



# Center for Stem Cell & Regenerative Medicine

## REQUEST FOR PROPOSALS BRCP Stem Cell Pilot Project Funding FY2010

RFP Issue Date: October 30, 2009  
Proposal Due Date: November 23, 2009, 5:00 pm EST

### Summary

The Center for Stem Cell and Regenerative Medicine (CSCRM) is accepting proposals for funding of Stem Cell-related Pilot Projects (SCPP) for the period from February 1, 2010 – January 31, 2011.

### About CSCRM

The Center for Stem Cell and Regenerative Medicine (CSCRM) is composed of investigators from Case Western Reserve University (CWRU), University Hospitals Case Medical Center (UHCMC), Cleveland Clinic (CC), Athersys Inc, and Ohio State University. CSCRM's mission is to rapidly translate cutting-edge adult-derived stem cell technology into the clinic and commercial arenas. Currently ten different non-embryonic and two pluripotent stem cell types are being investigated in a range of therapeutic areas including cancer, musculoskeletal, orthopedic, cardiovascular, hematopoietic and neurodegenerative disorders. We encourage you to visit, as well as save to your favorites, our website, <http://www.thestemcellcenter.org>.

This innovative collaborative Center was created in 2003 with a \$19.4 million three year award from the Third Frontier Program for a combined Wright Center of Innovation and a Biomedical Research and Technology Transfer awards. In July 2006, CSCRM received an additional Biomedical Research and Commercialization Project (BRCP) award of \$8 million. Current funds for this program come from the April 2009 award from the Research Commercialization Program (RCP) of \$5 million which includes \$200,000 annual funding for pilot projects. **Over the next two years, this fund will provide three \$50,000 grants annually to promote new projects in stem cell research. The remaining \$50,000 per year will be divided equally and awarded to the technology transfer offices at CWRU, UHCMC and CC to accelerate promising technologies submitted to them and needing additional data.** In addition to providing seed money for new research ideas, priority will be given to projects that bring new researchers into the stem cell arena or provide funding to researchers not currently receiving CSCRM research support. Projects must have a clinical and/or commercial direction though it may be more rudimentary than for a fully developed project.

## Important Dates:

**October 30, 2009** Issue RFP for Stem Cell Pilot Project funding.

**November 23, 2009** Proposals due to CSCRM administration via email to [stemcellcenter@case.edu](mailto:stemcellcenter@case.edu).

**November 30, 2009** Screened, accepted proposals forwarded to the Review Committee for scoring on scientific and commercialization merit. (Each proposal will be assigned a primary reviewer and a secondary reviewer.)

**December 18, 2009** Executive Committee will announce awardees.

**February 1, 2010** Pilot projects funding to commence.

## Proposal Guidelines and Format:

This is an open and competitive process. Feedback from the Review Committee will be sent out to all applicants by February 1, 2010. (Refer to the section Proposal Format and Scoring Criteria as well as the CSCRM Review Committee Project Score Sheet.)

- Applicants must not have student or trainee status.
- Collaborators must submit only one proposal; "mirror proposals" from multiple institutions will not be considered.
- Proposals are due no later than **5 p.m. EST, Monday November 23, 2009**. Proposals received after this date and time will not be considered for funding.
- Individuals may submit multiple proposals, if desired. However, each proposal must be submitted separately and must match program criteria.
- Proposals may be submitted in hard copy form, if desired, but must be accompanied by an electronic copy (PDF). If desired, proposals may be sent via electronic mail to [stemcellcenter@case.edu](mailto:stemcellcenter@case.edu) with return receipt requested. Please note that attached files of more than 10MB may be delayed or returned by the email system.
- Proposals not conforming to submission guidelines will not be considered for funding.

## Format:

- Proposals must use type size no smaller than **10 point** and at least **1" margins**
- The document must be saved in a **PDF** titled as follows: **your last name (period) first word of title (excluding articles, i.e. JONES.STEM)**.
- Proposal will have a **maximum of 10 pages** not including the NIH Approved Biographical Sketch and will be ordered as follows:
  1. Title page.
  2. Up to 3 pages background and results to date.
  3. Up to 2 pages for program plan.
  4. Up to 2 pages commercial potential, plan and commercial progress to date.
  5. 1 page detailed budget using the attached Excel spreadsheet.
  6. 1 page budget narrative.
  7. NIH Approved Biographical Sketch.

## Proposal Format and Scoring Criteria:

The funding to be awarded in this program is underwritten by the **Third Frontier Project**

**of the State of Ohio Department of Development.** Its 10-year objectives with regard to this program are to:

- Build world-class research capacity.
- Support early stage capital formation and the development of new products.

As such, projects funded by this program must be based on solid science and innovation and must have an identifiable and measurable clinical or commercial goal. To this end, project proposals must include the following information:

**Program background, scientific rationale, results and progress to date (3 pages):**

Information should include prior data and results that support the scientific plan being proposed, clinical rationale and significance, potential clinical need and impact, and competing work to be considered. If this is a previously-funded CSCRM project, a discussion of results to date obtained with CSCRM funding **must** be included.

**Program Plan (2 pages):** What is the scope of the work to be completed during the grant period? Include a description of the model, methods, experimental design that is sufficient for a reviewer to make reasonable judgments regarding the quality and depth of the science and technology involved. What personnel and equipment resources or external services will be needed or leveraged? What are the expected outcomes of the work?

**Commercialization Potential, Plan and Progress to date (2 pages):** What is the roadmap to commercialization for this technology? Has a "Product" been defined? Have any Intellectual Property filings been completed or planned? Have Invention Disclosures been filed with the Technology Transfer Offices. What is the regulatory path for this technology? Detail any substantive interactions with commercial entities. **Academic and Institutional proposal submitters are encouraged to contact their Offices of Technology Transfer for help or guidance in formulating their proposals. Contact information is provided at the end of this RFP.**

**Budget (1-2 pages):** Using the attached Excel spreadsheet please provide a one page detailed budget, including personnel, supplies, non-capital equipment, and outside services, and a one page budget narrative to justify your expenses. Budgets must be kept to \$50,000 or less. Please note **there are indirect costs of 20%** associated with these awards that your institution will want to collect so your actual budget is \$40,000 in direct costs. For accounts being setup outside of CWRU, there is an additional charge of \$2,500 for account setup and management.

**Please send proposals to** [stemcellcenter@case.edu](mailto:stemcellcenter@case.edu) or US Mail to:

Debra Grega  
Executive Director  
Center for Stem Cell and Regenerative Medicine  
Wolstein Research Building 2-501 LC: 7284  
10900 Euclid Avenue  
Cleveland OH 44106

If you have questions about this request for proposals, please contact Michael Gilkey at 216-368-2079 or email to [michael.gilkey@case.edu](mailto:michael.gilkey@case.edu).

### **Scientific and Commercialization Scoring Criteria:**

Scoring of submitted pilot grants will be performed by the Review Committee. This committee will be chosen from active CSCRM members and commercial partners.

#### **Scientific Scoring (7 domains to be considered):**

**Soundness of Prior Research:** Is the proposed work based upon sound and well developed scientific principles? Are these principles clearly defined in the scientific plan? Has the investigator adequately considered and cited competing work?

**Soundness of Scientific Plan:** Is the experimental design and rationale for the work proposed clearly articulated? Will the proposed plan yield results that have significant potential to make a compelling statement about the overall value of the technology being developed?

**Clinical Significance:** Does this address a relevant clinical need? How effective are the current treatment options? What is the opportunity for this new technology to make a significant difference in either the standard of care, the total cost of care, or the patient experience? How many patients could be positively affected by this technology?

**Environment:** Is there adequate additional support through institutional resources, CSCRM or other collaborators, complementary projects and funding sources? Is the project team the right one to get the work done?

**Innovation:** Does the technology and approach represent a significant innovative step?

**Scope and Budget:** Is the budget of the proposal realistic? Will the contribution made by a CSCRM investment significantly accelerate the work and/or take it to a substantially higher level of value or fundability?

**Leverage of CSCRM, Ohio, or Regional Resources:** Does this project involve collaborations that take advantage of or advance regional capabilities?

*Enthusiasm for each of these criteria will be graded High, Average and Low by the Primary and Secondary reviewers.*

#### **Commercialization Scoring (7 domains to be considered):**

**Commercial ('Productization') Feasibility:** How likely is it that a commercial product can be developed from this technology? Is there a product configuration anticipated? Are there significant hurdles to overcome from a cost, production, or regulatory standpoint?

**Intellectual Property:** Are there existing disclosures, filings, issued patents or copyrights? Is it likely that the project will bear new patentable matter?

**Overall Market Impact:** What is the size of the market? Is this a new platform technology or an incremental improvement over existing products? If the project is successful, does it have the potential to capture significant market share?

**Regulatory Feasibility:** What is the projected regulatory pathway (510(k) approval vs. IDE)? What is the regulatory timeline and necessary pathway for safety and efficacy studies? How has the FDA handled products of this sort in the past? Is this a technology

approach that the FDA has not encountered before?

**Potential for Commercial Partnership:** Have potential partners been identified? Is there a relationship in place already?

**Time to Market:** How many years before this technology could be brought to market?

**“Disruptive index”:** To what extent will this technology create a fundamental shift in the market, versus simply creating an incremental improvement over existing technology? Will this development allow a dramatic market expansion or create access to a patient population that could not be served previously? Does it represent a dramatic cost reduction over current approaches?

*Enthusiasm for each of these criteria will be graded High, Average and Low by the Primary and Secondary reviewers.*

**Commercialization Assistance:**

CCF Innovations:

Neil Veloso  
Senior Commercialization Officer  
veloson@ccf.org  
216.444.0386

Michael Villalobos  
Senior Commercialization Officer  
villalm@ccf.org  
(216) 445-0812

CCF Innovations  
9500 Euclid Avenue, Mail Stop D20  
Cleveland OH 44195

Case Office of Technology Transfer:

Michael Haag  
Director of Technology Transfer - Biomedical Licensing  
Case Western Reserve University  
Technology Transfer Office  
10900 Euclid Avenue  
Sears Building – Sixth Floor  
Cleveland, Ohio  
44106-7219  
michael.haag@case.edu  
216.368.6106

### CSCRM Review Committee Project Score Sheet

Project:

PI:

	Primary Reviewer	Secondary Reviewer	Comments
<b>Scientific Scoring</b>			
Soundness of Prior Research			
Soundness of Scientific Plan			
Clinical Significance			
Environment			
Innovation			
Scope and Budget			
Leverage of CSCRM/Regional Resources			
Composite Score			
<b>Commercialization Scoring</b>			
Commercialization ('Productization') Feasibility			
Intellectual Property			
Overall Market Impact			
Regulatory Feasibility			
Potential for Commercial Partnership			
Time to market			
'Disruptive Index'			
<b>Composite Score</b>			

**Scale: High = 3, average = 2 and low = 1**

Reviewer Comments: