

## State of Connecticut Stem Cell Research Grants Program- 2012 RFP

### Due Dates

Stem Cell Workshop/ Applicants' Conference- November 17, 2011

Letter of Intent Submission Deadline- December 2, 2011

Proposal Submission Deadline – January 13, 2012

### Proposal Instructions

It is the intent of the Connecticut Stem Cell Research Advisory Committee to fund the best basic and translational stem cell research proposals that could result in clinical application. The Advisory Committee intends to maintain a program of outstanding science that will continue Connecticut's pioneering role as an international center of excellence and leadership in stem cell research.

### Purpose

The Connecticut Stem Cell Research Grants Program, authorized in the Connecticut General Statutes (C.G.S.) §§ 19a-32d through 19a-32g, 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, Incorporated serves as administrative staff of the Advisory Committee, reviewing applications, and preparing and executing assistance agreements for the grants.

It is anticipated that up to ten million dollars will be available in the Connecticut Stem Cell Research Grants Fund through June 30, 2012. For each of the fiscal years ending June 30, 2013 to June 30, 2015, inclusive, it is anticipated that up to 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 Applicant:** 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.

**ESCRO Committee:** an Embryonic Stem Cell Research Oversight (ESCRO) committee means a committee established in accordance with the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time.

### Overview

It is the intent of the Connecticut Stem Cell Research Advisory Committee to consider funding any form of stem cell research, but priority will be given to human stem cell research. Other types of stem cell research will also be eligible, with priority given to studies with clear potential relevance to human health. Animal models will be considered, 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. Except under extraordinary circumstances, all research must be conducted in Connecticut. Research must be conducted at an eligible academic institution, hospital or company. Researchers at such entities may apply for any category of grants. The researcher's institution, hospital, or company must undertake responsibility for financial administration of the grant and for overall compliance with rules governing research at that entity. Except as specified, 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 for seed grants with the support of a faculty sponsor. Applicants from hospitals or companies must be permitted by their organization to hold research grants.

## Applicants' Conference- Stem Cell Workshop

An Applicants' Conference entitled "Stem Cell Workshop" (workshop) will be held on November 17, 2011 at 10 AM at the Legislative Office Building, 300 Capitol Avenue Hartford, CT. Applicants planning to submit a proposal are not required to attend this conference. Oral questions raised at the workshop may be answered orally; however, responses will not be official, and may not be relied upon, until a written reply is issued through the Stem Cell Research Advisory Committee and posted on the Department of Public Health's Stem Cell Research Program's website at: [http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389700&dphNav\\_GID=1825&dphNav\\_GID=1825](http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389700&dphNav_GID=1825&dphNav_GID=1825). Additionally, all materials and presentations from the Workshop will be archived and made available on this website.

This workshop is designed to educate and inform potential applicants for the Stem Cell Research grants-in-aid funds about the Stem Cell Research Grant Program managed by the State of Connecticut and to answer questions about the grant application, the review process and the administration of the program post-award. A formal invitation as well as more information on the workshop will be available on the Connecticut Innovations website, [www.ctinnovations.com](http://www.ctinnovations.com).

## When to Submit

Submit a one page letter of intent, in PDF format due to Connecticut Innovations by **4:30 pm on December 2, 2011**.

Submit completed, signed electronic copies of proposals, in one single PDF, **by 4:30 pm on January 13, 2012**.

**No additional proposals or supplemental materials will be accepted after the deadline.**

## Where to Submit

1. Letters of intent in **PDF** format should be sent electronically to [emily.smith@ctinnovations.com](mailto:emily.smith@ctinnovations.com)
2. A signed electronic copy of the proposal in one single **PDF** should be sent to [emily.smith@ctinnovations.com](mailto:emily.smith@ctinnovations.com)

Refer questions to Emily Smith: 860-257-2337 or [emily.smith@ctinnovations.com](mailto:emily.smith@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 hESC that is 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) and Embryonic Stem Cell Research Oversight (ESCRO) Committee, when applicable, regarding this type of research.

The grantee's institution, hospital or company must establish an ESCRO committee, or establish an affiliation with an existing ESCRO committee, established in accordance with the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time, [http://www.nap.edu/catalog.php?record\\_id=12923](http://www.nap.edu/catalog.php?record_id=12923) to oversee all hESC research at the institution, hospital or company. Each grantee's institution, hospital or company must submit a list of members of the ESCRO committee along with a copy of the policies and procedures of the ESCRO committee and the ESCRO committee approval for the research project prior to the execution of the assistance agreement and release of funds. The Advisory Committee reserves the right to delay or rescind funding if it is not satisfied that the ESCRO

committee is appropriately established and constituted. If an applicant institution, hospital or company does not have an established ESCRO committee, the application must summarize the entity's plans and timetable for establishing or affiliating with an ESCRO committee.

If research on non-federal hESC lines is to be conducted in a research environment that also receives federal funding support, the institution, hospital or company 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 execution of the assistance agreement and release of funds.

### **Types of awards**

Applications will be considered for (1) Seed Grants, (2) Established Investigators, (3) Group Projects, and (4) Core Facilities.

**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. Established investigators new to stem cell research or developing new research directions may apply for seed grants. Junior researchers in academic institutions, hospitals and companies are also encouraged to apply. In academic institutions, 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. A letter from the sponsor indicating support of the proposal must be included with the application and must describe the applicant's level of independence, as well as other resources/funding available for the project.

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 peer reviewed publications.

Requested funding for an Established Investigator Award may be up to \$750,000 (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. 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, hospital or company is involved, the proposed budget must specify how funding is to be distributed between collaborating entities. As with other grants, eligibility for funding is restricted to researchers at Connecticut institutions, hospitals or companies. 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. Two separate types of Group Project Awards are available. Priority will be given to projects involving disease directed collaborative arrangements between industry (e.g., biotechnology and pharmaceutical companies), medical centers and academic institutions, with the intention of beginning Federal Food & Drug Administration review within four years of the awarding of the grant.

- a. Requested funding for a Disease Directed Collaboration Group Project Award may be up to \$2 million (including indirect costs) and may be budgeted for up to 4 years. 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."
- b. Requested funding for a Group Project Award may be up to \$1.5 million (including indirect costs) and may be

budgeted for up to 4 years. 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 Connecticut institutions, hospitals or companies. Applications will be considered for additional support for new technology development or to sustain the works in progress at the core facilities, already established with the support of core grant funding under the Stem Cell Research Program grants-in-aid funding, which are to be made widely accessible to the Connecticut 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 continued support for the existing core facility, along with estimates of likely capacity and usage. Previously funded cores should provide specific details in their budget justification about the necessity of additional funding; including explanation of how new and existing funding will be integrated without overlap. Additionally, a plan for each existing core to attain future funding from sources other than the state of Connecticut must be noted in the budget justification section of the proposal.

Applicants should demonstrate 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, hospital or company.

For this round of funding, total available funding for Core Facilities Awards will not exceed \$ 1 million. Requested funding for a Core Facilities Award may be up to \$1 million (including indirect costs) and may be budgeted for up to 2 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 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, hospital or company.

**Note:** Group Project Awards and Core Facilities Awards may under special cases include startup funds for investigators 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 investigator 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:

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

## **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 utilize the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time, [http://www.nap.edu/catalog.php?record\\_id=12923](http://www.nap.edu/catalog.php?record_id=12923) and C.G.S. §§ 19a-32d through 19a-32g.

The Advisory Committee, in consultation with the Commissioner of Public Health, will make the funding decisions. The Advisory Committee reserves the right and discretion to fund one or more components or defined parts of an application's proposed research project. In the event of such a determination, the applicant will be required to submit a revised budget reflecting the Advisory Committee's funding decision and such other information as the Advisory Committee may require.

At time of application, an applicant may send to Connecticut Innovations the name(s) of any reviewers with whom there is a conflict of interest and who should not be considered as reviewers.

Decisions regarding funding are anticipated on or after July 2012.

## **II. Funding**

Notification of funding approval will be made by Connecticut Innovations.

The institution, hospital or company will then sign an assistance agreement indicating that the institution, hospital or company is in compliance with the requirements of applicable Connecticut General Statutes, Executive Orders and other administrative requirements. The institution, hospital or company must establish an ESCRO committee or become affiliated with an ESCRO committee that will 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 and the ESCRO approval for the research project prior to the execution of the assistance agreement and release of funds. The Advisory Committee reserves the right to delay or rescind funding if it is not satisfied that the ESCRO committee is appropriately established and constituted.

The funding period begins on the effective date specified in the assistance agreement. Expenditures incurred before the effective date of the assistance agreement may not be charged against the project. Funding not used in a completed grant year may be used in a subsequent grant year to discharge expenses incurred but not yet paid in the completed grant year. Any other carry over funding shall be expended only in accordance with the terms specified in the assistance agreement.

## **Transmittal of Funds**

Funds will be transmitted to the institution, hospital or company 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 assistance agreement 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, hospitals or companies may be subject to audit. Entities 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

Signed electronic proposals must have 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 electronic copy of the proposal and all attachments should be sent in one (1) PDF file.

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 or otherwise do not conform to the requirements of these Proposal Instructions may 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 required signature is omitted. The Cover Page must be signed by the Vice President for Research or other authorized officer to confirm institutional approval for the application including financial as well as other types of regulatory compliance (see #8 Special Considerations).

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

**Please make sure to note whether or not your proposal contains privileged or proprietary information and mark these portions in bold text.**

#### 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, hospitals or companies, 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. §§ 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 the State of Connecticut shall be entitled to royalties from the awardees and certain of its affiliates, at a minimum rate of 5 percent, on revenues generated from the exploitation of any invention or intellectual property that is conceived, created or developed during the stem cell research and development activities, and during the term of the funding or at any time during the 12-month period immediately following the term of funding, and which was made possible (in whole or in part) by, or otherwise resulted (in whole or in part) from the funding.

##### d. Bibliography

List the existing research and technology base that supports the proposed work. Please note that the bibliography shall not be included within the page limitations.

#### 5. Evidence of Commitment

##### a. Commitment of Institution, Hospital or Company and other Collaborators

Describe the commitment of the institution, hospital or company 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 time 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, hospitals or companies 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, hospital or company, 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 C.G.S. § 19a-32e, 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. Companies should prepare the budget on a quarterly basis.

**Salaries and Wages:** List the names of the principal investigator(s) and other senior associates and the estimated amount of time dedicated to this project (number of academic-year, summer, or calendar-year person-months if proposal is from academic institution) for which funding is requested. Salaries requested must be consistent with the regular practices of the institution, hospital or company.

Hospitals and companies may not use Connecticut Stem Cell Research Grant Funds to augment the existing salaries of investigators. For proposals from academic institutions, 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 usual accounting practices of the institution, hospital or company 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 to travel to conferences to present findings or to further the research. (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, hospital or company, explain why it cannot be used.

Include in this section a detailed description of the contributions from the institution, hospital or company and collaborators. Core Facility applicants must include a description of a plan to attain future funding from sources other than the state of Connecticut.

### **8. Special Considerations**

Several situations require written assurance that appropriate institutional, hospital or company 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. §§ 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.

This form is available by going to the following website:

[http://www.ct.gov/dph/lib/dph/stem\\_cell/grants/VERIFICATION\\_OF\\_VOLUNTARY\\_DONATION\\_2008.pdf](http://www.ct.gov/dph/lib/dph/stem_cell/grants/VERIFICATION_OF_VOLUNTARY_DONATION_2008.pdf).

### **9. Appendix**

Letters of commitment from the institution, hospital or company and collaborators should be included. For applicants at the postdoctoral fellow stage, a letter of support from the faculty sponsor should also be included.

### **IV. Project Administration**

Responsibility for general supervision of all project activities rests with the institution, hospital or company.

### **Adherence to Original Budget Estimates**

A reallocation of 10 percent or more in the aggregate of the total approved annual budget requires the prior written approval of Connecticut Innovations. Reallocation of more than 20% in the aggregate of any approved annual budget requires the prior written approval of the Advisory Committee. The written request to re-budget, signed by the principal investigator and the authorized institution, hospital or company representative, must fully explain the need for re-budgeting and must describe the impact if any on the conduct of the research.

### **Changes in Personnel**

Timely notification to Connecticut Innovations (who will notify the Advisory Committee) is required for any change in any principal investigator(s) before or after signing the assistance agreement. The notification must be submitted at least one month prior to effective change and must describe the impact, if any, on the conduct of the research. Curriculum Vitae must be provided for the proposed new principal investigator(s). A change in principal investigator that occurs after the peer review process is completed and prior to the signing of the contract may result in the denial or rescission of funding by the Advisory Committee. All changes involving senior personnel must be approved by the Advisory Committee in accordance with the terms specified in the assistance agreement. If the principal investigator terminates employment with the institution, hospital or company, the entity may terminate the project, or when appropriate, propose to the Advisory Committee a substitute principal investigator to continue the project. Any reduction in effort by a principal investigator will require written approval by either Connecticut Innovations (if the reduction is between 10% and 20% of any approved annual budget) or the Advisory Committee (if the reduction in effort equals more than 20% of any approved annual budget).

Funding cannot be transferred from the institution, hospital or company except when the grantee moves to another eligible entity within Connecticut and the transfer receives the prior approval of the Advisory Committee in accordance with the terms specified in the assistance agreement.

### **Change in Material Scope of Project**

A material change in the objective or scope of the project must be approved by the Stem Cell Research Advisory Committee in accordance with the terms specified in the assistance agreement.

### **Equipment**

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

### **Project Reports**

Principal investigators are required to submit both **Annual Technical and Fiscal Progress Reports** as follows:

For the first year of the project, reports shall summarize activity during the first ten months of the project. Thereafter, reports shall be submitted summarizing each subsequent 12 month period and then a final 14 month period. Reports shall be submitted within 30 days following the end of each reporting period.

Reports shall include the following:

- describe progress with reference to scheduled milestones;
- identify any significant scientific developments, publications, and all invention and intellectual property disclosures;
- describe collaborative work;
- describe any problems encountered; and
- include a detailed summary in lay language suitable for the public and press on a form provided by Connecticut Innovations

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

The Advisory Committee and/or their designees 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 an assistance agreement. 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 submitted publication, whether in peer-reviewed journals, meeting abstract formats, or in review articles or similar publications, or any internal presentation to the public and/or external discussion of the Project in oral presentations, posters or meeting abstracts 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, the Department of Public Health of the State of Connecticut or Connecticut Innovations, Inc.”

Each publication must be sent to Connecticut Innovations upon request.

#### **Documents as Public Records**

All documents submitted to the Connecticut Stem Cell Research Grants program 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, hospital or company 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. Applicants are required to identify the words or paragraphs on specific pages of the application that contain trade secrets or other proprietary information. Notwithstanding the foregoing, all applicable laws governing access to public records will be observed.

#### **Inventions, Software, and Copyrights**

As required by C.G.S. §§ 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. 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.

#### **Award Documentation**

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

## Attachment I- CT Stem Cell Research Proposal

### Cover Page

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

- Indicate type of project:
- Seed Grant
  - Established Investigator Grant
  - Disease Directed Collaboration Group Grant
  - Group Project Grant
  - Core Facility Grant

Title of Project:

Institution/Hospital/Company:

PI Name (sponsor 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.

PI Department/Mailing Address:

PI Phone:

PI Email:

Amount Requested: \$

Authorized Representative and Title:

I certify that the statements herein are true, complete and accurate to the best of my 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:

Items included in Project (please check where appropriate):

- Proprietary and privileged information (identify such words/paragraphs on specific pages in bold type)
- Recombinant DNA and/or hazardous reagents
- Human eggs, embryos, and/or human embryonic stem cells
- Animal subjects
- Human subjects

## **Attachment II- CT Stem Cell Research Proposal**

### **Project Summary (in non-scientific language)**

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

Title of Project:

Principal Investigator:

Institution/Hospital/Company:

Collaborator(s):

One sentence description: This projects purpose is to

Project Summary (please limit to this side of form):

## Attachment III- CT Stem Cell Research Proposal

**Budget-** Attachment III should be completed by the institution, hospital, or company.

Budget for Year No.

Cumulative Budget

<b>A. Senior Personnel</b> (PI, Co-PI, Faculty and other Senior Associates).	<b>Grant Funded Person Months</b>	<b>Funding Requests</b>
1.		
2.		
3.		
4. Others (List individually on Budget Justification Page)		
5. Total Senior Personnel (1-4)		
<b>B. Other Personnel</b> (List individually on Budget Justification Page)		
1. Post-Doctoral Associates		
2. Other Professionals (Technician, Programmer)		
3. Graduate Students		
4. Other (specify)		
<b>Total Salaries and Wages</b> (A&B)		
<b>C. Fringe Benefits</b> (If charged as direct costs)		
<b>Total Salaries, Wages, and Fringe Benefits</b> (A,B,&C)		
<b>D. Permanent Equipment</b> (Describe on Budget Justification page)		
<b>E. Other Direct Costs</b> (Describe on Budget Justification Page)		
1. Materials and Supplies		
2. Publication Costs/ Page Charges		
3. Computer Services		
4. Other		
<b>Total Other Direct Costs</b>		
<b>F. Indirect Costs</b> (Describe on Budget Justification Page)		
<b>G. TOTAL COSTS</b> (A through F)		
H. Projected Revenues		
I. Total Contributions from Other Sources		