NEW JERSEY COMMISSION ON SPINAL CORD RESEARCH



RESEARCH PROGRAM GUIDELINES

INTRODUCTION

Approximately 6,000 New Jersey residents suffer from traumatic injuries or diseases that damage the spinal cord. Approximately 300 new injuries occur each year. The economic consequences of the resulting physical disabilities are enormous. The personal toll on individuals and families with spinal cord injuries and their communities is incalculable.

Therefore, in September 1999, Governor Christine Todd Whitman signed legislation creating the New Jersey Commission on Spinal Cord Research (NJCSCR), allocating funding to the New Jersey Spinal Cord Research Fund.

The charge to the NJCSCR is:

The NJCSCR will solicit and approve support of research projects, administer the awards through research grants, and promote development of spinal cord research projects within the State of New Jersey that focus on treatments and cures. The NJCSCR will compile a research directory of all spinal cord research projects being conducted within the State and provide the Governor and the Legislature with an annual report by January 30th of each year describing the status of the NJCSCR's activities and the results of its funded research projects.

PROGRAM OBJECTIVES

The NJCSCR is committed to accelerating research to develop effective interventions and cures for paralysis and other consequences of spinal cord injury and disease. Its primary objectives are:

- To advance the field of spinal cord repair and regeneration and the New Jersey research community by encouraging established scientists to apply their expertise to the spinal cord.
- To facilitate the application of innovative ideas from other areas of science to the challenges of spinal cord injury repair.
- To foster collaborative, interdisciplinary approaches to spinal cord research.
- To nurture the next generation of spinal cord researchers through support of young scientists and postdoctoral fellows.
- To prevent or treat secondary biological conditions resulting from spinal cord injury.
- To promote dissemination of the research findings generated by those scientists supported by the NJCSCR.

NJCSCR awards are intended to promote innovative, groundbreaking research, not to provide long-term support. Grantees are eligible to apply for funding for additional research projects, but all applications will be reviewed competitively.

FUNDING PRIORITES

The New Jersey Commission on Spinal Cord Research will fund research activities that hold promise of developing effective interventions and cures for paralysis and other consequences of spinal cord injury and disease. The areas of research listed below highlight the focus of current NJCSCR emphasis and funding:

- Studying strategies to promote neuronal growth and survival, encourage the formation of synapses, enhance appropriate myelination, restore axonal conduction, replace injured cells, or otherwise improve function after spinal cord injury.
- Evaluating efficacy of drugs and other interventions that prevent or reduce secondary neuronal injury or providing insight into the mechanisms causing progressive damage.
- Defining anatomical characteristics of spinal cord injury or disease in well-defined animal models and in the human spinal cord, specifically documenting the cellular systems vulnerable to injury or disease and the functional losses which occur as a result thereof.
- Elucidating biological or physical mechanisms underlying approaches to improve functions compromised by spinal cord injury, e.g., bladder, bowel and sexual function, and alleviate chronic pain, spasticity, and severe hypertension.
- Developing strategies to prevent or treat secondary complications arising from injury or disease to the spinal cord.
- Developing innovative restorative rehabilitation strategies to promote recovery of biological function.
- Translating basic and pre-clinical findings into clinical application.
- Supporting the investigation of promising new approaches.

ELIGIBILITY

The following researchers are eligible to submit proposals to the NJCSCR for research grant awards. All applicants, organizations/institutions must be located within the State of New Jersey.

- Ph.D., M.D., or other such professionals.
- Independent investigators at any stage of professional development.
- Postdoctoral fellows, Graduate fellows.
- Established investigators new to the field of spinal cord injury research.
- Young Investigators (five years' post-completion of formal training)

Collaborations between basic research scientists and clinicians with spinal cord injury experience are encouraged. Young investigators are encouraged to partner with established investigators to nurture their scientific growth.

All applicants including Principal Investigators and organizations/institutions are encouraged to collaborate with other New Jersey-based researchers as well as with researchers located out-of-state, or out of the country.

Senior scientists, young investigators, postdoctoral and graduate fellows may serve as Principal Investigator. If the applicant is a fellow, he/she must submit a letter of support from the laboratory's senior scientist, as well as two other appropriate letters of reference.

PROTECTION OF HUMAN SUBJECT, ANIMAL WELFARE, AND RECOMBINANT DNA

Compliance with National Institutes of Health regulations for the protection of human subjects, animal welfare, recombinant DNA, and inclusion of women and minorities in clinical trials is required for all grants.

It is the responsibility of the <u>applicant as a potential recipient of a NJCSCR grant</u> to assure that the rights and welfare of all human subjects used in any NJCSCR sponsored research are protected. Any applications involving human subjects must be reviewed and approved by the appropriate institutional review board.

It is the responsibility of the <u>applicant as a potential recipient of a NJCSCR grant</u> to assure proper care and treatment of all laboratory animals used in any NJCSCR sponsored research. Any applications involving laboratory animals must be reviewed and approved by the appropriate institutional review committee.

It is the responsibility of the <u>applicant as a potential recipient of a NJCSCR grant</u> to assure that the physical and biological containment needed for research involving any recombinant DNA molecules is within policies set out in the current "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules." Any applications involving recombinant DNA molecules must be reviewed and approved by the appropriate institutional review board.

RESEARCH GRANTS AVAILABLE

The NJCSCR will offer three types of grant awards: Individual Research Grants, Exploratory Research Grants, and Postdoctoral and Graduate Fellowship Grants. All qualifying institutions in the State of New Jersey may apply. A Letter of Intent is not required.

Qualifying Institutions

For the purpose of all NJCSCR grants, a qualifying institution is defined as any academic institution, research organization, public or private institution or other entity, located in the State of New Jersey, with a demonstrated capability to conduct grant funded research, and specifically approved by the vote of the Commission, but in no case can an individual be a qualifying research institution.

The NJCSCR reserves the right to distribute funds among the grants in all its grant programs. The NJCSCR reserves the right not to fund any grant in any of its grant programs to the maximum amount, or not to fund any grant in any grant program at all. Estimated amount of

money available in the grant programs for all grant categories in the 2024 grant cycle is \$3 million. Funding estimates may vary and are subject to annual appropriations.

Individual Research Grant Awards:

The NJCSCR will fund research activities that hold the promise of developing effective interventions and cures for paralysis and other consequences of spinal cord injury disease. All qualifying institutions in the State of New Jersey may apply. Individual Research Grant awards will be awarded to independent investigators with a record of productivity, a demonstrated commitment to spinal cord research, and only for projects that will address significant questions that will advance knowledge in the field.

Maximum funding is up to \$200,000 per year including direct and indirect costs, (10% maximum for the latter). Applicants are encouraged to apply for a one-year, two-year, or three-year award.

The NJCSCR discourages salary for established investigators, unless justified by unusual circumstances.

The NJCSCR will allow the purchase of equipment without justification up to \$2,499. For all requests to purchase equipment valued at \$2,500 or above, you must provide detailed justification.

The NJCSCR will allow a maximum of \$1,000 for travel to a scientific meeting, to another lab to learn a new technique, etc.; details must be provided (travel by whom, to which meeting, or to which lab, and why).

The NJCSCR discourages funding for training unless a compelling justification is provided.

The goals of this program are (1) to encourage independent investigators to undertake research on spinal cord regeneration, recovery, and rehabilitation; (2) to encourage scientists who are well-established in other areas to transfer their efforts to spinal cord research; and (3) enable researchers with novel scientific and clinical ideas to test them and develop pilot data needed to seek larger awards from the National Institutes of Health, and other funding sources.

Successful applicants are offered the opportunity to participate in an approved spinal cord injury techniques course. The NJCSCR will make available up to \$5,000 for a grantee to attend a spinal cord injury techniques course. Grantees are responsible for making all necessary travel and course participation arrangements and payments. Reimbursements will be made to those who provide proof of course completion and expense receipts.

Principal investigators must be affiliated with a New Jersey State academic institution, research organization, public or private agency or other entity with demonstrated capability to conduct research responsibly. Senior scientists, young investigators, and postdoctoral fellows may serve as principal investigator. If the applicant is a fellow, s/he must submit a letter of support from the laboratory's senior scientist, as well as two other appropriate letters of reference. Unaffiliated individuals will not be funded. Individuals of any nationality or citizenship status may apply, provided they are employed by or affiliated with a qualified New Jersey State organization/institution.

Awards will begin on or about December 1, 2023. Three-year awards are made through one-year contracts. Each funding award within the three-year period will be contingent upon the

availability of funds. Second- and third-year support for all Individual Research Grants is contingent upon submission of a Progress Report. The Progress Report must be favorably reviewed by an independent scientific merit review panel and recommended to the NJCSCR for continued funding. A Final Narrative Report is required and must be submitted to the office within 60 days of termination of an Individual Research Grant. An Evaluation Form must be submitted to the NJSCSR office each year for two years following termination of an Individual Research Grant. All forms are available at www.state.nj.us/health/spinalcord.

Postdoctoral and Graduate Student Fellowship Grants Awards:

Postdoctoral Fellowships are three-year awards of \$50,000 per annum. They provide an annual stipend of \$36,000, a research allowance of \$13,000, and a travel budget of \$1,000. No part of the award may be used for institutional overhead or indirect costs. Institutions may supplement stipends, but not with other full-time fellowship awards, or other NJCSCR monies. Candidates of outstanding quality must hold a Ph.D., and/or M.D., or equivalent graduate degree. Appropriate degrees must be awarded prior to activation of award. Candidates must be accepted for postdoctoral training under the supervision of an appropriate mentor at a qualifying academic research institution in New Jersey. A candidate may not apply for a NJCSCR Postdoctoral Fellowship and a NJCSCR Individual Research grant in the same grant cycle. If a first-year fellow applies for and is awarded a NJCSCR Individual Research Grant, funding will be contingent upon cancellation of the second year of the fellowship. Non-research activities, such as teaching, may not occupy more than 10% of the fellow's time. Second and third year Postdoctoral Fellowship funding is contingent upon the availability of funds and upon the submission and successful review of a Progress Report and a recommendation from the mentor. The Progress Report must be favorably reviewed by an independent scientific merit review panel and recommended to the NJCSCR for continued funding.

Graduate Student Fellowships are two-year awards of \$30,000 per annum. They provide an annual stipend of \$25,000, a research allowance of \$4,000, and a travel budget of \$1,000. No part of this award may be used for institutional overhead, or indirect costs, or for tuition. Institutions may supplement stipends, but not with other full-time fellowship awards or other NJCSCR monies. Applicants must be full-time graduate students in residence in a proposed course of study directly related to regeneration and repair of the damaged spinal cord. Students must begin study in the semester following activation unless special permission is received prior to activation date. The NJCSCR prefers to support graduate student candidates who have completed the first year of graduate study and are concentrating on research projects at least 80% of their time. Applicants may serve as teaching assistants while holding a NJCSCR Graduate Student Fellowship without special permission. Second—year Graduate Student Fellowship funding is contingent upon the availability of funds and upon the submission and successful review of a Progress Report and a recommendation from the mentor. The Progress Report must be favorably reviewed by an independent scientific merit review panel and recommended to the NJCSCR for continued funding.

Postdoctoral and Graduate Student Fellowship awards will begin on or about December 1, 2023. Successful Postdoctoral and Graduate Student Fellowship applicants are also offered the opportunity to participate in an approved spinal cord injury techniques course. The NJCSCR will make available up to \$5,000 for a grantee to attend a spinal cord injury techniques course. Grantees are responsible for making all necessary travel and course participation arrangements and payments. Reimbursements will be made to those who provide proof of course completion and expense receipts.

A Final Narrative Report is required and must be submitted to the office within 60 days of termination of a Fellowship Research Grant. An Evaluation Form must be submitted to the NJSCSR office each year for two years following termination of a Fellowship Research Grant. All forms are available at www.state.nj.us/health/spinalcord.

Exploratory Research Grant Awards:

The purpose of the Exploratory Research Grant award is to enable independent investigators to apply their specific expertise to spinal cord research. The award is designed to provide the resources necessary to acquire preliminary data that will allow the successful applicant to obtain continued support from the NJCSCR, NIH, and/or other funding agencies. It is specifically intended to facilitate the application of innovative ideas from other areas of science to the challenges of spinal cord injury and repair.

In addition to scientific merit and relevance, consideration will be given to collaborative proposals that are inter-institutional and/or inter-state in nature. Priority will also be given to investigators outside the field who bring their expertise into spinal cord injury research. Successful applicants will have familiarized themselves with state-of-the-art knowledge necessary to put the proposed study into the appropriate spinal cord context.

In the field of spinal cord injury research, as elsewhere in the biomedical sciences, a constant infusion of new ideas, techniques, and points of view is essential to maintain its vitality, foster discovery and stimulate innovation. Inherent in the concept of innovation is the departure from current thinking or practice. Innovative projects are unlikely to be supported by substantial preliminary data, and for that and other reasons will necessarily be more speculative than conventional projects. These are high-risk, high reward projects that may lead to breakthroughs, the development of novel techniques, agents, methodologies, models or applications, or other insights that could have major impact on the field of spinal cord injury research.

The Exploratory Research Grant Program is intended to provide support for the early and conceptual stages of such investigations. Through the use of the Exploratory Research Grant Program, the NJCSCR will encourage the pursuit of novel scientific ideas, model systems, tools, agents, targets and technologies that have the potential to substantially advance spinal cord injury research and open new areas of inquiry.

Applications for Exploratory Research Grant awards should describe projects that are exploratory and novel and are clearly distinct from projects typically supported through more traditional mechanisms. These studies should break new ground or extend previous discoveries toward new directions or applications. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data.

Two-year non-renewable awards are offered to applicants at a maximum funding level of up to \$100,000 per year including direct and indirect costs, (10% maximum for the latter). All awards are made through one-year contracts.

The NJCSCR discourages salary for established investigators, unless justified by unusual circumstances.

The NJCSCR will allow the purchase of equipment without justification up to \$2,499. For all requests to purchase equipment valued at \$2,500 or above, you must provide detailed justification.

The NJCSCR will allow a maximum of \$1,000 for travel to a scientific meeting, to another lab to learn a new technique, etc.; details must be provided (travel by whom, to which meeting, or to which lab, and why).

The NJCSCR discourages funding for training unless a compelling justification is provided.

Each funding award within the two-year period will be contingent upon the availability of funds. Second year support for all Exploratory Research Grants is contingent upon the submission and successful review of a Progress Report. The Progress Report must be favorably reviewed by an independent scientific merit review panel and recommended to the NJCSCR for continued funding. Awards will begin on or about December 1, 2023. A Final Narrative Report is required and must be submitted to the office within 60 days of termination of an Exploratory Research Grant. An Evaluation Form must be submitted to the NJSCSR office each year for two years following termination of an Exploratory Research grant. All forms are available at www.state.nj.us/health/spinalcord.

REVIEW PROCESS

All research proposals will be reviewed for scientific merit, technical merit, research significance, and relevance to the NJCSCR priorities by an independent scientific merit review panel. The independent scientific merit review panel will forward its recommendations to the NJCSCR for final review and action. Scientists supported by the NJCSCR are expected to fully report the results of their research to the NJCSCR, and may be asked to report on their results, or work in progress, at a symposium organized by the NJCSCR. Grantees also are expected to acknowledge the support of the New Jersey Commission on Spinal Cord Research in all presentations and publications.

All grant applications must be submitted following the guidelines below. Grant applications that do not adhere to these guidelines will be returned to the applicant without further consideration. Grant applications sent by mail, fax or e-mail will NOT be accepted.

In our effort to reduce paper and speed the process by which grants are awarded, the NJCSCR utilizes an electronic grants submission and review process. All interested grant applicants must submit their applications online through the State of New Jersey System for Administering Grants Electronically (SAGE) hosting service.

Online applications for the NJCSCR will be made available for the preparation and submission of all grant applications. Forms for the various grant programs are available to applicants after they have started an online application. To start an application for a particular grant category, you will need to login as a new user at www.SAGE.NJ.GOV.

NJCSCR Research Program Guidelines governing grants, grant deadlines, progress reports, narrative reports, final narrative reports, and other additional information on the grant program can be viewed and downloaded from the NJCSCR web site at: www.state.nj.us/health/spinalcord

PROPOSAL SUBMISSION

For all grant categories, applicants must complete an online application. Online applications must be submitted via the SAGE system no later than 3:00PM, MAY 1, 2023. No grant applications will be accepted past this stated deadline. No exceptions will be made.

Policy on Post-Submission Materials

Post-submission materials are those submitted after submission of the grant application, but prior to Independent Scientific Merit Peer Review. They are not intended to correct oversights or errors discovered after submission of the application, but rather allow applicants the opportunity to respond to unforeseen events.

Allowable Post-Submission Materials

- -List of Publications
- -Citations of Issued Patents
- -Revised Budget Pages
- -New Funding
- -Adjustments Resulting from Natural Disasters
- -Biographical Sketches
- -Letters of Support or Collaboration
- -News of Professional Promotion or Positive Tenure Decision
- -News of the Addition or Removal of any Faculty Member Involved in a Training Program
- -News of a Change in Mentor or other Senior/Key Personnel
- -News of an Article Accepted for Publication
- -Other Information Deemed Appropriate and Necessary by the Commission Office

Deadline for Receipt of Post-Submission Materials

Post-submission materials must be received by the Commission Office no later than 30 calendar days after the grant application submission deadline. Post-submission materials will not be accepted after this time. Contact the Commission's Office directly for guidance related to deadlines and submission instruction. The Commission's Office is responsible for uploading acceptable post-submission materials into the grant application.

Certification and Statement Regarding Institutional Responsibilities

Upon acceptance of a grant award, the applicant's organization assumes legal and financial responsibility for awarded funds and the conduct of supported activities. It is the responsibility of the applicant's institution and Principal Investigator to assure the accuracy and validity of all fiscal, scientific, and administrative information pertaining to the awarded grant. Failure to comply with these terms may result in grant termination.

Grant awards are not intended to cover the total cost of research described in the grant proposal. The applicant organization is expected to take responsibility for adequate facilities and basic administrative services, and a salary for the Principal Investigator. The applicant organization must carefully review the Research Program Guidelines prior to submitting budget requests.

The NJCSCR does not support:

- Building construction, maintenance, or major alterations.
- Secretarial and telephone services.
- Library services including the purchasing and binding of books and periodicals.
- Dues for membership and registration fees in scientific societies or professional meetings.
- Recruiting and relocation expenses.
- Foreign Travel.
- Furniture for laboratories, office equipment & supplies, unless otherwise noted within the specific grant program.

GRANT REVIEW PROCESS

For all grant categories, the determination of grant awards will be made through a three-step review process:

1. Administrative Review (NJCSCR office):

Upon receipt, all grant applications will be reviewed by the NJCSCR office for compliance with all applicable New Jersey State statutes and regulations, and to ensure completeness, and accuracy. In the event a grant application needs correction due to a budgetary issue, the applicant will be contacted to provide a revised budget.

2. Independent Relevance Review (Appointed Panel):

Independent relevance review will be conducted by a three-person panel appointed by the NJCSCR; members will have varied expertise. The panel will determine the relevance of all applications to the NJCSCR Research Guidelines and assign scientific reviewers for each proposal.

The decision to forward an application for independent scientific merit review is based only on relevance to the NJCSCR mission, priorities, and research guidelines, and does not guarantee that an award will be made.

3. **Scientific Merit Review** (Independent Scientific Merit Review Panel):

Members of the independent scientific merit review panel will evaluate all grant applications, applying the criteria described below. This panel will assign scores to each application and make funding recommendations to the NJCSCR. If it is determined that *ad hoc* expertise is needed, additional scientific referees may be used.

The Independent Scientific Merit Review Panel will forward its recommendations to the NJCSCR for final review and action.

All grants triaged by either the Relevancy Review Panel and/or the Independent Scientific Merit Review Panel will not be submitted to the NJCSCR and will not be funded.

The authority to authorize or not authorize grants is fully vested in the NJCSCR according to New Jersey Statute N.J.S.A. 52:9E-1-10.

CRITERIA FOR INDEPENDENT SCIENTIFIC REVIEW

Grant applications will be judged on scientific and technical merit, relevance to the NJCSCR's mission and priorities, clinical relevance, and interdisciplinary collaborations. The independent scientific reviewers will perform two levels of review:

- 1. Each panel member will peer review his/her assigned proposals for scientific and technical merit and significance and determine an initial score for each proposal.
- 2. The panel will then convene for group discussion, final scoring, and ranking of all proposals; the panel will also recommend a cut-off point for funding.

The following topics will be addressed during the review process:

- Is the research proposal of significance to the field of spinal cord injury research?
- Is the proposed research innovative, including novel concepts, approaches, and/or methods?
- Is the research proposal relevant to NJCSCR priorities?
- Is the research proposal original in theory and application?
- Does prior research and theory provide a rational basis for the proposed research?
- Is the proposed project adequate in terms of experimental design and analyses, anticipation of potential problems, and consideration of alternative approaches?
- Does the researcher have access to appropriate facilities, equipment, expertise, and research environment either in-house and/or with collaborators or consultants?
- Does the design include interdisciplinary collaborations, and if so, is the proposed combination of disciplines both novel and likely to generate meaningful results?
- Are the qualifications, productivity, and time commitments of principal investigator and key staff commensurate with the proposed project?
- If a human model is proposed, is the availability of subjects adequate and system of education and protection of subjects appropriate?
- Is there evidence of compliance with National Institutes of Health regulations for the protection of animal welfare?
- Is the justification for procedures assessing the effects of interventions on recovery recognized, standardized, and generally accepted?
- Is the budget reasonable and justified for the project proposed? Is there evidence of institutional commitment and/or cost sharing in the proposal?

- Are there other factors both pro and con that may affect the ability of the applicant to successfully complete the research goals?
- Will the project make an original and important contribution to the field of spinal cord research and more specifically, to the mission of the NJCSCR?
- Special criteria have been developed to facilitate the review of Exploratory Research grants in light of their speculative nature.

RESULTS NOTIFICATION

All applicants including Principal Investigators and organizations/institutions will be formally notified of the outcome of his/her application at the conclusion of the selection process anticipated to be no later than November 30, 2023, unless otherwise noted within the grant program description. At that time, formal notification will be made to the institutions of successful applicants and contracts will be initiated shortly thereafter.

Blinded reviews will be provided to both funded and non-funded applicants, and to the mentors of post-doctoral and graduate student fellows; no further information shall be provided.

Non-funded applicants also will be notified. <u>There is no appeal process.</u> All non-funded applicants in any given grant cycle who are not funded are eligible to revise their applications based on reviewer feedback and reapply, one time only, through the reapplication process. All scored-but-not-funded applications may be resubmitted at the next application cycle.

Applications that are triaged may only be resubmitted once, at the next application cycle and only if the applicant has substantively responded to the major criticisms of the review panel. All reapplications will be reviewed as new competing proposals.

ANTICIPATED RESULTS

The goal of the NJCSCR is to assume a catalytic role in the worldwide movement to develop effective interventions and cures for paralysis and other consequences of spinal cord injury and disease.

Through the judicious use of funds raised through violations under Title 39 of the Revised Statute, or any other motor vehicle, or traffic violation in the State of New Jersey, the NJCSCR will encourage and support meritorious scientific research in the State of New Jersey in fulfillment of that goal.

This will benefit the State of New Jersey in savings on medical and support costs, enhance the development of the State's public and private biomedical sector, establish leadership in the field of spinal cord repair, and most importantly, help develop effective interventions for paralysis and other consequences of spinal cord injury and disease.