respect to the ethical and scientific merit of each application.

(d) The Peer Review Committee shall establish guidelines for the rating and scoring of such applications by the Stem Cell Research Peer Review Committee.

(e) All members of the committee shall become and remain fully cognizant of the National Academies Guidelines For Human Embryonic Stem Cell Research, as from time to time amended, and the committee may make recommendations to the Stem Cell Research Advisory Committee and the Commissioner of Public Health concerning the adoption of said guidelines, in whole or in part, in the form of regulations adopted pursuant to chapter 54 of the general statutes.

Sec. 5. Subsection (c) of section 4-28e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(c) (1) For the fiscal year ending June 30, 2001, disbursements from the Tobacco Settlement Fund shall be made as follows: (A) To the General Fund in the amount identified as "Transfer from Tobacco Settlement Fund" in the General Fund revenue schedule adopted by the General Assembly; (B) to the Department of Mental Health and Addiction Services for a grant to the regional action councils in the amount of five hundred thousand dollars; and (C) to the Tobacco and Health Trust Fund in an amount equal to nineteen million five hundred thousand dollars.

(2) For the fiscal year ending June 30, 2002, and each fiscal year thereafter, disbursements from the Tobacco Settlement Fund shall be made as follows: (A) To the Tobacco and Health Trust Fund in an amount equal to twelve million dollars; (B) to the Biomedical Research Trust Fund in an amount equal to four million dollars; (C) to the General Fund in the amount identified as "Transfer from Tobacco Settlement Fund" in the General Fund revenue schedule adopted by the General Assembly; and (D) any remainder to the Tobacco and Health Trust Fund.

(3) For each of the fiscal years ending June 30, 2008, to June 30, 2015, inclusive, the sum of ten million dollars shall be disbursed from the Tobacco Settlement Fund to the Stem

Cell Research Fund established by section 2 of this act, for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research.

Sec. 6. (*Effective from passage*) The sum of twenty million dollars is appropriated to the Stem Cell Research Fund established by section 2 of this act, from the General Fund, for the fiscal year ending June 30, 2005.

Approved June 15, 2005

APPENDIX B
ADVISORY COMMITTEE MEMBERSHIP LISTS

STEM CELL RESEARCH ADVISORY COMMITTEE

MEMBER	AFFILIATION
Robert Galvin, M.D., M.P.H. Chair	Commissioner CT Department of Public Health 410 Capitol Avenue P.O. Box 340308 Hartford, CT 06134-0308
Ernesto Canalis, M.D.	St. Francis Hospital & Medical Center Department of Research 114 Woodland Street Hartford, CT 06105-1299
Kevin Eggan, Ph.D.	Harvard University Stem Cell Institute Resigned 5/25/07
Gerald Fishbone, M.D.	Hospital of St. Raphael 1450 Chapel Street New Haven, CT 06511
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M. William Lensch, Ph.D.	Division of Hematology/Oncology Children's Hospital Boston Karp Family Research Laboratories, 7th Floor 300 Longwood Avenue Boston, MA 02115
Robert Mandelkern	Parkinson Disease Representative to CT Stem Cell Coalition
Kevin L. Rakin	Canaan Partners 191 Post Road West Westport, CT 06880
Amy Wagers, Ph.D.	Joslin Diabetes Center Dev and Stem Cell Biology Room 620 C One Joslin Place Boston, MA 02215
Milton B. Wallack, DDS	295 Washington Avenue Hamden, CT 06518
Xiangzhong (Jerry) Yang, Ph.D.	Director, Center for Regenerative Biology University of Connecticut Advanced Technical Laboratory Bldg. 1392 Storrs Road, Unit 4243 Storrs, CT 06269-4243

STEM CELL RESEARCH PEER REVIEW COMMITTEE	
Michael Kyba, Ph.D.	Assistant Professor Center for Developmental Biology The University of Texas Southwestern Medical Center at Dallas 6000 Harry Hines Boulevard, NB5.208 Dallas, Texas 75390-9133
Miodrag Stojkovic, Ph.D.	Deputy Director Principe Felipe Centro de Investigacion C/ E.P. Avda. Autopista del Saler 16-3 (Junto Oceanografico) 46013 Valencia, Spain
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Leslie Weiner, M.D.	Chair, Department of Neurology Keck School of Medicine University of Southern California 2025 Zonal Avenue, RMR 506 Los Angeles, CA 90033
Ian Wilmut, Ph.D.	Professor Reproductive Science Centre for Reproductive Biology Reproductive and Developmental Sciences The Queen's Medical Research Institute The University of Edinburgh 47 Little France Crescent Edinburgh EH16 4TJ Scotland UK

APPENDIX C
Public Act 06-33

Public Act No. 06-33

AN ACT CONCERNING THE STEM CELL RESEARCH ADVISORY COMMITTEE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 19a-32f of the 2006 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) (1) There is established a Stem Cell Research Advisory Committee. The committee shall consist of the Commissioner of Public Health and eight members who shall be appointed as follows: Two by the Governor, one of whom shall be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of bioethics; one each by the president pro tempore of the Senate and the speaker of the House of Representatives, who shall have background and experience in private sector stem cell research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in stem cell research; one by the minority leader of the Senate, who shall have background and experience in either private or public sector stem cell research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology; and one by the minority leader of the House of Representatives, who shall have background and experience in business or financial investments. Members shall serve for a term of four years commencing on October first, except that members first appointed by the Governor and the majority leaders of the Senate and House of Representatives shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the Stem Cell Research Peer Review Committee established pursuant to section 19a-32g. All initial appointments to the committee shall be made by October 1, 2005. Any vacancy shall be filled by the appointing authority.

(2) On and after July 1, 2006, the advisory committee shall include eight additional members who shall be appointed as follows: Two by the Governor, one of whom shall

be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of ethics; one each by the president pro tempore of the Senate and the speaker of the House of Representatives, who shall have background and experience in private sector stem cell research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in stem cell research; one by the minority leader of the Senate, who shall have background and experience in either private or public sector stem cell research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology; and one by the minority leader of the House of Representatives, who shall have background and experience in business or financial investments. Members shall serve for a term of four years, except that (A) members first appointed by the Governor and the majority leaders of the Senate and House of Representatives pursuant to this subdivision shall serve for a term of two years and three months, and (B) members first appointed by the remaining appointing authorities shall serve for a term of four years and three months. No member appointed pursuant to this subdivision may serve for more than two consecutive four-year terms and no such member may serve concurrently on the Stem Cell Research Peer Review Committee established pursuant to section 19a-32g of the 2006 supplement to the general statutes. All initial appointments to the committee pursuant to this subdivision shall be made by July 1, 2006. Any vacancy shall be filled by the appointing authority.

(b) The Commissioner of Public Health shall serve as the chairperson of the committee and shall schedule the first meeting of the committee, which shall be held no later than December 1, 2005.

(c) All members appointed to the committee shall work to advance embryonic and human adult stem cell research. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from the committee.

(d) Notwithstanding the provisions of any other law, it shall not constitute a conflict of interest for a trustee, director, partner, officer, stockholder, proprietor, counsel or employee of any eligible institution, or for any other individual with a financial interest in any eligible institution, to serve as a member of the committee. All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10. **[**No**]** Members may participate in the affairs of the committee with respect to the review or consideration of grant-in-aid applications, including the approval or disapproval of such applications, except that no member shall participate in the affairs of the committee with respect to the review or consideration of any grant-in-aid application filed by such member or by any eligible institution in which such member has a financial interest, or with whom such member engages in any business, employment, transaction or professional activity.

(e) The Stem Cell Research Advisory Committee shall (1) develop, in consultation with the Commissioner of Public Health, a donated funds program to encourage the development of funds other than state appropriations for embryonic and human adult stem cell research in this state, (2) examine and identify specific ways to improve and promote for-profit and not-for-profit embryonic and human adult stem cell and related research in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing embryonic and human adult stem-cell-related businesses, recruiting new embryonic and human adult stem-cell-related businesses to the state and recruiting scientists and researchers in such field to the state, (3) establish and administer, in consultation with the Commissioner of Public Health, a stem cell research grant program which shall provide grants-in-aid to eligible institutions for the advancement of embryonic or human adult stem cell research in this state pursuant to section 19a-32e, and (4) monitor the stem cell research conducted by eligible institutions that receive such grants-in-aid.

(f) Connecticut Innovations, Incorporated shall serve as administrative staff of the committee and shall assist the committee in (1) developing the application for the grants-in-aid authorized under subsection (e) of this section, (2) reviewing such applications, (3) preparing and executing any assistance agreements or other agreements in connection with the awarding of such grants-in-aid, and (4) performing such other administrative duties as the committee deems necessary.

(g) Not later than June 30, 2007, and annually thereafter until June 30, 2015, the Stem Cell Research Advisory Committee shall report, in accordance with section 11-4a, to the Governor and the General Assembly on (1) the amount of grants-in-aid awarded to eligible institutions from the Stem Cell Research Fund pursuant to section 19a-32e, (2) the recipients of such grants-in-aid, and (3) the current status of stem cell research in the state.

Approved April 24, 2006

APPENDIX D
Stem Cell Research Application and Guidelines

Connecticut Stem Cell Research Grants Program

Submission Deadline –July 10, 2006

Proposal Instructions

Purpose

The Connecticut Stem Cell Research Grants Program, authorized in the Connecticut General Statutes (C.G.S.) Sections 19a-32d through 19a-32g, a Statute Permitting Stem Cell Research and Banning the Cloning of Human Beings, supports the advancement of embryonic and/or human adult stem cell research in Connecticut.

Proposals must describe the applicant's organization, the applicant's plans for stem cell research, proposed funding for such research from sources other than the state of Connecticut, and 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.

The Connecticut Stem Cell Research Advisory Committee, in consultation with the Commissioner of Public Health, administers and monitors the grant program. Connecticut Innovations, Inc. serves as administrative staff of the Advisory Committee, reviewing applications, and preparing and executing assistance agreements for the grants.

Twenty million dollars is available in the Connecticut Stem Cell Research Grants Fund through June 30, 2007. For each of the fiscal years ending June 30, 2008 to June 30, 2015, inclusive, ten million dollars will also be available.

Definitions

Embryonic Stem Cells: cells created through the joining of a human egg and sperm or through nuclear transfer that are sufficiently undifferentiated such that they cannot be identified as components of any specialized cell type.

Nuclear Transfer: the replacement of the nucleus of a human egg with a nucleus from another human cell.

Eligible Institution: a nonprofit, tax-exempt academic institution of higher education, a hospital that conducts biomedical research, or any entity that conducts biomedical research or embryonic or human adult stem cell research.

Institutional Review Committee: the local institutional review committee specified in 21 USC 360j(g)(3)(A)(i), and when applicable, an institutional review board established in accordance with the requirements of 45CFR 46, Subpart A.

ESCRO Committee: an institutionally-based Embryonic Stem Cell Research Oversight (ESCRO) committee in accordance with the 2005 National Academy of Sciences' Guidelines.

Overview

It is the intent of the Connecticut Stem Cell Research Grants Program to consider funding any form of stem cell research, but priority will be given to human embryonic stem cell research that is not currently eligible for federal funding. Other types of stem cell research will also be eligible, with priority given to human studies with clear potential relevance to human health. Animal models are not excluded from consideration but applicants will need to demonstrate a direct relevance to human stem cell biology and its therapeutic implications.

Who May Submit

Connecticut researchers engaged in the advancement of embryonic or human adult stem cell research are encouraged to submit proposals. Research must be conducted at an eligible institution. The applicant's institution must undertake responsibility for financial administration of the grant and for overall compliance with rules governing research at that institution. In general, applicants at academic research institutions must be faculty members. Non-tenure track faculty members may apply if their institutional policies permit them to hold independent grants. Postdoctoral fellows may apply with the support of a faculty sponsor. Researchers at eligible institutions, including for-profit companies, may apply for all types of grants.

When to Submit

Submit a one page letter of intent by **June 1, 2006**.

Completed hard copy, signed proposals, as well as electronic copies of proposals are due at Connecticut Innovations by **4:30 p.m. on July 10, 2006.**

Where to Submit

(1) Letters of intent should be sent electronically to russ.tweeddale@ctinnovations.com

(2) An original signed proposal should be delivered to:

Connecticut Stem Cell Research Grants Program
Connecticut Innovations
c/o Russ Tweeddale
200 Corporate Place, 3rd Floor
Rocky Hill, CT 06067

(3) An electronic copy of the proposal should be sent to russ.tweeddale@ctinnovations.com

Refer questions to Russ Tweeddale: 860-563-5851 or
Russ.tweeddale@ctinnovations.com

Special Considerations for Human Embryonic Stem Cell (hESC) Research

A priority for the Connecticut Stem Cell Research Grants Program is to support research on human embryonic stem cells that are not currently eligible for federal funding. The state is committed to the highest standard of ethical oversight and transparency, and expects all grant recipients to be in full compliance with all applicable laws, regulations and guidelines, including a review and approval by the Institutional Review Board (IRB) when applicable, regarding this type of research.

The grantee's institution must establish an Embryonic Stem Cell Research Oversight (ESCRO) committee along the lines recommended by the National Academies Guidelines for Human Embryonic Stem Cell Research, as amended from time to time, http://www.nap.edu/books/0309096537/html to oversee all hESC research at the institution. Each grantee's institution must submit a list of members of their ESCRO committee along with a copy of the policies and procedures of the ESCRO committee prior to the release of funds.

If a proposed project has not yet been approved, or if an ESCRO committee has not yet been convened to consider the project, the application must summarize institutional plans and timetable for both establishing an ESCRO committee and reviewing funding applications. Release of funds is contingent on ESCRO approval of the project.

If research on non-federal hESC lines is to be conducted in a research environment that also receives federal funding support, the institution must have established a detailed policy for the segregation of funding in compliance with federal funding restrictions. The policy must be in place before the release of funds.

Types of awards

Applications will be considered for (1) Seed Grants, (2) Established Investigators, (3) Group Projects, (4) Core Facilities and (5) Hybrid Projects. Initially, the Connecticut Stem Cell Research Grants Program expects to spend a substantial part of its overall budget on a limited number of Group Projects, Core Facilities and/or Hybrid Projects. Total annual funding for Seed Grant Awards will not exceed 10% of the total annual budget for the Connecticut Stem Cell Research Grants Program.

1. Seed Grant Awards: These awards are intended to support the early stages of projects that are not yet ready for larger scale funding whether from federal or nonfederal sources. Priority will be given to junior faculty members at the start of their independent careers. Postdoctoral fellows, or equivalent, may apply with the support of a faculty sponsor or equivalent.

Requested funding for a Seed Grant Award may be up to $200,000 (including indirect costs) and may be expended over 2 years. The yearly budget must not exceed $100,000. Project Descriptions for Seed Grant applications are limited to 5 pages (inclusive of the main text, methodology, figures and legends). Other proposal requirements are described under "Guidelines for Preparation of Proposals."

2. Established Investigator Awards: These awards are intended for investigators with a track record of independent research including prior grant support and regular publications.

Requested funding for an Established Investigator Award may be up to $1 million (including indirect costs) and may be expended over 4 years. Funding is encouraged to be evenly budgeted over the duration of the award. Project Descriptions for Established Investigator applications are limited to 10 pages (inclusive of the main text, methodology, figures, and legends). Other proposal requirements are described under "Guidelines for Preparation of Proposals."

3. Group Project Awards: These awards are intended to support coordinated approaches to ambitious strategic goals that are beyond the scope of a typical single laboratory. Priority will be given to projects involving collaboration across disciplines and/or institutions, and proposals should include explanations of the need for collaboration, along with plans for managing the collaborative process, including division of responsibilities among collaborators and timelines for achieving expected project milestones. If more than one institution is involved, the proposed budget must specify how funding is to be distributed between collaborating institutions. As with other grants, eligibility for funding is restricted to researchers at CT institutions. Group Projects may have multiple co-principal investigators, but one individual must be identified as the lead investigator and primary contact with the Connecticut Stem Cell Research Program.

Requested funding for a Group Project Award may be up to $4 million (including indirect costs) and may be budgeted for up to 4 years. Project Descriptions for Group Project applications are limited to 50 pages (inclusive of the main text, methodology, figures, and legends). Other proposal requirements are described under "Guidelines for Preparation of Proposals."

4. Core Facilities Awards: These awards are intended to provide shared core facilities for stem cell researchers at eligible CT institutions, as defined by statute. Priority will be given to cores that are beyond the means of most individual labs, that will be made widely accessible to the CT stem cell research community, and that are likely to advance stem cell research throughout the state. Proposals must include an explanation of the need for the core, along with estimates of likely capacity and usage. Priority will also be given to applicants with a proven expertise in the relevant technology and ability to provide a high quality service. Funds may be used to cover equipment, salaries or other costs associated with establishing and operating cores. Cores will also be allowed to establish a reasonable fee-for-service schedule in order to recover additional costs associated with their operation. Proposed fees must be specified and approved by the institution.

Requested funding for a Core Facilities Award may be up to $5 million (including indirect costs) and may be expended over 4 years. Project Descriptions for Core Facilities applications are limited to 50 pages (inclusive of the main text, methodology, figures, and legends). Other proposal requirements are described under "Guidelines for Preparation of Proposals."

Note: Group Project Awards may include shared core equipment as part of their budget. Core Facility Awards are distinct, however, in that they are intended specifically to provide services to the wider Connecticut research community, rather than being restricted to participants in a specific collaborative project or to members of the host institution.

5. Hybrid Awards: Applicants may choose to submit 'hybrid' applications that include elements from both Group Projects (category 3) and Core Facilities (category 4). As with Group Projects, such Hybrid applications may have multiple co-principal investigators, but one individual must be identified as the lead investigator and primary contact with the Connecticut Stem Cell Research Grants Program.

Requested funding for a Hybrid Award may be up to $5 million (including indirect costs) and may be expended over 4 years. Project Descriptions for Hybrid applications are limited to 50 pages (inclusive of the main text, methodology, figures, and legends). Other proposal requirements are described under "Guidelines for Preparation of Proposals."

Note: Group Project or Hybrid Awards may under special cases include startup funds for identified faculty members yet to be hired. Such proposals require detailed justification, including the identification of the person to be hired *and* a detailed description of his/her contribution to the specific project. Release of funds will be contingent on the faculty member accepting and taking up the position. Justification must include the need for additional recruitment and an explanation of how the funding will be used to support the overall goals of the project. Funds may not be used for general research infrastructure not directly related to the goals of the Connecticut Stem Cell Research Grants Program.

Selection Criteria

The criteria to be employed in the evaluation shall include, but not be limited to, the following:

A. Scientific merit of the proposed research
B. Conformance to high ethical standards
C. Ability to perform the proposed research
D. Commitment of host institution and (where applicable) collaborators to the proposed project, including cost sharing
E. Potential for collaboration across disciplines and institutions
F. Benefits (including financial benefits) to the state of Connecticut
G. Alignment with funding priorities as determined from time to time by the Connecticut Stem Cell Research Advisory Committee

I. Proposal Review

The Connecticut Stem Cell Research Peer Review Committee will review all proposals and make recommendations to the Connecticut Stem Cell Research Advisory Committee with respect to the ethical and scientific merit of each proposal. The Peer Review Committee will be guided by the National Academies Guidelines for Human Embryonic Stem Cell Research, as amended from time to time, http://www.nap.edu/books/0309096537/html and C.G.S. Sections 19a-32d through 19a-32g.

The Advisory Committee, in consultation with the Commissioner of Public Health, will make the funding decisions. Decisions regarding funding are anticipated in September 2006.

II. Funding

Notification of funding approval will be made by the Commissioner of Public Health.

The institution will then sign a contract indicating that the institution is in compliance with the requirements of applicable Connecticut General Statutes, Executive Orders and other administrative requirements. The institution must establish an ESCRO committee to review and approve proposals involving the use or creation of human embryonic stem cells and must submit a list of members of the ESCRO committee along with a copy of the policies and procedures of the committee prior to the release of funds.

The funding period begins on the effective date specified in the contract. Expenditures incurred before the

effective date of the contract may not be charged against the project. Expenditures may be made within 60 days after the scheduled expiration date of the contract, only to honor services or goods encumbered before the expiration date. Any requests for rollovers or extensions must be approved by the appropriate body.

Transmittal of Funds

Funds will be transmitted to the institution over the duration of the grant according to each year's budget request. Multi-year projects will receive the first installment immediately following the signing of the contract for the project, and subsequent installments will be transmitted after technical and fiscal progress reports are received and approved.

Audit of Funds

Expenditures by institutions may be subject to audit. Institutions submitting proposals for funding must agree to cooperate by providing information for audit and a full review of the project.

III. Guidelines for Preparation of Letter of Intent and Proposals

Letter of Intent

Applicants are asked to submit a letter of intent that includes the following information:

- Title of proposed project
- Type of award
- Estimate of requested funding amount
- Contact information for Principal Investigator
- Brief description of proposed project

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows staff to estimate the potential review workload and plan the review.

Proposal

Original signed proposals must be stapled in the upper left-hand corner but otherwise unbound with pages numbered at the bottom, with one-inch margins, and with 12 point font. They may be single-spaced and shall be printed only on one side. Any reprints, appendices, or other materials to be considered with the proposal must be attached to the original proposal as well as electronic copies.

The total length of the proposal is dependent upon the type of award being sought and is outlined above under the heading "Types of Awards." Proposals that do not follow the prescribed format or are incomplete when they are submitted will be rejected as ineligible for consideration.

Proposals shall include the following:

1. Cover Page (Attachment I)

Use the format provided in Attachment I. A proposal is incomplete if any of this information or signatures are omitted. The Cover Page must be signed by the Vice President for Research or authorized official to confirm institutional approval for the application including financial as well as other types of regulatory compliance (see #9 Special Considerations).

A separate page (Attachment I), should be completed by an investigator at each participating institution. For projects with multiple investigators, the lead investigator should be indicated.

2. Project Summary (Attachment II)
Use the format provided in Attachment II. The summary shall include a statement of objectives and the scientific methods to be employed written in lay language. Limit summaries to the space provided on Attachment II. Note: Because the Project Summary will be available to the public, do not include proprietary information in the Summary.

3. Table of Contents

4. Project Description
Page limits for each type of Award are defined above under the heading "Types of Awards." The description of the project shall include the following subsections:

a. Project Objectives and Significance of Proposed Work
Describe the goals and objectives of the project. Discuss the rationale for choosing these objectives. Explain how these objectives compare to the state of the art and what distinguishes this proposed work from other efforts.

b. Project Plan
Describe the technical plan over the life of the project, how the proposed work will be organized into tasks and how the tasks are interrelated. Define clear, quantitative milestones and provide an expected schedule for reaching these milestones, including regulatory approvals where applicable. For projects involving several co-investigators and/or institutions, describe the expected contributions of each participant. Summarize the technical tasks that must be accomplished, with special emphasis on new or innovative technologies required for success of the project. Describe the technical challenges and the approach to overcoming any barriers. Assess the probability of success of this project.

c. Intellectual Property
Describe the plans and timeline to protect the intellectual property. Describe the plans and timeline for licensing the technology. As required by C.G.S. Sections 19a-32d through 19a-32g, applicants must 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."*

In evaluating proposed arrangements, it is expected that, at a minimum, the State of Connecticut shall be entitled to a 5% share of royalties and other income directly resulting from any covered invention conceived and reduced to practice with financial contribution from the State's grant. For purposes of this section, a "covered invention" shall be defined as a novel and unique discovery that is protectable under Title 35 of the United States Code. All such covered inventions shall be promptly reported to the Department of Public Health.

d. Bibliography
List the existing research and technology base that supports the proposed work.

5. Evidence of Commitment

a. Commitment of Institution and other Collaborators
Describe the commitment of the institution and that of other collaborators to this project.

b. Commitment of the Key People
- Describe their qualifications

- Describe the focus of each person's efforts
- Estimate the percentage of effort each person will devote to this project
- Describe the project management plan

c. Commitment to Sharing Resources

The Connecticut Stem Cell Research Grants Program expects grant recipients and their institutions to share reagents, data and protocols developed in connection with these grants. In particular such resources shall be made freely available to other Connecticut-based researchers. Describe plans for sharing such anticipated resources. If this is expected to involve significant costs to the recipient institution, the budget may include a component to cover these costs.

d. Financial Commitment from other Sources

Describe financial commitments to the project from other sources. As required by Public Act 05-149, applicants must submit "proposed funding for such research from sources other than the state of Connecticut."

e. Available Facilities and Major Items of Equipment

Describe the facilities and major equipment available for this project.

6. Biographical Sketches

Submit a brief biographical sketch, including patents, selected publications, and recently funded projects for each principal investigator (four page maximum per person). For Seed Grant Awards, provide a biographical sketch for the applicant and, if appropriate, for the faculty sponsor.

7. Budget

a. Budget Detail (Attachment III)

Each proposal must contain a budget for each year of support requested and a cumulative budget for the full term of requested support. Identify each year's request ("First year," "Second year," or "Cumulative Budget") at the top right of each page. Use the prescribed budget format provided in **Attachment III.**

Salaries and Wages: List the names of the principal investigator(s), faculty, and other senior associates and the estimated number of academic-year, summer, or calendar-year person-months for which funding is requested. Salaries requested must be consistent with the institution's regular practices. Connecticut Stem Cell Research Grant Funds may not be used to augment the total salary or rate of salary of faculty members during the period covered by the term of faculty appointment. Nor may funds be used to reimburse faculty members for consulting or other time in addition to a regular full-time institutional salary covering the same general period of employment.

For postdocs, graduate students and technical staff, etc., list only the total number of persons and total amount of salaries per year in each category.

Fringe Benefits: If the institution's usual accounting practices provide that its contributions to employee benefits (social security, retirement, etc.) be treated as direct costs, funds may be requested to defray such expenses as a direct cost.

Equipment: The Connecticut Stem Cell Research Grants Program wishes to avoid expensive duplication of research infrastructure wherever possible. Therefore, any budget requests for major equipment must be carefully justified.

Identify items exceeding $1,000 or more and a useful life of more than one year as Permanent Equipment. Special purpose research equipment having a unit acquisition cost of $10,000 or more purchased or leased with project funding is subject to reasonable research equipment inventory controls, maintenance procedures, and organizational policies that enhance its multiple or shared use on other projects, if the other use does not interfere with the work on the project for which the equipment is acquired.

Travel: Funds may be requested for fieldwork necessary to carrying out the project and up to $5,000 per year per principal investigator to travel to conferences to present findings. (Documentation of expenses will be required in subsequent fiscal reports).

Other Direct Costs: The budget should itemize other anticipated direct costs, including materials and supplies, publication costs, and computer services. Other examples include payments to service charges, and construction of equipment or systems not available off-the-shelf.

Publication Costs/Page Charges: The budget may request funds for the costs of publishing the results of the project, including costs of reports, reprints, page charges, other journal costs and necessary illustrations.

Cost of sharing reagents: If the project is expected to generate reagents or data that will be of general value to the research community, the budget may include a component to cover the reasonable costs of generating and distributing such resources.

Indirect Costs: Budgets may include indirect costs, which may not exceed 25 percent of the Modified Total Direct Costs (MTDC). MTDC are described in Attachment A of OMB Circular A122 and consist of all salaries and wages, fringe benefits, materials and supplies, services, travel, and sub-grants and subcontracts up to the first $25,000 of each sub-grant or subcontract (regardless of the period covered by the sub-grant or subcontract). Equipment, capital expenditures, charges for patient care, rental costs and the portion in excess of $25,000 shall be excluded from MTDC. Participant support costs shall generally be excluded from MTDC.

b. Budget Explanation/Justification

In a separate section titled "Budget Explanation/ Justification," clearly delineate the specific use and justification of funds. Breakdowns should be as accurate and specific as possible. For equipment funding requests, describe and justify each piece of requested equipment. Identify location of use. If comparable equipment is available at the institution, explain why it cannot be used.

Include in this section a detailed description of the contributions from the institution and collaborators.

9. Special Considerations

Several situations require written assurance that appropriate institutional clearance procedures are in place:

1. Projects that involve the use of recombinant DNA and/or hazardous reagents.
2. Projects that involve use of human eggs, embryos and/or human embryonic stem cells.
3. Projects that involve the use of human subjects.
4. Projects that involve the use of animal subjects.

All proposals must be in compliance with federal, state and local laws and all applicable permitting requirements. Prior to conducting research involving human embryonic stem cells, documentation verifying that any human embryos, embryonic stem cells, unfertilized human eggs or human sperm used in such research have been donated voluntarily as required by C.G.S. Sections 19a-32d through 19a-32g

must be provided to the Commissioner of Public Health on a form available from the Connecticut Department of Public Health.

10. Appendix

Letters of commitment from the institution and collaborators should be included.

V. Project Administration

Responsibility for general supervision of all project activities rests with the institution.

Adherence to Original Budget Estimates

Reallocation of more than 10 percent of the annual budget requires the approval of Connecticut Innovations. The written request to re-budget, signed by the principal investigator and the authorized institutional representative, must fully explain the need for re-budgeting. Reallocation of more than 20% of the annual budget also requires approval of the Advisory Committee.

Changes in Personnel

Timely notification to Connecticut Innovations (who will notify the Advisory Committee and Peer Review Committee) is required for any change in any principal investigators. All changes involving senior personnel must be approved by the Advisory Committee. If the principal investigator terminates employment with the institution, the institution may terminate the project, or when appropriate, propose to the Advisory Committee a substitute principal investigator to continue the project.

Funding cannot be transferred from the institution. If grantee moves to another eligible institution within Connecticut, funding will be transferable with the approval of Connecticut Innovations and the Advisory Committee.

Equipment

Title to equipment purchased or fabricated with funds or matching funds vests in the institution.

Project Reports

Principal investigators are required to submit **Annual Technical Progress Reports**. Reports shall

- summarize activity during the past year,
- describe progress with reference to scheduled milestones,
- identify any significant scientific developments and all invention disclosures,
- describe collaborative work,
- describe any problems encountered,
- include a statement of expenditures for the past 12 months
- include a two page summary in lay language suitable for the public and press.

Institutions are required to submit **Semi-Annual Fiscal Reports** for each project.

Failure to submit required reports could result in deferral of subsequent installment payments or termination of support and forfeiture of funds.

The Advisory Committee and the Peer Review Committee reserve the right to conduct site visits for funded projects.

Principal investigators are required to submit a **Final Report** within 90 days after the expiration of a contract**.** This report must include information needed for purposes of program management, evaluation, fiscal accountability, and informing the public about the results of research supported under the Connecticut Stem Cell Research Grants Program.

Acknowledgment of Support and Disclaimer

Any publication, oral presentation, or meeting abstract based on research activity supported by the funding must contain the following acknowledgment: "This material is based upon work supported by the State of Connecticut under the Connecticut Stem Cell Research Grants Program. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the State of Connecticut."

Proposal as Public Record

Funded proposals will become a matter of public record and will be available to the public, except as described below. Information or material that Connecticut Innovations and the institution mutually agree to be of a privileged nature will be held in confidence to the extent permitted by law. Without assuming any liability for inadvertent disclosure, Connecticut Innovations will seek to limit dissemination of such information only to its employees, selected employees at the Connecticut Department of Public Health, the Connecticut Stem Cell Peer Review Committee, and to the Connecticut Stem Cell Research Advisory Committee. Accordingly, a proposal which indicates the inclusion of "Proprietary and Privileged Information" on the cover page, will be released to the Connecticut Stem Cell Peer Review Committee, and to the Connecticut Stem Cell Research Advisory Committee only after those reviewers have signed a non-disclosure document reflecting applicable state law.

Inventions, Software, and Copyrights

As required by C.G.S. Sections 19a-32d through 19a-32g, applicants must 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."* The State of Connecticut encourages the publication and distribution of the results of the project performed under its funding and expects the results to be publicly available. The Commissioner of Public Health retains the right to use published materials resulting from the performance of work under Connecticut Stem Cell Research Grants Program funding for state purposes.

Attachment I CT Stem Cell Research Proposal Cover Page

Attachment I should be completed by the principal investigator of each participating institution. For projects with multiple investigators, the lead investigator should be indicated.

Indicate type of project:

_____ Seed Grant

_____ Established Investigator Grant

_____ Group Project Grant

_____ Core Facility Grant

_____ Hybrid Grant

Title of Project

Institution

PI Name (and sponsor name where applicable) **Signature (s)**

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibilities for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Department/Business Address

Phone **Email**

Amount Requested $

Authorized Representative **Title**

I certify that the statements herein are true, complete and accurate to the best of knowledge, and accept the obligation to comply with all terms and conditions of the Connecticut Stem Cell Research Grants Program ***and all applicable laws and ethical standards*** if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Signature **Date**

DNA and/or Hazardous Reagents

☐ Human Eggs, Embryos and/or Human Embryonic Stem Cells

☐ Animal Subjects

☐ Human Subjects

Items included in Project (check where appropriate)

☐ Proprietary and Privileged Information (identify such sections or pages)

☐ Recombinant

Attachment II

CT Stem Cell Research Proposal Summary (in Non-Scientific Language)

Attachment II should be completed by the principal investigator of each participating institution. For projects with multiple investigators, the lead investigator should be indicated.

Title of Project

Amount requested $

Principal Investigator

Institution

Collaborator (s)

One sentence description. This Project's purpose is to

Project Summary (Limit to this side of form)

Attachment III CT Stem Cell Research Proposal Budget

To be completed by each Institution

Budget for Year ___
Cumulative Budget ___

A. Senior Personnel PI, CO-PI's, Faculty and Other Senior Associates (List each separately with Title and Organization on Budget Explanation page. Show number in brackets.)	**Grant Funded Person-Mos.**	**Funding Requests**
1.		
2.		
3.		
4. ( ) Others (List individually on Budget Explanation Page)		
5. ( ) Total Senior Personnel (1-4)		
B. Other Personnel (Show numbers in brackets)		
1. ( ) Post-Doctoral Associates		
2. ( ) Other Professionals (Technician, Programmer, Etc.)		
3. ( ) Graduate Students		
4. ( ) Other -Specify		
Total Salaries And Wages (A&B)		
C. Fringe Benefits (If charged as Direct Costs)		
Total Salaries, Wages, and Fringe Benefits (A+B+C)		
D. Permanent Equipment (Describe on Budget Explanation Page)		
E. Other Direct Costs (Describe details on Budget Explanation Page)		
1. Materials And Supplies		
2. Publication Costs/Page Charges		
3. Computer Services		
4. Other		
Total Other Direct Costs		
F. Indirect Costs (Describe on Budget Explanation Page)		
G. Total Costs (A Through F)		
H. Projected Revenues		
I. Total Contributions from Other Sources		

APPENDIX E
Public Act 06-77

AN ACT DESIGNATING THE MONTH OF NOVEMBER AS LUNG CANCER AWARENESS MONTH AND CONCERNING THE ESTABLISHMENT OF A PUBLIC UMBILICAL CORD BLOOD BANK.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (a) of section 10-29a of the 2006 supplement to the general statutes is amended by adding subdivision (51) as follows (*Effective October 1, 2006*):

(NEW) (51) Lung Cancer Awareness Month. The Governor shall proclaim the month of November to be Lung Cancer Awareness Month to heighten public awareness of the fact that lung cancer is the leading cause of cancer death of both men and women in the United States. Suitable exercises shall be held in the State Capitol and elsewhere as the Governor designates for the observance of the month.

Sec. 2. (*Effective from passage*) (a) The Commissioner of Public Health, in consultation with the Stem Cell Research Advisory Committee established pursuant to section 19a-32f of the 2006 supplement to the general statutes, shall establish an ad hoc committee to examine and evaluate the feasibility of (1) establishing a public umbilical cord blood bank for the purpose of collecting and storing umbilical cord blood and placental tissue donated by maternity patients at hospitals licensed in this state, (2) entering into a multistate public umbilical cord collaboration, and (3) developing a public-private partnership with existing umbilical cord blood banks. The committee shall hold its first meeting not later than sixty days after the effective date of this section. Other topics may be included at the discretion of either the commissioner or the Stem Cell Research Advisory Committee.

(b) (1) The ad hoc committee shall be appointed by the Commissioner of Public Health and shall consist of the Commissioners of Public Health and Economic and Community Development, or their designees; one member of the Stem Cell Research Advisory Committee established pursuant to section 19a-32f of the 2006 supplement to the general statutes, selected by the Stem Cell Research Advisory Committee; one researcher from a private institution of higher education in the state; one researcher from a public institution of higher education in the state; one representative of an educational and business support network organization for bioscience in the state; one individual who is a member in good standing of the American Association of Blood Banks, with expertise in umbilical cord blood banking and the Food and Drug Administration's federal safety standards for umbilical cord blood banks; one individual with multiple years of experience in establishing, executing and administering an umbilical cord blood registry. The Commissioner of Public Health shall serve as chairperson of the committee.

(2) The Commissioner of Public Health, in consultation with the Stem Cell Research Advisory Committee, may expand the membership of the ad hoc committee to include additional members if either decides such expansion would be useful.

(c) On or before January 5, 2007, the Commissioner of Public Health shall submit, in accordance with section 11-4a of the general statutes, the results of the examination, along with any recommendations, to the Governor and the joint standing committee of the General Assembly having cognizance of matters relating to public health.