State of Connecticut Regenerative Medicine Research Fund- 2016 RFP

Due Dates
Proposal Submission Deadline – Monday, December 14, 2015 by 5:00 p.m., EST

Purpose
The Connecticut Regenerative Medicine Research Fund authorized in the Connecticut General Statutes (C.G.S.) §§ 19a-32d through 19a-32g as amended by PA-14-98, supports regenerative medicine and the advancement of embryonic and/or human adult stem cell research in Connecticut. Regenerative medicine includes research and translational/clinical applications involved in “the process of creating living, functional cells and/or tissue to repair or replace tissue or organ function lost due to aging, disease, damage or congenital defect”. Translational work is defined as a set of experiments that apply discoveries generated during research in the laboratory and in preclinical studies to a disease indication/application so that further information can be gathered in support of trials and studies in humans. The Regenerative Medicine Research Fund also supports stem cell research, including basic stem cell research, disease modeling and drug testing.

It is the intent of the Regenerative Medicine Research Advisory Committee to fund the best basic and translational research proposals that could result in significant advancements in the stem cell and regenerative medicine fields. 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 and regenerative medicine research.

The Regenerative Medicine Research Advisory Committee, in consultation with Connecticut Innovations, administers and monitors the program. It is anticipated that up to ten million dollars will be available in the Connecticut Regenerative Medicine Research Fund for the 2016 RFP call.

Overview
It is the intent of the Regenerative Medicine Research Advisory Committee to consider funding any form of regenerative medicine research as described in the Purpose section. Priority will be given to translational research with potential for clinical application, disease directed research, and/or clear potential relevance to human health.

Who May Submit
Connecticut investigators engaged in stem cell and regenerative medicine research are encouraged to submit proposals. All research for which funds are requested must be conducted in Connecticut. Eligible applicants include nonprofit, tax-exempt academic institutions of higher education, hospitals that conduct biomedical research, or other entities (e.g., companies) that conduct biomedical or regenerative medicine research. Investigators at such entities may apply for any category of financial assistance. The investigator’s institution, hospital, or company must undertake responsibility for financial administration of the award and for overall compliance with rules governing research at that entity.

Please note 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 awards with the support of a faculty sponsor or equivalent. Applicants from institutions, hospitals, or companies must be permitted by their organization to hold research grants/awards.

When and Where to Submit
Submit completed, signed electronic copies of proposal, in one single PDF, which does not exceed 9 MB, by 5:00 pm EST on December 14, 2015 to regenmedrfp@ctinnovations.com. Application forms and additional information including a list of Frequently Asked Questions (FAQs) can be found on the Regenerative Medicine Research Fund website: http://www.bioinnovationct.com/regen/. If there are additional questions beyond those addressed in the FAQs, they should be submitted in writing via email to CI at regenmed@ctinnovations.com.
NO PROPOSALS OR SUPPLEMENTAL MATERIALS WILL BE ACCEPTED BY CONNECTICUT INNOVATIONS AFTER THE SUBMISSION DEADLINE.

Special Considerations for Human Embryonic Stem Cell (hESC) Research
The Connecticut Regenerative Medicine Research Fund welcomes human embryonic stem cell (hESC) research proposals that are not currently eligible for federal funding. The State is committed to the highest standard of ethical oversight and transparency, and expects all financial assistance 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 institution, hospital or company will be required to 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 awardee’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 to oversee all hESC research at the institution, hospital or company. Each awardee’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 may be considered for different types of awards: (1) Seed, (2) Established Investigator, (3) Group Projects, and (4) Core Facilities.

<table>
<thead>
<tr>
<th>Award</th>
<th>Purpose</th>
<th>Funding Amount</th>
<th>Application Page Limit (maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seed</td>
<td>intended to support the early stages of projects that are not yet ready for larger scale funding</td>
<td>up to $200,000 up to 2 years</td>
<td>5 pgs</td>
</tr>
<tr>
<td>Established</td>
<td>intended for investigators with a track record of independent research</td>
<td>up to $750,000 up to 4 years</td>
<td>10 pgs</td>
</tr>
<tr>
<td>Group</td>
<td>intended to support coordinated approaches to ambitious strategic goals that are beyond the scope of a typical single laboratory</td>
<td>up to $1.5M up to 4 years</td>
<td>25 pgs</td>
</tr>
<tr>
<td>Core</td>
<td>intended to provide shared core facilities for stem cell investigators at eligible Connecticut institutions, hospitals or companies</td>
<td>up to $500,000 1 year</td>
<td>20 pgs</td>
</tr>
</tbody>
</table>
1. Seed 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 non-federal sources. Established investigators new to regenerative medicine (including stem cell research) or developing new research directions may apply for seed awards. 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 Award may be up to $200,000 (including indirect costs, which may not exceed 25 percent of the Modified Total Direct Costs (MTDC)) and may be expended over 2 years. Project Descriptions for Seed 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 support and peer reviewed publications.

Requested funding for an Established Investigator Award may be up to $750,000 (including indirect costs, which may not exceed 25 percent of the Modified Total Direct Costs (MTDC)) and may be expended over 4 years. 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 financial assistance, eligibility for funding is restricted to investigators at Connecticut institutions, hospitals or companies. Group Projects may have multiple co-investigators, but one individual must be identified as the principal investigator and serve as the primary contact with the Regenerative Medicine Research Fund. The Regenerative Medicine Research Fund encourages proposals that include collaborative arrangements between industry (e.g., biotechnology and pharmaceutical companies), medical centers and academic institutions. With the goal of promoting the development of novel treatments for disease, priority will be given to those highly meritorious projects for which, after successful completion of the proposed studies, clinical research or commercialization would be the anticipated next step.

Requested funding for a Group Project award may be up to $1.5 million and may be expended up to 4 years. Group Project applications are limited to 25 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 regenerative medicine investigators (including stem cell researchers) at eligible Connecticut institutions, hospitals or companies. Preference will be given to applications requesting additional support for new core technology development; or to sustain the works in progress at existing core facilities, previously established with the support of the Regenerative Medicine Research Fund. Technologies and services provided by core facilities are to be made widely accessible to the Connecticut regenerative medicine and stem cell research community.

Proposals must include an explanation of the need for continued support of an existing core facility, or a justification for initiating a new 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. Cores should provide information in the budget justification section of the proposal on the total operating budget of the core for the prior three years, the percentage of the operating budget derived from the Connecticut Stem Cell Research Program or the Regenerative Medicine Research Fund in the
prior three years, and the percentage of operating budget derived from fee-for-service activities (internal and external to the organization). These details should include a breakdown as to the number of users that are internal and external to the organization, as well as the percentage of users external to the host organization for the last 3 years. The proposed core budget should include the entire budget for running the core with an explanation of how funds will be obtained for those parts of the core for which funding from the Regenerative Medicine Research Fund is not requested (e.g. philanthropic funds, other grants, user fees). Additionally, a plan for becoming a self-sustaining enterprise through funding from sources other than the State of Connecticut is required as part of the budget justification section of the proposal.

Applicants should demonstrate a proven expertise in the relevant technologies and ability to provide high quality service. Funds may be used to cover equipment, salaries, or other costs associated with establishing and operating cores. Cores should establish a reasonable fee-for-service schedule to internal and external customers, in order to recover additional costs associated with their operation. Proposed fees must be specified and approved by the institution, hospital or company.

Total available funding for Core Facilities Awards will not exceed $1 million. Requested funding for a Core Facilities Award may be up to $500,000 (including indirect costs which may not exceed 25 percent of the Modified Total Direct Costs (MTDC)) and may be budgeted for up to 1 year. Project Descriptions for Core Facilities applications are limited to 20 pages (inclusive of the main text, methodology, figures, and legends). Other proposal requirements are described under “Guidelines for Preparation of Proposals.”

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

- Alignment with funding priorities as determined by the Connecticut Regenerative Medicine Research Advisory Committee, namely:
  - Translational research and potential for clinical application
  - Research for which federal regenerative medicine research funding is not available
- Potential for commercialization including benefits (i.e., financial benefits) to the State of Connecticut
- 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

Additional criteria that may impact funding are listed below. These elements are highly desirable as part of the application, but not required.

- **Follow-on Requests**: Preference will be given to applications that previously received funding through the Connecticut Stem Cell Research Program and/or the Regenerative Medicine Research Fund and provide a clear plan for how additional funding will allow progression towards the clinic or a commercializable product.
- **Collaborations and Leverage**: Preference will be given to collaborative research projects across organizations. Academic-biopharma collaborations are encouraged. For academic-biopharma collaborations, financial, intellectual property or in-kind support from the biopharma organization should be detailed.

Proposal Review
All proposals will be reviewed by a Peer Review Committee that will make recommendations to the Regenerative Medicine Research Advisory Committee with respect to the ethical, technical and scientific merits of the 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 as amended by PA-14-98.

The Advisory Committee, in consultation with Connecticut Innovations, will make 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 the 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; up to five individuals may be listed (see Section 10 (a) of application).

**Funding**

Decisions regarding funding are anticipated on or before June 30th, 2016. Notification of funding approval will be made by Connecticut Innovations. 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 funding year may be used in a subsequent funding year to discharge expenses incurred but not yet paid in the completed year. Any other carry over funding shall be expended only in accordance with the terms specified in the assistance agreement.

**Funding Availability**

Funding is contingent upon the authorization and availability of state funds for this program.

**Transmittal of Funds**

Funds will be transmitted to the institution, hospital or company over the duration of the award 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. It is the responsibility of the awardee to keep accurate and appropriate records and pertinent receipts. Entities submitting proposals for funding must agree to cooperate by providing information for audit and a full review of the project.

**Guidelines for Preparation of Proposals**

**Proposal**

Signed electronic proposals must have pages numbered at the bottom, with one-inch margins, 11 point font (Arial or Helvetica), and single line spacing. The electronic copy of the proposal and all attachments should be sent in one (1) single PDF file not to exceed 9 MB. 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.”

**IMPORTANT:** 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.

- Attachment I contains the following section(s):
  1. **Cover Page**

Use the format provided in Attachment I. A proposal is incomplete if any of this information or required signatures 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 principal investigator should be indicated.
Note: If the proposal contains privileged or proprietary information, mark these portions in **yellow highlighted text**.

- **Attachment II contains the following section(s):**

  2. Project Summary

  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. “Lay language” should be suitable for the general public’s understanding and assume only basic scientific knowledge. The lay language summary should include a (i) basic introduction of the project, (ii) current research relating to the project, (iii) how research will be conducted, (iv) anticipated project milestones/accomplishments, and (v) future project research directions/next steps. Limit summaries to the space provided on Attachment II.

  - Applicants who are resubmitting a proposal that was previously submitted to the Regenerative Medicine Research Fund and did not receive financial assistance must provide an additional one (1) page “Introduction”, in which they explain how the current submission of the proposal was revised and how the scientific peer review concerns have been addressed.

**Note:** Because the Project Summary will be available to the public, do not include proprietary information in the Summary.

3. Table of Contents

Provide a listing of proposal contents with corresponding page numbers.

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 efforts by other investigators in the space. Describe the clinical implications of this research.

- **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 each of the 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 potential pitfalls and alternative strategies that may impact the success of the project. Assess the probability of success of this project.

  For projects involving several co-investigators and/or organizations, describe a leadership plan that addresses roles/areas of responsibility, fiscal and management coordination, process for making decisions on scientific direction and allocation of resources, data sharing and communication among investigators, publication and intellectual property policies, and dispute resolution.

5. Intellectual Property

Describe the strategy and timeline to protect the intellectual property. If intellectual property has already been filed, include appropriate references. Describe the future plans and timeline for commercializing and licensing the technology. As required by C.G.S. §§ 19a-32d through 19a-32g as amended by PA-14-98, 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 financial assistance.”
In evaluating proposed arrangements, it is expected that the State of Connecticut shall be entitled to a percentage of royalties from the awardees and certain of its affiliates, on revenues generated from the exploitation of any invention or intellectual property that is conceived, created, improved upon, or developed during the 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.

6. 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. References should include a full author list (do not use “et al.”), title, and journal publication information (journal, year, volume, and page numbers).

➢ Attachment III contains the following section(s):
7. Evidence of Commitment
Materials supporting the application which demonstrate commitment from any relevant collaborators or strategic partners on the proposal should be provided in this section.

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. Letters of commitment should be provided in Attachment V: Appendix.

b. Commitment of the Key People
Detail the contributions of key contributors to the project, including:
(i) a description of their qualifications;
(ii) details regarding the focus of each person’s efforts;
(iii) detail the percentage of effort each key person will allot to the project (see example table below). The percentage of effort reflects the amount of support each person will be dedicating to the project;
(iv) a description of the project management plan.

![Example Table]

<table>
<thead>
<tr>
<th>Year No.:</th>
<th>Contribution: Individual Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Senior Personnel (PI, Co-PI, Faculty and other Senior Associates)</td>
<td>% of total effort</td>
</tr>
<tr>
<td>1.</td>
<td>![ ]</td>
</tr>
<tr>
<td>2.</td>
<td>![ ]</td>
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<tr>
<td>3.</td>
<td>![ ]</td>
</tr>
<tr>
<td>4. Others (List Individually on Budget Justification Page)</td>
<td>![ ]</td>
</tr>
<tr>
<td>5. Total Senior Personnel</td>
<td>![ ]</td>
</tr>
<tr>
<td>B. Other Personnel</td>
<td>![ ]</td>
</tr>
<tr>
<td>1. Post-Doctoral Associates</td>
<td>![ ]</td>
</tr>
<tr>
<td>2. Other Professionals (Technician, Programmer)</td>
<td>![ ]</td>
</tr>
<tr>
<td>3. Graduate Students</td>
<td>![ ]</td>
</tr>
<tr>
<td>4. Other (specify)</td>
<td>![ ]</td>
</tr>
</tbody>
</table>

c. Commitment to Sharing Resources
The Regenerative Medicine Research Fund expects award recipients and their institutions, hospitals or companies to share reagents, data, and protocols developed in connection with these awards. In particular such resources shall be made freely available to other Connecticut-based investigators. 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-32g as amended by PA-14-98, 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.

f. Other Support and Potential Overlap
List all active, pending (including proposals for the current proposal cycle) and recently completed (completed in the past 3 years) grants/financial assistance and provide the following information: grant title, funding agency, your role, percent effort, total direct costs, funding period, and overall objectives. For active and pending grants, state whether scientific or budgetary overlap exists with the current application. If funding is recommended, the principal investigator will work with Connecticut Innovations and the Advisory Committee to eliminate overlap, typically by modification of the scope and budget of the current or competing grants.

8. Biographical Sketches
Submit a brief biographical sketch for key people (using the NIH biographical sketch format http://grants.nih.gov/grants/funding/phs398/biosketch.pdf including patents and selected publications (4 page maximum per person). For Seed Awards, provide a biographical sketch for the applicant and, if appropriate, for the faculty sponsor.

- Attachment IV contains the following section(s):

9. Budget
a. Budget Detail
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 IV. Companies should prepare the budget on a quarterly basis.

Salaries and Wages: List the names of the principal investigator and other senior associates and estimate the percentage of time each person is dedicated to the project for which funding is requested. Salaries requested must be consistent with the regular practices of the institution, hospital or company. Regenerative Medicine Research funds must not be used to augment the existing salaries of investigators. Funds must not be used to reimburse faculty members for consulting or other activities that are in addition to a regular full-time institutional salary. 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 Regenerative Medicine Research Fund wishes to avoid expensive duplication of research infrastructure wherever possible. Therefore, any budget requests for major equipment must be carefully justified.

Identify items exceeding $5,000 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. Up to $5,000 per year to travel to scientific conferences to present findings or to further the research may be requested. (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 and computer services. Other examples include payments for service charges, animal per diem, 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-award and subcontracts up to the first $25,000 of each sub-award or subcontract (regardless of the period covered by the sub-award or subcontract). MTDC shall exclude equipment, capital expenditures, charges for patient care, rental costs and the portion of each sub-award, or subcontract in excess of $25,000.

**b. Budget Explanation/Justification**
In a separate section titled “Budget Explanation/Justification,” clearly delineate the specific use and justification of funds; the breakdown 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 also comply with specific budget requirements in the Core Facilities Awards section and must include a description of a plan to attain future funding from sources other than the State of Connecticut.

10. Special Considerations
   **a. Conflict of Interest**
   List the name(s) of any reviewers with whom there is a conflict of interest and who should not be considered as reviewers. Include the names and affiliation; up to five (5) individuals may be listed.

   **b. Clearance Procedures**
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 hESC, 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 as amended by PA-14-98, must be provided to Connecticut Innovations via email submission to regenmed@ctinnovations.com on a form available at the following website link: www.bioinnovationct.com/regen/. Induced pluripotent stem cells (iPSC) require appropriate approval from the applying institution.

- Attachment V contains the following section(s):
  - 11. Appendix (Attachment V)
    Letters of commitment from the institution, hospital, or company and/or 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
Requests for award funding beyond that which has been approved is not allowed. However, reallocation of funding dollars – meaning movement of dollars from one budget category to another – is allowable under Fund guidelines. A reallocation of 10% 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 or senior personnel 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 personnel. 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 awardee 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.

Material Change in Scope of Project
A material change in the objective or scope of the project must be approved by the Regenerative Medicine 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 Annual Scientific Research Progress Reports in accordance with the Special Reporting Requirements in the assistance agreement to regenmed@ctinnovations.com. Reports shall:

- summarize the overall goal(s) of the project and project’s general activity;
- summarize scientific progress and achievements relative to each scheduled milestone within the reporting period;
- identify any significant scientific developments including intellectual property developed or produced;
- describe collaborative work, including cross-disciplinary teams at the same institution, new collaboration across different universities/organizations/states;
- describe any problems encountered;
- detail new assays, cell lines, therapeutics, and/or diagnostics developed
- include a list of new project publications (i.e. peer review articles, published papers and conference presentations), noting which are funded and/or supported in part by the award;
- describe additional research funds from other sources you were able to secure which were related to the project (including investment and grant dollars);
- detail new products/services developed
- detail new personnel towards the project (direct personnel on institutional/organizational payroll, including new hires and personnel retained; and indirect personnel, including engagement of vendors, service providers, etc.);
- include a detailed summary in lay language suitable for the public and press on a form provided by Connecticut Innovations. Lay summaries should include a basic introduction of the project, current research relating to the project, how research is conducted, project milestones/accomplishments achieved thus far, and future project research and next steps.

Institutions, hospitals and companies are required to submit Annual Fiscal Reports for each project.

REQUIRED REPORTING TEMPLATES WITH NECESSARY INFORMATION CAN BE FOUND ON THE REGENERATIVE MEDICINE RESEARCH FUND WEBSITE http://www.bioinnovationct.com/regen/, under the “Documents” tab.

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

Principal investigators are required to submit a Final Report within 30 days after the expiration of an assistance agreement in order to stay in good standing. Not submitting a report in a timely fashion could jeopardize the potential for future funding. 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 Regenerative Medicine Research Fund.

The Advisory Committee and/or their designees reserve the right to conduct site visits for funded projects.

Acknowledgment of Support and Disclaimer

Any submitted publication, whether in peer-reviewed journals, meeting abstract formats, 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: “Supported by the Connecticut Regenerative Medicine Research Fund.”

Documents as Public Records

All documents submitted to the Connecticut Regenerative Medicine Research Fund 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, select employees at the Connecticut Department of Public Health, the Regenerative Medicine Peer Review Committee, and to the Connecticut Regenerative Medicine 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 Regenerative Medicine Peer Review Committee, and to the Connecticut
Regenerative Medicine 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 in yellow highlighted text 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. The lay language summary is not to include proprietary information.

**Inventions, Software, and Copyrights**

The State of Connecticut encourages the publication and distribution of the results of the project performed under its funding. Connecticut Innovations retains the right to use published materials resulting from the performance of work under the Connecticut Regenerative Medicine Research Fund for state purposes. As required by C.G.S. §§ 19a-32d through 19a-32g as amended by PA-14-98, 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 regenerative medicine research made possible by the awarding of such financial assistance.”

**Legal Documentation**

Applications selected to receive funding will be required to execute appropriate legal documentation, including an Assistance Agreement and Royalty Agreement, as a condition of receipt of funding.
Attachment I- Connecticut Regenerative Medicine Research Proposal

Cover Page

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

Indicate type of award:  ☐ Seed  ☐ Established Investigator  ☐ Group Project  ☐ Core Facility

Title of Project:

Institution/Hospital/Company:

Principal Investigator Name (sponsor where applicable):

Signature(s): __________________________ Date:

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 financial assistance is awarded as a result of this application.

Principal Investigator Department/Mailing Address:

Principal Investigator Phone:

Principal Investigator 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 Regenerative Medicine Research Fund and all applicable laws and ethical standards if financial assistance 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:

Is this proposal a resubmission to the Connecticut Regenerative Medicine Research Fund?  ☐ Yes  ☐ No

Items included in Project (please check where appropriate):

☐ Proprietary and privileged information (identify such words/paragraphs on specific pages in yellow highlighted text)
☐ Recombinant DNA and/or hazardous reagents
☐ Human eggs, embryos, and/or human embryonic stem cells (hESC)
☐ Animal subjects
☐ Human subjects

How did you hear about the Connecticut Regenerative Medicine Research Fund?

☐ Submitted/received prior Stem Cell Research Grant or Regenerative Medicine Research Fund Award
☐ CI/Regenerative Medicine Website (www.ctinnovations.com/regenmed)
☐ Social Media (Please specify:  ☐ LinkedIn  ☐ Twitter  ☐ Facebook)
☐ Press
☐ Event
☐ University Contact; Tech Transfer Office
☐ Other; Specify ________________________________
Attachment II- Connecticut Regenerative Medicine Research Proposal

Included sections: Project Summary (in non-scientific language); Table of Contents; Project Description; Intellectual Property; Bibliography

Attachment II should be completed by the investigator of each participating institution, hospital, or company for the project. For projects with multiple investigators, each collaborating investigator should be detailed on the form. The Project Summary should be written in lay language suitable for the general public and the press; and include a basic introduction of the project, current research relating to the project, how research is conducted, project milestones/accomplishments achieved thus far, and future project research.

Title of Project:

Principal Investigator:

Institution/Hospital/Company:

Collaborator(s):

One sentence description: This project's purpose is to

Project Summary (please limit to this side of form):
Attachment III- Connecticut Regenerative Medicine Research Proposal

Included sections: Evidence of Commitment; Biographical Sketches

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

Title of Project:
Principal Investigator:
Institution/Hospital/Company:
Collaborator(s):
Details:
**Attachment IV- Connecticut Regenerative Medicine Research Proposal**

*Included sections: Budget; Special Considerations*

Attachment IV should be completed by the institution, hospital, or company.

<table>
<thead>
<tr>
<th>A. Senior Personnel (PI, Co-PI, Faculty and other Senior Associates)</th>
<th>Funding Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>4. Others (List individually on Budget Justification Page)</td>
<td></td>
</tr>
<tr>
<td>5. Total Senior Personnel (1-4)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B. Other Personnel (List individually on Budget Justification Page)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Post-Doctoral Associates</td>
<td></td>
</tr>
<tr>
<td>2. Other Professionals (Technician, Programmer)</td>
<td></td>
</tr>
<tr>
<td>3. Graduate Students</td>
<td></td>
</tr>
<tr>
<td>4. Other (specify)</td>
<td></td>
</tr>
</tbody>
</table>

**Total Salaries and Wages (A&B)**

<table>
<thead>
<tr>
<th>C. Fringe Benefits (If charged as direct costs)</th>
<th></th>
</tr>
</thead>
</table>

**Total Salaries, Wages, and Fringe Benefits (A,B,&C)**

<table>
<thead>
<tr>
<th>D. Permanent Equipment (Describe on Budget Justification page)</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>E. Other Direct Costs (Describe on Budget Justification Page)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs/ Page Charges</td>
<td></td>
</tr>
<tr>
<td>3. Computer Services</td>
<td></td>
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<tr>
<td>4. Other</td>
<td></td>
</tr>
</tbody>
</table>

**Total Other Direct Costs**

<table>
<thead>
<tr>
<th>F. Indirect Costs (Describe on Budget Justification Page)</th>
<th></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>G. TOTAL COSTS (A through F)</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>H. Projected Revenues</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>I. Total Contributions from Other Sources</th>
<th></th>
</tr>
</thead>
</table>
**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.

Description:
Attachment V- Connecticut Regenerative Medicine Research Proposal

Appendix - Attachment V should be completed by the institution, hospital, or company.

Additional materials in support of the application may be included in this section. Letters of commitment from the institution and collaborators (e.g., strategic partners) and other materials from Attachment III (Evidence of Commitment) may be provided in this section. Additional materials should be titled and made reference as to which section they apply to.

Title of Project:
Principal Investigator:
Institution/Hospital/Company:
Collaborator(s):
Details: