



NATIONAL CENTER FOR
REGENERATIVE MEDICINE

**REQUEST FOR PROPOSALS RCP
Stem Cell Pilot Project Funding 2012**

**RFP Issue Date: December 1, 2011
Proposal Due Date: December 21, 2011, 5:00 pm EST**

Summary

The National Center of Regenerative Medicine (NCRM) is accepting proposals for funding of Stem Cell-related Pilot Projects (SCPP) for the period from January 1, 2012 – April 27, 2012. This is a very short time so experiments must be planned out and begun as soon as possible.

About NCRM

The National Center of Regenerative Medicine (NCRM) 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. NCRM'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> and <http://www.ncrm.us>.

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, NCRM 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. Additional funds of up to \$20,000 from the Case Western Reserve University Clinical and Translational Science Collaborative (CTSC) for Core Utilization Pilot Awards will be added into this year's funds. **NCRM can provide two \$35,000 grants this year to promote new projects in stem cell research and an additional \$10,000 can be requested from the CTSC to use one of their approved facilities.** In addition to providing **seed money for new research ideas**, priority will be given to projects that involve multiple institutions, have robust experimental plans and when completed lead to additional funding opportunities. Projects must have a clinical and/or commercial direction though it may be more rudimentary.

Important Dates:

December 1, 2011 Issue RFP for Stem Cell Pilot Project funding.

December 21, 2011 Proposals due to NCRM administration via email to Michael Gilkey, meg14@case.edu.

December 22, 2011 Screened, accepted proposals forwarded to Executive Committee for scoring on scientific and commercialization merit.

December 28, 2011 Executive Committee will choose awardees and NCRM will announce awardees.

January 1, 2012 Pilot projects funding to commence. It may be necessary to begin experiments before accounts are set up so that no delays happen to the proposal.

Proposal Guidelines and Format:

This is an open and competitive process. Due to the short turnaround time required for funding limited feedback from the Executive Committee will be sent out to all applicants by February 1, 2012. (Refer to the section Proposal Format and Scoring Criteria as well as the NCRM 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, Wednesday December 21, 2011**. 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 must be submitted in electronic format using either Word or PDF files to Michael Gilkey, meg14@case.edu.
- 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 **Word or 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 and narrative.
 6. 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 NCRM project, a discussion of results to date obtained with NCRM 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): 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 \$35,000 or less. Please note **there are indirect costs of 20%** associated with these awards that your institution will want to collect so your actual direct budget is less. Of special consideration are CTSC Core Utilization funds of \$10,000 per pilot project. Projects can request \$10,000 to pay for CTSC approved core facility services. These dollars will not actually go to the awardee but will stay in the indicated core facility and indirect costs cannot be assessed on these funds.

Please send proposals and direct questions to michael.gilkey@case.edu or 216-368-2079.

Scientific and Commercialization Scoring Criteria:

Scoring of submitted pilot grants will be performed by the Executive Committee. This will be an expedited review but is based on current NIH criteria and each domain's weighting is shown out of a total of 100 points.

Scientific Scoring (5 domains to be considered):

Soundness of Scientific plan and Originality of the proposed Project: Is the proposed work based upon sound and well developed scientific principles? Is the experimental design and rational for the work proposed clearly articulated? Does the technology and approach represent a significant innovative step? (25 Points)

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? (25 Points)

Environment & Timeline: Is there adequate additional support through institutional resources, NCRM or other collaborators, complementary projects and funding sources? Is the project team the right one to get the work done? Does the applicant justify the ability to perform the proposed project within the time frame allotted? (25 points)

Scope and Budget: Is the budget of the proposal realistic? Will the contribution made by a NCRM investment significantly accelerate the work and/or take it to a substantially higher level of value or fundability? Are there additional funds that can match these funds? (15 points)

Leverage of NCRM, Ohio, or Regional Resources: Does this project involve collaborations that take advantage of or advance regional capabilities? (10 points)

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? (20 points)

Intellectual Property: Are there existing disclosures, filings, issued patents or copyrights? Is it likely that the project will bear new patentable matter? (10 points)

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? (15 points)

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? (15 points)

Potential for Commercial Partnership: Have potential partners been identified? Is there a relationship in place already? (20 points)

Time to Market: How many years before this technology could be brought to market? (10 points)

“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? (10 points)

Enthusiasm for each of these criteria will be graded by the reviewer based on the score guide below.

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses
Minor Weakness: An easily addressable weakness that does not substantially lessen impact		
Moderate Weakness: A weakness that lessens impact		
Major Weakness: A weakness that severely limits impact		

Commercialization Assistance:

CCF Innovations:

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NCRM Review Committee Project Score Sheet

Project:

PI:

	Reviewer Score	Comments
Scientific Scoring	(1-9)	
Soundness of Scientific plan and Originality of the project		
Clinical Significance		
Environment & Timeline		
Scope and Budget		
Leverage of NCRM/Regional Resources		
Scientific Composite Score		
Commercialization Scoring	(1-9)	
Commercialization ('Productization') Feasibility		
Intellectual Property		
Overall Market Impact		
Regulatory Feasibility		
Potential for Commercial Partnership		
Time to market		
'Disruptive Index'		
Commercial Composite Score		
Overall Composite Score		

Reviewer Comments: