

Stem Cell Research Project

2013 Request for Applications (RFA)

Issue Date:
March 5, 2013

Internal Due Date
March 15, 2013

Application Due Date:
April 16, 2013

Main Contact:
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Application Instructions for the 2013 Stem Cell Research Project

Description

In the 2008 legislative session, the Stem Cell Research Act (Neb.Rev.Stat. § 71-8801 et seq) was passed. This Act established the Stem Cell Research Advisory Committee. The Committee is responsible for developing a grant process and making grant awards to Nebraska institutions or researchers to conduct stem cell research that does not use human embryonic stem cells. The Act defines the types of research projects that are acceptable. The Act states that:

No state facilities, no state funds, fees, or charges, and no investment income on state funds shall be used to destroy human embryos for the purpose of research. In no case shall state facilities, state funds, fees, or charges, or investment income on state funds be used to create a human embryo by somatic cell nuclear transfer for any purpose.

For purposes of the Act, human embryo means the developing human organism from the time of fertilization until the end of the eighth week of gestation and includes an embryo or developing human organism created by somatic cell nuclear transfer; somatic cell nuclear transfer means a technique in which the nucleus of an oocyte is replaced with the nucleus of a somatic cell.

Eligibility

Grants will be awarded to Nebraska institutions or researchers as defined below:

- Sponsoring Institution. Proposals for funding may be submitted by an institution in Nebraska that has an ongoing, large-scale research program that is conducive to the completion of a complex project in stem cell research that does not use human embryonic stem cells (e.g., the University of Nebraska-Lincoln, Creighton University, the University of Nebraska Medical Center, and Boys Town's National Research Hospital).
- Principal Investigator. The leader of a project is the "principal investigator". Researchers with a doctoral degree in science (PhD or equivalent), or a professional degree in a medical field (MD, DMD, DVM, or similar), are eligible to submit a proposal to the Stem Cell Research Advisory Committee as a Principal Investigator (PI). The PI must be employed at an institution in Nebraska that meets the criteria for "Sponsoring Institution" (see above). Researchers that are classified as Post-doctorates or Fellows are not eligible.

Availability of Funds and Matching Requirements

The amount of money available for new grant awards is \$440,000. The maximum grant award is \$110,000 for one year. No single institution or researcher is eligible to receive more than 70 percent of the funds available for distribution.

Each Sponsoring Institution or researcher is responsible to provide a dollar-for-dollar match. The matching funds must be obtained from sources other than funds provided by the Stem Cell Research Act (e.g., principal investigator's salary provided by the sponsoring institution, other research grants from federal sources, stipends for students and post-doctorates).

Prior to Submission

- Each proposal must be vetted and approved by a local committee appointed by the Sponsoring Institution before it is accepted by the Stem Cell Research Advisory Committee for full review. The composition of the committee is at the discretion of the higher education institution.
- Approval of the application by the Sponsoring Institution should be based upon the degree to which the proposal appears to meet the selection criteria outlined below.

Submission

- Proposals that have been vetted and approved by the Sponsoring Institution are submitted via their Office of Sponsored Programs to the Division of Public Health of the Nebraska Department of Health and Human Services.
- Each Sponsoring Institution may submit a maximum of five (5) proposals in a given funding cycle.
- No Principal Investigator may hold more than a single award.

Application Format

Although there is no page limit for the total application, some sections have page limitations. Grant applications that exceed the specified page limits will not be reviewed. The application will consist of the following components:

1. Face Page: one page maximum
2. Table of Contents: one page maximum
3. Abstract and Specific Aims of the Project: maximum of 30 lines of text
4. Description of Key Personnel: two page maximum
5. Biographical Sketches: two page maximum per researcher (may use NIH 398 form)
6. Previous and Current Related Projects Funded: may use NIH 398 form
7. Research Plan Description: five page maximum
8. References: the citations should be single-spaced with no page limit
9. Budget and Budget Justification: the applicant may request a one year grant for up to \$110,000

Professional salaries for the Principal Investigator and doctoral level co-investigators as well as clerical or administrative assistance are NOT allowed. Allowable budget items include non-professional salaries (e.g., laboratory assistants, post-doctorates, and graduate assistants), equipment, travel, and other expenses such as consultant costs. There is a two page maximum on the budget justification.

Selection Criteria

- Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced?
- Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternatives?
- Innovation: Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- Principal Investigator: Is the PI appropriately trained and well suited to carry out this work? Is the work proposal appropriate to the experience level of the PI and other researchers (if any)?
- Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

Proposal Evaluations

- Proposals are evaluated by the Stem Cell Advisory Committee using the current NIH scoring system from 1 to 9 where the lowest scores indicate the highest level of merit (http://grants.nih.gov/grants/peer_review_process.htm). The Committee's recommendations are then forwarded for funding to Nebraska's Chief Medical Officer who will notify all applicants of their funding status.
- The Committee may seek outside expertise and assistance in providing the most knowledgeable and fair evaluations of the grant proposals.
- The Committee will provide the applicant with up to three strengths and weaknesses of their application.

Submission Instructions

1. The completed application must include all of the items listed on the checklist shown on page 7 of this document.
2. If any portion of the application is received after the due date and time, that portion of the application will not be reviewed.
3. The narrative sections must be typed on 8 ½" x 11" size pages that are single-spaced with one-inch margins and font no smaller than 12 point, such as Times New Roman or Tahoma (as in this document).
4. Do not exceed page limits identified on page 4 of this document and repeated on the checklist, page 7. The pages must be numbered consecutively from the face page to the last page of the application.
5. The applicant is required to submit the application electronically as a PDF or Word document no later than 4:00 pm on April 16, 2013 to both Dave Palm (david.palm@nebraska.gov) and Pat DeLancey (patti.delancey@nebraska.gov).

Timeline

March 5, 2013	Notice of availability of funds is distributed to the appropriate institutions
April 16, 2013	Deadline for submission of applications
Mid-June, 2013	Selection of awards

July 1, 2013

Grant period begins

Contact Person

RFA material requests or questions about the grant program should be directed to:

Dave Palm
Office of Community and Rural Health
Box 95026
Lincoln, NE 68509-5026
(402) 471-0146
david.palm@nebraska.gov

This RFA, including all templates, is also available in Microsoft Word/Excel format by contacting Pat DeLancey at (402) 471-2353 or patti.delancey@nebraska.gov

Notification

When the evaluation process is complete, the Chief Medical Officer of the Division of Public Health will notify all applicants about the funding status of their respective applications. By submitting an application, the applicant agrees to abide by the Terms and Assurances, Attachment A. A completed audit certification will be completed by the applicant and provided prior to an award being made. The start date for these grants will be July 1st of each year.

Checklist for the 2013 Stem Cell Research Project

Do not include this form in your application. It is for your use only to be sure you have included the required information in the required manner. The information must be in your application in the following order:

- ___ Face Page (page 9 of RFA)
- ___ Table of Contents: one page maximum (page 10 of RFA)
- ___ Abstract and Specific Aims of the Project: maximum of 30 lines of text (page 11 of RFA)
- ___ Description of Key Personnel: two page maximum (page 12 of RFA)
- ___ Biographical Sketches: two page maximum per researcher (may use NIH 398 form); (page 14 of RFA)
- ___ Previous and Current Related Projects Funded: may use NIH 398 form (page 15 of RFA)
- ___ Research Plan Description: five page maximum (page 16 of RFA)
- ___ References: single-spaced but no page limit (page 19 of RFA)
- ___ Budget (page 20 of RFA)
- ___ Budget Justification: two page maximum (page 23 of RFA)
- ___ Terms and Assurances (Attachment A)

Application due date is April 16, 2013.

Application and Instructions

The application and selected instructions are on the following pages. Applicants should use this format and follow all instructions.



Nebraska Department of Health and Human Services Stem Cell Research Grant Application Follow Instructions Carefully	Leave Blank for Department of Health and Human Services
1. Title of Project (Do not exceed 56 characters , including spaces and punctuation.)	
2. Principal Investigator Name (Last, first, middle)	2a. Degree(s)
2b. Position Title	2c. Mailing Address (Organization, street, city, state, zip) Organization: Street Address: City, State, Zip:
2d. Department, Service, Laboratory or Equivalent	
2e. Major Subdivision	
2f. PI Contact Numbers (Area code, number and extension) Telephone FAX E-mail Address	2g. <input type="checkbox"/> New Application <input type="checkbox"/> Revised Application (This application replaces a prior Unfunded version of the new competing application # _____).
3. Human Subjects If Yes, IRB approval or exemption date <input type="checkbox"/> No <input type="checkbox"/> Yes _____	4. Vertebrate Animals If Yes, Review Board approval date <input type="checkbox"/> No <input type="checkbox"/> Yes _____
5. Recombinant DNA If Yes, Review Board approval date <input type="checkbox"/> No <input type="checkbox"/> Yes _____	6. Proposed Project Period: July 1, 2013 – June 30, 2014 Total Direct Costs Requested:
7. Administrative official to be notified if award is made Name Title Address Telephone FAX E-mail Address	8. Name of Official Signing for Applicant Organization Name Title Address Telephone FAX E-mail Address
9. Principal Investigator/Program Director Assurance: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I agree to accept responsibility 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.	Signature of person named in 2. (In ink. "Per" signature not acceptable.) Date _____
10. Application Organization, Certification and Acceptance: I certify that the above statements herein are true, complete and accurate to the best of my knowledge and accept the obligation to comply with Department regulations and conditions if a grant is awarded as a result of this application.	Signature of person named in 8. (In ink. "Per" signature not acceptable.) Date _____

Principal Investigator/Program Director (Last, first, middle):

Table of Contents

Please number each page and indicate on table of contents

Section 1. General Information

Face Page.....	1
Table of Contents.....	2
Abstract and Specific Aims of the Project.....	3
Description of Key Personnel	4
Biographical Sketch: Principal Investigator and Others	6
Previous and Current Related Projects Funded	7
Research Plan Description	8
References	11
Detailed Budget for Proposed Project Period	12
Budget Justification	15

Number pages consecutively at the bottom throughout the application. Do not use suffixes such as 3a, 3b.

Principal Investigator/Program Director (Last, first, middle):

Abstract: List the application's specific aims, and make a clear statement of the project's relevancy to stem cell research. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. **There is a maximum of 30 lines of text.**

Instructions for the Description of Key Personnel Section

Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested. *The PI must be an independent investigator with an appropriate faculty appointment, adequately assigned laboratory space, and the ability to apply for federal grants as a PI.*

Junior applicants may apply if they provide a statement or letter from their Chairperson specifically confirming their faculty level appointment, the amount of independent research space available to them and that they are considered eligible to apply for federal grants as a PI.

Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel. For each individual, provide: name, organization, and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project, for example, principal investigator, graduate research assistance, etc. (two page maximum and use format on the next page).

Principal Investigator/Program Director (Last, first, middle):

Key Personnel. See specific instructions on previous page. Use another page as needed to provide the required information in the format shown below.

Name

Organization

Role on Project

Principal Investigator/Program Director (Last, first, middle):

Biographical Sketch			
Give the following information for the key personnel and consultants and collaborators. Begin with the principal Investigator/program director. Photocopy this page for each person.			
Name		Position Title	
Education (begin with baccalaureate or other initial professional education, such as nursing, and include post-doctoral training)			
Institution and Location	Degree	Year Conferred	Field of Study

Research and professional experience: Concluding with present position, list, in chronological order, previous employment, experience, and honors. List, in chronological order, the titles, all authors, and complete references of recent peer reviewed publications and to representative earlier publications **pertinent to this application only**. This section should not exceed one additional page. Applicants may use the NIH 398 form in place of this form.

Principal Investigator/Program Director (Last, first, middle):

Previous and Current Related Projects

Please list all active and pending extramural sources of funding, as well as previously funded projects from the past three years. For each project, list: (1) the project title; (2) budget amount and PI percent effort; (3) source and period of funding; and (4) project abstract including Specific Aims. Identify any potential overlap with the proposed research.

Specific Instructions for the Research Plan

The research plan should include sufficient information to facilitate an effective review. Be specific and informative and avoid redundancies. Reviewers often consider brevity and clarity in the presentation to be indicative of a principal investigator's focused approach to a research objective and ability to achieve the specific aims of the project.

Organize Sections A-D of the Research Plan to answer these questions: (A) What do you intend to do? (B) Why is the work important? (C) What has already been done? (D) How are you going to do the work? Do not exceed five pages, including all tables and graphs. **A five page absolute maximum will be strictly enforced. Applications that exceed this limit, or that exceed the type size limitations, will be returned without review.** You may use any page distribution within this overall limitation adhering to the following format:

- A. Specific Aims.** State the broad, long-term objectives and describe concisely and realistically what the specific research described in this application is intended to accomplish and any hypotheses to be tested.
- B. Background and Significance.** Briefly sketch the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps in which the project is intended to fill. State concisely the importance of the research described in this application by relating the specific aims to the broad, long-term objectives.
- C. Preliminary Studies.** Provide an account of the principal investigator's preliminary studies pertinent to the application and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.
- D. Research Design and Methods.** Outline the research design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Provide a tentative sequence or timetable for the investigation. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Gender and Minority Inclusion: Applications for grants that involve human subjects are required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions in which disproportionately affect them.

IRB, IACUC, and IBC Approval: If this proposal employs the use of human subjects or materials (IRB), use of Animals (IACUC) or use of recombinant DNA (IBC), the necessary approval(s) by the appropriate IRB, IACUC or IBC must be obtained prior to the actual expenditure of any awarded funds. IRB, IACUC and IBC applications should be submitted through campus approval channels in a timely way to allow "just-in-time" processing and funding of possible awards. No research employing human subjects, animal subjects or recombinant DNA may be initiated prior to full approval of related protocol applications."

Although no specific page limitation applies to the following sections (E-G) of the application, it is important to be succinct.

- E. Consultants/Collaborators.** Include biographical sketch pages for each consultant and collaborator and place them with those of the other participants on the project.
- F. Contractual Arrangements.** Provide a detailed explanation of the programmatic, fiscal, and administrative arrangements made between the applicant organization and the collaborating organizations and individuals. Attach confirming letters countersigned by an authorized official of the collaborating institutions and principal investigator or copies of written agreements.
- G. Literature Cited.** Do not scatter literature citations throughout the text. List them on a separate page at the end of the Research Plan. Each literature citation must include the title of the article, the names of all authors, the name of the book or journal, volume number, page numbers, and year of publication. Make every attempt to be judicious in compiling a relevant and current list of literature citations.

Principal Investigator/Program Director (Last, first, middle):

Research Plan

The research plan should describe specific aims, background and significance, preliminary studies, and research and design methods – five page maximum (see instructions on previous pages).

Principal Investigator/Program Director (Last, first, middle):

References

References should be single-spaced with no page limit.

Instructions for the Budget

Detailed Budget for Project Period. List only the direct costs requested in this application. Direct costs are those that can be identified specifically within a particular cost objective. **Indirect costs or overhead costs are unallowable.**

The budget sheet following these instructions must be completed for funding proposed for Year 2013. The budget justification has a two page limit.

Applications which fail to present itemized budgets and justification will be judged incomplete and will not be considered for funding.

Personnel: Personnel costs should include salaries, wages, and associated fringe benefits paid for services rendered to the research project. Personnel costs should be budgeted in relation to the amount of time and effort expected to be devoted to the project by each individual involved. Salary support for the Principal Investigator or other faculty will not be permitted on these grants. Personnel costs should be itemized by position title.

Percent of Effort on Project. Indicate the percent of each appointment at the applicant organization to be devoted to this project.

Institutional Base Salary. Institutional base salary is defined as the annual compensation that the applicant organization pays for the individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary **may not** be increased as a result of replacing institutional salary funds with grant funds.

Dollar Amount Requested

Salary Requested. Enter the dollar amounts for each position for which funds are requested. The maximum salary that may be requested is calculated by multiplying the individual's base salary, defined above, by the percent of effort on this project. Professional salaries for the Principal Investigator and doctoral level co-investigators as well as clerical or administrative assistance are NOT allowed. The applicant must designate the percent of FTE for the Principal Investigator and indicate any matching funds.

Fringe Benefits. Fringe benefits may be requested in accordance with the existing rate established by the applicant organization.

Totals. Calculate the totals for each position and enter the **subtotal** in each column where indicated.

Supplies. Supplies, both laboratory and office, that are expected to be consumed in the conduct of the project should be budgeted. Itemize supplies in separate categories such as glassware, chemicals, radioisotopes, office supplies, etc.

Travel. Travel expenses are allowable only when incurred for the purposes of collecting, receiving, or delivering samples. State the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested. **Travel expenses to attend national, international, professional research, or educational conferences are not allowed.**

Other

Consultant Costs. Whether or not costs are involved, provide the names and organizational affiliations of any consultants, including physicians in connection with patient care, who have agreed to serve in that capacity. Consultants are usually individuals organizationally separate from the Principal Investigator. Consultant fees are not allowed for full-time faculty or researchers in other departments of the same institution of the Principal Investigator. Briefly describe the services to be performed, including the number of days of consultation, the expected rate of compensation, travel, per diem, and other related costs.

Equipment. **No office equipment will be allowed.**

Other Expenses. Other expenses include postage, data processing, and other types of operating expenses not classified elsewhere in these instructions. These costs will only be allowable to the extent that they are incurred for the direct benefit of an approved grant (e.g., postage, copy and printing costs for forms, correspondence, and reports required or generated by an approved grant). **The cost of publishing the findings in a scientific journal will be allowed up to \$500.** Each item in this cost category must be identified with its associated costs. In general, telephone costs are not allowable except long distance calls required by the nature of the project. Indirect or overhead costs, such as rent and utilities, are not allowable.

Matching Funds. The law (Neb.Rev.Stat. § 71-8801 et seq) states that a dollar-for-dollar match must be provided by the institutions or researchers from sources other than the funds provided by the State of Nebraska for non-embryonic stem cell research. Federal funds can be considered as the match. In the line-item budget shown on page 22 of this RFA, there is a column for matching funds. If the matching funds are being supported by the institution and can not be shown in the specific line item categories, applicants should list the match under the total column and explain the sources of the match in the budget narrative. Of course, if the matching funds are included as line items, they should also be explained in the budget narrative.

Principal Investigator/Program Director (Last, first, middle):

Line-Item Budget

Line Item	Grant Funds Requested	Matching Funds: Cash	Total Project Cost
Personnel			
PI ___% FTE	\$0		
Laboratory Asst __% FTE			
Others/Specify			
SUBTOTAL			
Benefits			
SUBTOTAL			
Operating Expenses			
Supplies			
Other (specify)			
SUBTOTAL			
Travel			
(reimbursed at .565/mile)			
SUBTOTAL			
Other (specify)			
Equipment			
Consultants			
SUBTOTAL			
TOTAL			

Instructions for Budget Justification

Applicants must explain the budget in detail noting how estimated expenditures support the project aims. Describe the components of each line item and how the final figure was calculated. For example, explain the specific functions of the personnel and consultants. Also, justify the purchase of major equipment, usual supplies, and travel. The amounts in the budget justification total should equal the amounts in the line-item budget. There is a two page limit on the budget justification.

Principal Investigator/Program Director (Last, first, middle):

Budget Justification (two page limit)