

January 15, 2016



Spinal Cord Injury and Traumatic Brain Injury Grant Program: July 1, 2015 -January 15, 2016 Report

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About the Minnesota Office of Higher Education

The Minnesota Office of Higher Education is a cabinet-level state agency providing students with financial aid programs and information to help them gain access to postsecondary education. The agency also serves as the state's clearinghouse for data, research and analysis on postsecondary enrollment, financial aid, finance and trends.

The Minnesota State Grant Program is the largest financial aid program administered by the Office of Higher Education, awarding up to \$180.6 million in need-based grants to Minnesota residents attending eligible colleges, universities and career schools in Minnesota. The agency oversees other state scholarship programs, tuition reciprocity programs, a student loan program, Minnesota's 529 College Savings Plan, licensing and early college awareness programs for youth.

Minnesota Office of Higher Education

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Introduction

The State of Minnesota established the Spinal Cord Injury and Traumatic Brain Injury Grant Program effective July 1, 2015. Minnesota 2015 Session Law, Chapter 69 directed the Commissioner of the Minnesota Office of Higher Education to establish a grant program for institutions in Minnesota for research into new and innovative treatments and rehabilitative efforts for the functional improvement of people with spinal cord and traumatic brain injuries. Research areas are to include, but are not limited to, pharmaceutical, medical device, brain stimulus and rehabilitative approaches and techniques. Appendix A provides a copy of the grant program's funding statute.

For the 2016/2017 biennium, \$500,000 was made available each year from the Omnibus Higher Education Bill to support the Spinal Cord Injury and Traumatic Brain Injury Grant program. As directed by the program's statute, the Commissioner of the Office of Higher Education, in consultation with the program's advisory council awarded 50 percent of the grant funds for research involving spinal cord injuries and 50 percent to research involving traumatic brain injuries.

Schedule for Proposal Solicitation and Proposals Received

To support research projects with fiscal year 2016 program funding, the following timeline was used to solicit proposals and award grant funds:

October 7, 2015 Request for Proposals available to applicants.

November 16, 2016 Deadline for receipt of intent to submit forms.

4:30 p.m., December 7, 2015 Deadline for receipt of proposals.

January 11, 2016 Notification of recommendation for grant award.

February 8, 2016 – June 30, 2017 Project funding interval.

A copy of the Request for Proposals for the Minnesota Spinal Cord Injury and Traumatic Brain Injury Research Grant Program is provided in Appendix B. Six proposals were received that requested funding as Spinal Cord Injury Research Grants. Listed below are the six proposals with budget requests totaling \$749,748.

Proposal #	Title and Applicant	Amount Requested
SCI-1	Regents of the University of Minnesota	•
	William Durfee, Professor	\$124,748
	Mobile Standing Wheelchair with FES Assist	•
SCI-2	Mayo Clinic	
	Tamara Vos-Draper	\$125,000
	Mobile Device for Self-Monitoring Of Seating Pressures for Wheelchair	
	Users with Spinal Cord Injuries	
SCI-3	Mayo Clinic	
	Mi-Hyeon Jang	\$125,000
	Identifying Molecular Targets for Promoting Functional Recovery	
	Following Spinal Cord Injury	
SCI-4	Courage Kenny Rehabilitation Institute, a part of Allina Health	
	Nancy A. Flinn, OTR/L, PhD	\$125,000
	Effectiveness of Neuromuscular Electrical Stimulation on	
	Upper Extremity Function in Individuals with Cervical Spinal Cord Injury	
SCI-5	Hennepin County Medical Center/University of Minnesota	
	David Darrow, MD MPH and Uzma Samadani, MD, PhD	\$125,000
	Epidural Stimulation for Spinal Cord Injury	
SCI-6	Regents of the University of Minnesota	
	Ann M. Parr, MD PhD	\$125,000
	Oligodendrocyte Progenitor Cells and Scar Ablation for the Treatment of	
	Chronic Spinal Cord Injury	
TOTAL AMO	UNT REQUESTED	\$749,748

Eleven proposals were received that requested funding as Traumatic Brain Injury Research Grants. Listed below are the eleven proposals with budget requests totaling \$1,323,462.

Proposal #	Title and Applicant	Amount
		Requested
TBI-1	Regents of the University of Minnesota	
	Henry Buchwald, MD, PhD	\$124,740
	Post-Concussion TBI Rehabilitation by a Physical Exercise Program	
	for Former NFL Players	
TBI-2	Regents of the University of Minnesota	
	Jessica Brown, PhD, CCC-SLP	\$115,556
	Visual Attention of Adults with Traumatic Brain Injury (VAATBI)	
TBI-3	Regents of the University of Minnesota	
	Dezhi Liao, Associate Professor	\$107,011
	Blocking Tau Mislocalization in Traumatic Brain Injuries	

TBI-4	Essentia Institute of Rural Health	
	Pat Conway, PhD, MSW	\$121,915
	Outcomes of People from Rural and Urban Settings Who Experience a	
	Traumatic Brain Injury and Participate in Rehabilitation	
TBI-5	Mayo Clinic	
	Thomas Bergquist	\$104,679
	Impact of Coping Skills Intervention for Patients with Acquired	
	Brain Injury and Their Caregivers	
TBI-6	Regents of the University of Minnesota	
	G.W. Gant Luxton, PhD	\$125,000
	Mechanotransduction and Blast-Induced Traumatic Brain Injury	
TBI-7	Hennepin County Medical Center	
	Sarah Rockswold, MD	\$125,000
	Neuroimaging and Neurovision Rehabilitation of Oculomotor	
	Dysfunction in Mild Traumatic Brain Injury	
TBI-8	Hennepin County Medical Center	
	Chad Richardson, MD	\$125,000
	Traumatic Brain Injury Classification and Outcome Assessment	
TBI-9	Regents of the University of Minnesota/Minneapolis VA Health Care	
	System	\$125,000
	Tasha Nienow, Assistant Professor	
	TDCS as an Adjunct to Cognitive Remediation for Patients	
	with Traumatic Brain Injury	
TBI-10	Regents of the University of Minnesota	
	Andrew W. Grande, MD	\$124,999
	Therapeutic Application of Non-hematopoietic Umbilical Cord	
	Blood Stem Cells (nh-UCBSCs) in Traumatic Brain Injury:	
	Immune Modulation with Acute and Long Term Benefits	
TBI-11	Regents of the University of Minnesota	
	Afshin A. Divani, PhD	\$124,562
	The Use of Tauroursodeoxycholic Acid for Treatment of	
	Blast-Induced Traumatic Brain Injury	
TOTAL AMO	UNT REQUESTED	\$1,323,462

Fiscal Year 2016 Spinal Cord Injury and Traumatic Brain Injury Research Projects

Pursuant to the language of the statute establishing the research grant program, members of the Spinal Cord and Traumatic Brain Injury Advisory Council reviewed research proposals and recommended proposals for funding to the Commissioner. The Proposal Review Form used by Advisory Council members is found in Attachment C. The four fiscal year 2016 projects recommended and funded were:

Project Title: Epidural Stimulation for Spinal Cord Injury

Principal Investigators: David Darrow, MD MPH, Uzma Samadani, MD, PhD

Institutional Affiliation: Hennepin County Medical Center/University of Minnesota

Grant Award: \$125,000

Project Purpose: Preliminary studies have demonstrated epidural spinal cord stimulation as a method for recovering volitional movement and the ability to stand in patients with paraplegia. While very few patients have undergone implantation of an epidural spinal cord stimulator for spinal cord injury (SCI), the results are a promising frontier for a disabling injury. This project is a collaboration between Hennepin County Medical Center and the University of Minnesota. The project aims to expand the number of patients studied by enrolling patients at Hennepin County Medical Center in order to further prove its utility while investigating optimal stimulation parameters to afford volitional movement. In order to better facilitate home rehabilitation with epidural spinal cord stimulation, the project will utilize a novel and innovative wireless accelerometer system to provide real-time feedback to patients undergoing home volitional movement training. This method uniquely facilitates the necessary audiovisual feedback needed for patients with higher cervical injuries and provides the data needed to understand plasticity of the response to stimulation and aid in epidural stimulation parameter space optimization. In addition, the project will utilize a hybrid approach for searching the parameter space of epidural stimulation settings in order to create a Clinical Decision Support System tool for future clinicians prescribing this treatment.

Project Title: Oligodendrocyte Progenitor Cells and Scar Ablation for the Treatment of Chronic Spinal

Cord Injury

Principal Investigator: Ann M. Parr, MD, PhD **Institutional Affiliation:** University of Minnesota

Grant Award: \$125,000

Project Purpose: This project focuses on the critical need for new treatment paradigms for patients with chronic spinal cord injuries. One major barrier to regeneration after SCI is the formation of the glial scar. This project will use a novel method for neatly ablating glial scar tissue in chronic SCI which, in combination with other therapies, shows significant promise in improving locomotor outcomes in individuals with previously untreatable, chronic SCI. The research team has successfully removed existing glial scars in chronically contused rat spinal cords using a rose Bengal-based phototoxic approach. This represents the most promising novel therapeutic approach to scar ablation in the central nervous system for chronic SCI. With a focus on translation to the clinic, proposed methods are compatible with cGMP manufacturing processes to enable seamless clinical translation of the research. This innovative project could provide pre-clinical data for an application to the FDA for a Phase I clinical trial.

Project Title: Neuroimaging and Neurovision Rehabilitation of Oculomotor Dysfunction in Mild

Traumatic Brain Injury

Principal Investigator: Sarah Rockswold, MD

Institutional Affiliation: Hennepin County Medical Center

Grant Award: \$125,000

Project Purpose: Too may trials in traumatic brain injury (TBI) have only studied the structural pathology following injury rather than treatment effects. This project seeks to find the anatomical/physiologic substrate in the brain and the effectiveness of neurovision rehabilitation (NVR) for persistent oculomotor dysfunction (OMD) which creates such major difficulty for a significant segment of the mild traumatic brain injury (mTBI) population. mTBI is a significant cause of disability, especially when symptoms become chronic. In Hennepin County Medical Center's experience, this chronicity is often linked to OMD. OMD will continue until properly identified and treated, especially with neurovision rehabilitation. Because of controversy in the ophthalmology community regarding the effectiveness of NVR, it is inconsistently performed. In addition, the exact neurostructural and biological changes resulting in OMD following mTBI is unknown. Pilot study data which compares mTBI patients with OMD to mTBI patients without vision difficulty are promising as there is already significantly reduced activation on task fMRI in the OMD group despite the small sample size. The combined approach of this study using state-of-the-art imaging and a robust clinical model of post-traumatic OMD, with successful NVR intervention, will provide the basis for establishing biomarkers in TBI.

Project Title: Traumatic Brain Injury Classification and Outcome Assessment

Principal Investigator: Chad Richardson, MD

Institutional Affiliation: Hennepin County Medical Center

Grant Award: \$125,000

Project Purpose: This research seeks to create an objective, multimodal classification scheme and outcome assessment for TBI based on radiographic measures, eye tracking, and blood-based proteomic and genomic analysis. The study's hypothesis is that eye-tracking and serum markers will be able to serve as objective classifiers and outcome measures for TBI. Assessment of brain injured patients at the time of injury with Glasgow Coma Scale Score and other standardized measures fails to capture the extent and heterogeneity of underlying pathology. Clinical trials for brain injury relying on these inaccurate and nonspecific assessments thus contain highly heterogeneous experimental groups and subsequently fail to demonstrate treatment effects. Compounding the problem is a lack of objective outcome measures that account for the intrinsic variability of a diverse population and subtle improvements in function. Eye tracking and analysis of blood-based biomarkers are both promising as more specific and objective measures of classifying TBI and assessing outcome, yet still require validation. This study will establish a new diagnostic classification scheme and enable outcome measures that will dramatically improve the success of future clinical trials.

Additional Funds for Grant Program Purposes

The statute language allows the Commissioner of the Office of Higher Education to accept additional funds from private and public sources for the purposes of issuing grants for the research programs. On January 7, 2016, the Get Up Stand Up to Cure Paralysis Foundation (GUSU) donated \$15,000 to the Minnesota Spinal Cord and Traumatic Brain Injury Research Grant Program. This donation was made to benefit research for spinal cord injury for functional recovery in the State of Minnesota exclusively. As GUSU intended, this donation will be added to the grant funds made available for the next cycle of awards for spinal cord injury research grants.

Grant Selection Process

The 2015 statute language establishing the grant program also established the Spinal Cord and Traumatic Brain Injury Advisory Council. The Commissioner in consultation with the Advisory Council has the responsibility for awarding the SCI/TBI research grants. Working through the Open Appointments process of the Minnesota Secretary of State's office, the 12 members of the Advisory Council were appointed by September 1, 2015, and the first meeting was held on September 29, 2015. Dr. Walter Low, Professor, Associate Head for Research and Director of the Research Laboratories in the Department of Neurosurgery at the University of Minnesota, serves as chair of the Minnesota Spinal Cord and Traumatic Brain Injury Advisory Council. The full membership of the Advisory Council is shown below:

Member	Representing				
Dr. Walter Low	University of Minnesota Medical School				
Dr. Isobel Scarisbrick	Mayo Medical School				
Dr. Mary Radomski	Courage Kenny Rehabilitation Center				
Dr. Sarah Rockswold	Hennepin County Medical Center				
Dr. Ann Parr	Neurosurgeon				
Mr. Robert Wudlick	Spinal cord injury				
Mr. Matthew Rodreick	Family member of a person with a spinal cord injury				
Ms. Kristina Nozal	Traumatic brain injury				
Mr. Stephen Thell	Veteran who has a spinal cord injury or a traumatic brain injury				

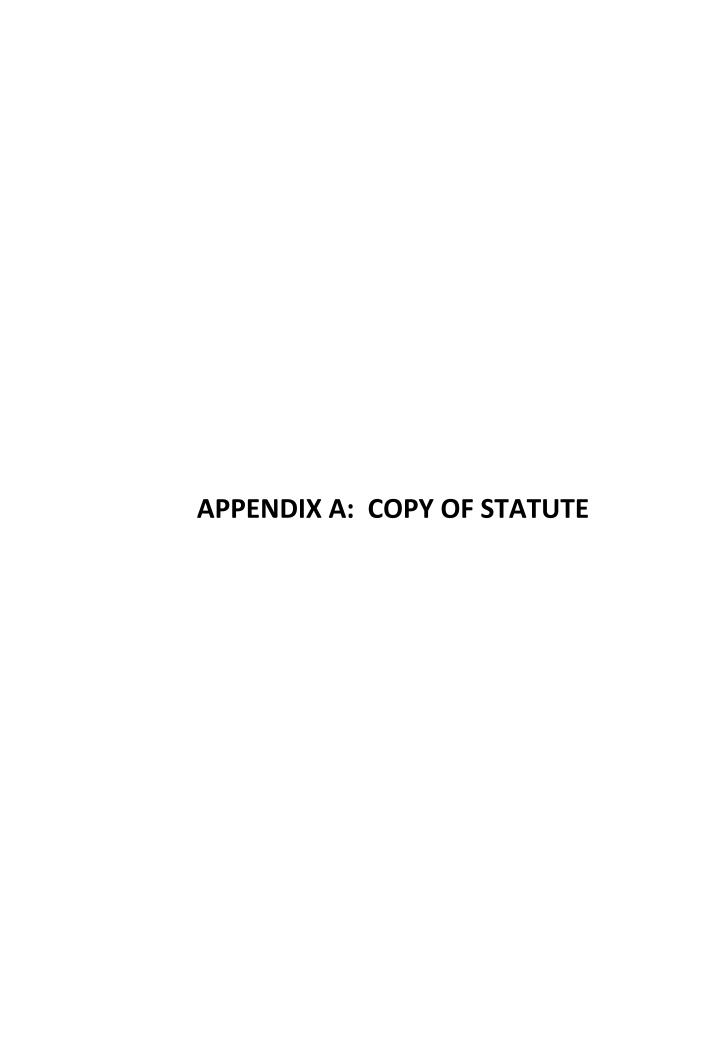
Ms. Susan McGuigan	Family member of a person with a traumatic brain injury
Dr. Mark Gormley	Physician specializing in the treatment of spinal cord injury representing Gillette Children's Specialty Healthcare
Dr. Uzma Samadani	Physician specializing in the treatment of traumatic brain injury

A second meeting was held on January 7, 2016, and the council members completed their reviews of the 17 submitted research proposals and recommended four proposals for funding as FY 2016 research grant proposals.

To complete this tasks, a review panel of Advisory Council members was established for each specialty area (Traumatic Brain Injury and Spinal Cord Injury). Each proposal was reviewed and scored by four review panel members. For the review, Advisory Council members with a scientific background gave particular attention to the scientific and technical merit of the proposal and Advisory Council members with patient or community perspectives gave particular attention to the importance of the proposed research for patients. Proposals were scored individually and discussed during the January 7 meeting. Advisory Council members were required to disclose any conflict of interest with any submitted proposals. If conflict of interest was present, the Advisory Council member did not review the proposal and was excluded from the room when the proposal was discussed.

Project Timeline and Anticipated Outcomes

The project directors for Fiscal Year 2016 projects have a time period of February 8, 2016 or the grant execution date through June 30, 2017 for conducting their research project. Advisory Council members anticipate that through the innovations cited in the recommended research projects, and collaboration with other nationally known researchers, the novel outcomes from the funded projects should lead to advances in the fields of spinal cord injury and traumatic brain injury.



LAWS OF MINNESOTA 2015

Ch. 69, art. 3

Sec. 13. [136A.901] SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM.

Subdivision 1. **Grant program.** The commissioner shall establish a grant program to award grants to institutions in Minnesota for research into spinal cord injuries and traumatic brain injuries. Grants shall be awarded to conduct research into new and innovative treatments and rehabilitative efforts for the functional improvement of people with spinal cord and traumatic brain injuries. Research topics may include, but are not limited to, pharmaceutical, medical device, brain stimulus, and rehabilitative approaches and techniques. The commissioner, in consultation with the advisory council established under section 136A.902, shall award 50 percent of the grant funds for research involving spinal cord injuries and 50 percent to research involving traumatic brain injuries. In addition to the amounts appropriated by law, the commissioner may accept additional funds from private and public sources. Amounts received from these sources are appropriated to the commissioner for the purposes of issuing grants under this section.

Subd. 2. **Report.** By January 15, 2016, and each January 15 thereafter, the commissioner shall submit a report to the chairs and ranking minority members of the senate and house of representatives committees having jurisdiction over the Office of Higher Education, specifying the institutions receiving grants under this section and the purposes for which the grant funds were used.

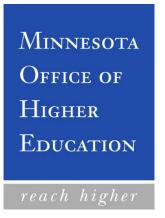
Sec. 14. [136A.902] SPINAL CORD AND TRAUMATIC BRAIN INJURY ADVISORY COUNCIL.

Subdivision 1. Membership. The commissioner shall appoint a 12-member advisory council consisting of:

- (1) one member representing the University of Minnesota Medical School;
- (2) one member representing the Mayo Medical School;
- (3) one member representing the Courage Kenney Rehabilitation Center;
- (4) one member representing Hennepin County Medical Center;
- (5) one member who is a neurosurgeon;
- (6) one member who has a spinal cord injury;
- (7) one member who is a family member of a person with a spinal cord injury;
- (8) one member who has a traumatic brain injury;
- (9) one member who is a veteran who has a spinal cord injury or a traumatic brain injury;
- (10) one member who is a family member of a person with a traumatic brain injury;
- (11) one member who is a physician specializing in the treatment of spinal cord injury representing Gillette Children's Specialty Healthcare; and
 - (12) one member who is a physician specializing in the treatment of traumatic brain injury.
- Subd. 2. **Organization.** The advisory council shall be organized and administered under section 15.059, except that subdivision 2 shall not apply. Except as provided in subdivision 4, the commissioner shall appoint council members to two-year terms and appoint one member as chair. The advisory council does not expire.
- Subd. 3. **First appointments and first meeting.** The commissioner shall appoint the first members of the council by September 1, 2015. The chair shall convene the first meeting by November 1, 2015.
- <u>Subd. 4. **Terms of initial council members.** The commissioner shall designate six of the initial council members to serve one-year terms and six to serve two-year terms.</u>
- Subd. 5. Conflict of interest. Council members must disclose in a written statement any financial interest in any organization that the council recommends to receive a grant. The written statement must accompany the grant recommendations and must explain the nature of the conflict. The council is not subject to policies developed by the commissioner of administration under section 16B.98.
 - Subd. 6. **Duties.** The advisory council shall:
 - (1) develop criteria for evaluating and awarding the research grants under section 136A.901;
- (2) review research proposals and make recommendations by January 15 of each year to the commissioner for purposes of awarding grants under section 136A.901; and
 - (3) perform other duties as authorized by the commissioner.

APPENDIX B:	COPY OF REQUEST	FOR PROPOSALS

OFFICE OF HIGHER EDUCATON 1450 Energy Park Drive, Suite 350 St. Paul, MN 55108 651-642-0567 or 1-800-657-3866



REQUEST FOR PROPOSALS FOR THE MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

Laws of Minnesota 2015, Chapter 69, Article X, Section 13

DEADLINES

Intent to Submit Form – November 16, 2015 Grant Proposal – December 7, 2015

PROJECT PERIOD:

Alternative Format

Upon request, the Request for Proposals can be made available in an alternative format by contacting Nancy B. Walters, Ph.D., Office of Higher Education, 1450 Energy Park Drive, Suite 350, St. Paul, MN 55108, phone (651) 259-3907, fax (651) 642-0675. TTY users should contact the Minnesota Relay Service at 1-800-627-3529 and request assistance in contacting the Office of Higher Education.

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM TABLE OF CONTENTS

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REQUEST FOR PROPOSALS UNDER MINNESOTA 2015 SESSION LAW SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

October 2015 Minnesota Office of Higher Education

I. <u>OVERVIEW</u>

The state of Minnesota established the Spinal Cord Injury and Traumatic Brain Injury Grant Program effective July 1, 2015. Minnesota 2015 Session Law, Chapter 69 directed the Commissioner of the Minnesota Office of Higher Education to establish a grant program for institutions in Minnesota for research into new and innovative treatments and rehabilitative efforts for the functional improvement of people with spinal cord and traumatic brain injuries. Research areas may include, but are not limited to, pharmaceutical, medical device, brain stimulus, and rehabilitative approaches and techniques.

For the 2016/2017 biennium \$500,000 is available each year from the Omnibus Higher Education Bill to support the Spinal Cord Injury and Traumatic Brain Injury Grant Program. The Commissioner of the Office of Higher Education, in consultation with the program's advisory council shall award 50 percent of the grant funds for research involving spinal cord injuries and 50 percent to research involving traumatic brain injuries. See Appendix A for a description of the grant program and advisory council membership and duties.

The overall objective of this program is to foster and encourage innovative research for treatment and rehabilitative techniques for spinal cord and traumatic brain injuries. Funding support for research innovations may reflect an early investment as a researcher prepares to seek a larger grant award from a federal program or nonprofit organization. Therefore, preliminary data is not required but encouraged.

Because the nature and scope of the research proposed may vary, it is anticipated that the size of each award may vary, as well. Awards pursuant to this request are contingent upon the availability of funds and the receipt of meritorious proposals. As a small grant program, proposals will be funded up to a maximum total request of \$125,000 per grant period, which includes indirect costs set at 8% of total direct costs.

II. ELIGIBLE GRANT APPLICANTS

Eligible grant applicants must be lead institutions/organizations located within Minnesota and fall into one or more of the following categories: public/state controlled institution of higher education; private institution of higher education; nonprofit with 501(c)(3) IRS status (other than institution of higher education); nonprofit without 501(c)(3) IRS status (other than institution of higher education); small business; and for-profit organization (other than small business).

Eligible principal investigators must have the skills, knowledge, and resources necessary to carry out the proposed research. This program is not for postdoctoral fellowships, therefore postdoctoral fellows will not be considered as principal investigators. Collaborations are encouraged with Minnesota-based researchers as well as researchers located outside the state of Minnesota.

III. RESTRICTIONS

Successful proposals will be relative to the topic of spinal cord and brain injury and have high scientific merit.

The initial grant award period for this program is 17 months. Subsequent grant award periods will be for 12 months covering July through June of the State's fiscal year. Grant funds may be carried over from the first fiscal year of the biennium to the second fiscal year. The opportunity to carry funds over from one biennium to the next is being investigated.

The principal investigator must be affiliated with a Minnesota-based research institution/organization.

IV. PROPOSAL SUBMISSION

Proposals must be submitted by **Monday, December 7, 2015 at 4:30 pm.** There is no limit on the number of proposals that an eligible applicant may submit.

Applicants **are required** to use the format that follows. The proposal must be self-contained within specified page limitations. Internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. For the application, the following areas must be identified and addressed in the order shown.

- 1. Proposal Cover Sheet as the first page of the document. Use Appendix B.
- 2. Principal Investigator/Institutional Assurance Form. Use Appendix C.
- 3. Program Abstract summarizing the focus, delivery, and desired outcome of the proposed research. Use Appendix D.
- 4. Table of Contents with pagination.
- 5. Research Plan not to exceed (10) numbered, double-spaced pages using 12-point Times Roman font. Do not double space charts, tables, or graphs. This page limit excludes the documents reference in numbers 1-4 and numbers 6-11.

The Research Plan should address the project period and funding requested, show the scope of the overall project and justify how the proposed research will provide new or innovative treatments and rehabilitative efforts for functional improvement of people with spinal cord and traumatic brain injuries.

The Research Plan narrative should be structured in accordance with the following format:

Introduction: State the overall objective or goal of the proposed research. Review the most significant previous work and describe the current status of research in the field. Document with references. Describe any preliminary work the principal investigator/collaborator has done which lead to this proposal.

Specific Aims: List the specific aims.

Procedural Methods: Give details of the research plan, including a description of the experiments or other work proposed; the methods; species of animals, techniques to be used; the kinds of data expected to be obtained; and the means by which the data will be analyzed or interpreted. If clinical studies are involved, give details of responsibility for patient selection and patient care. Include a discussion of pitfalls that might be encountered, and of the limitations of the procedures proposed. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. Describe the principal experiments or observations in the sequence in which they will be conducted, and indicate a tentative schedule of the main steps of the investigation.

Significance: Describe how the proposed project addresses a critical barrier to progress in the field. Discuss any new and innovative ideas and contributions that the project offers. Make clear the potential importance of the proposed project for stimulating further research or attracting federal grant support.

Facilities Available: Describe the facilities available for this project including laboratories, clinical resources, office space, animal quarters, etc. List major items of equipment available for proposed work.

Collaborative Arrangements: If the proposed project requires collaboration with other investigators, describe the collaboration and provide evidence to assure the reviewers that the other collaborators agree (letters of support in the appendix).

- 6. Reference page citing research-based references that support proposed activities.
- 7. Budget and Budget Justification Pages. On the budget page list the direct costs for all budget categories. Supplies and other costs must relate directly to performance of the projects. Indirect costs cannot exceed 8% of total direct costs. All costs must be specifically justified on the one page budget justification form. Use Appendix E.
- 8. Senior/Key Personnel Report. Provide required information for senior/key personnel. Use Appendix F.
- 9. Biographical Sketch of Principal Investigator and Senior/Key Personnel including his/her bibliographies; 4-page maximum for each individual. Use format of Appendix G.
- 10. Other Grant Support for Principal Investigator and Senior/Key Personnel. Indicate current support relevant to the proposed project; 3-page maximum for each individual. Use format of Appendix H.
- 11. Additional Appendices are allowed and may contain such items as letters of agreement from collaborators, letters of support, additional scientific materials, etc. **Do not** include the applicant institution's public relations or promotional materials.
- 12. Intent to Submit Proposal Form. So that OHE staff may plan for proposal review, return the INTENT TO SUBMIT form (Appendix I) by November 16, 2015.

V. PROPOSAL REVIEW CRITERIA

Proposals will be evaluated according to the following criteria:

- 1. Significance (1-9 points)
 - The proposed project addresses an important problem or a critical barrier to progress in the field.
 - If the aims of the project are achieved, scientific knowledge, technical capacity, and/or clinical practice will be improved.
 - Successful completion of proposed project aims will change the concepts, methods, technologies, treatment, or rehabilitative services that drive this field.
- 2. Innovation (1-9 points)
 - The proposal challenges and seeks to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches or methodologies, instrumentation, or interventions.
 - A refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed.
- 3. Approach (1-9 points)
 - The overall strategy, methodology, and analyses are well-reasoned and appropriate to accomplish the specific aims of the proposed project.
 - Potential problems, alternative strategies, and benchmarks for successes are presented.
 - If the project is in the early stages of development, the proposed strategy will establish feasibility and manage particularly risky aspects of the proposed project.
 - If the project involves human subjects and/or NIH-defined clinical research, plans are in place for Protection of Human Subjects and inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children, justified in terms of the proposed scientific goals and research strategy.
- 4. Investigator(s) (1-9 points)
 - The PI, collaborators, and other researchers are well suited for the project.
 - Early Stage Investigators or New Investigators have appropriate experience and training.
 - Established Investigators have demonstrated an ongoing record of accomplishments that have advance their field(s).
 - If the project is collaborative or multi-PI, the investigators have complementary and integrated expertise and their leadership approach, governance, and organizational structure are appropriate for the project.
- 5. Appropriateness of Facilities/Environment (1-9 points)
 - The scientific environment in which the work will be done will contribute to the probability of success.
 - Institutional support, equipment and other physical resources available to the investigators are adequate for the proposed project.
 - The project will benefit from unique features of the scientific environment, subject populations, or collaborative arrangements.
- 6. Budget (narrative evaluation comments only)
 - The budget is clear, concise, and justified by narrative describing proposed costs.
 - The budget is cost effective and reflective of RFP and program objectives.

VI. PROPOSAL REVIEW PROCESS

Upon receipt by OHE, proposals will be reviewed to determine if all required materials are included and if the proposal responds to program requirements. **Incomplete proposals, late proposals, and proposals not responding to submission guidelines and proposals from ineligible applicants will not be judged.**

Qualifying proposals will be reviewed and recommendations made by members of the Spinal Cord and Traumatic Brain Injury Advisory Council. The strengths and weaknesses of each proposal will be reviewed in accordance with the criteria described under Section V, Proposal Review Criteria. A formal decision on the recommendations of the advisory council will be made in January 2016.

VII. GRANT ADMINISTRATION REGULATIONS

Conflict of Interest

Advisory council members must disclose in a written statement any financial interest in any organization that the council recommends to receive a grant. The written statement must accompany the grant recommendations and must explain the nature of the conflict.

Grant Award Process

Grant contracts will be processed electronically through the Statewide Integrated Financial Tools (SWIFT), the state's accounting system, after approval of awards and acceptance of negotiated awards by the project director.

Applicable Regulations

All contracts will contain an audit clause indicating that the relevant records, documents, and accounting procedures and practices of the grantee are subject to examination by the grant contracting agency and either the legislative auditor or the state auditor, as appropriate, for a minimum of six years.

Fiscal Procedures

All Spinal Cord Injury and Traumatic Brain Injury Research Grant Program funds should be assigned to individual accounts which can be readily identified and verified. If an institution receives more than one grant, separate accounts should be established for each grant. Once a grant contract has been fully executed, the grant award will be made. Submission of an interim narrative report and an interim statement of project expenditure will be required. Final narrative and financial reports must be submitted and approved prior to grant closeout. Request to change project activities, project personnel, or to move funds between approved budget lines must be submitted <u>in advance</u>, with appropriate justification. Unexpended funds must be returned to the Office of Higher Education. Expenditures in excess of approved budget amounts will be the responsibility of the grant recipient.

Final Reports

Each approved project must submit a final narrative and financial report within sixty (60) days of the conclusion of grant activities. Program financial reports must be submitted from and signed by the office of the institution's chief fiscal officer. At a minimum, the final narrative report must include the reporting that documents how well the objectives of the research program have been met.

Copies of materials which resulted from the grant should be submitted along with the final narrative report or as materials are subsequently published.

Attribution

Program material must bear the following acknowledgement:

"Funds for this research project were provided by the State of Minnesota Spinal Cord Injury and Traumatic Brain Injury Research Grant Program administered by the Minnesota Office of Higher Education."

Publications from Funded Research Projects

Copies of all publications from funded research projects must be provided to the Minnesota Office of Higher Education.

Ownership of Copyrights and Patents

Ownership of any copyrights, patents, or other proprietary interests that may result from grant activities, shall be governed by applicable federal and state regulations and local institutional/organizational policies.

VIII. GRANT CLOSE-OUT, SUSPENSIONS, AND TERMINATION

Close-out: Each grant shall be closed out as promptly as feasible after expiration or termination. In closing out the grant, the following shall be observed:

- Upon request, the Office of Higher Education (OHE) shall promptly pay the grant recipient for any allowable reimbursable costs not covered by previous payments.
- The grant recipient shall immediately refund the OHE any unobligated balance of cash advanced to the grant recipient.
- The grant recipient shall submit all financial, performance, evaluation, and other reports required by the terms of the grant.
- The close-out of a grant does not affect the retention period for State and/or Federal rights of access to grant records.

Suspension: When a grant recipient has materially failed to comply with the terms of a grant, OHE may, upon reasonable notice to the grant recipient, suspend the grant in whole or in part. The notice of suspension will state the reason(s) for the suspension, any corrective action required of the grant recipient, and the effective date.

Termination: OHE may terminate any grant in whole, or in part, at any time before the date of expiration whenever OHE determines that the grant recipient has materially failed to comply with the terms of the grant. OHE shall promptly notify the grant recipient in writing of the termination and the reason(s) for the termination, together with the effective date.

The grant recipient may terminate the grant in whole or in part upon written notification to OHE, setting forth the reasons for such termination, the effective date and, in the case of partial termination, the portion to be terminated.

IX. TIMELINE FOR PROPOSALS, AWARDS, AND FUNDED PROJECTS

October 7, 2015 Request for Proposals available to applicants.

November 16, 2015 Deadline for receipt of intent to submit forms.

(Submission of intent to submit forms is suggested but not required.)

4:30 p.m., December 7, 2015 Deadline for receipt of proposals.

January 11, 2016 Notification of recommendation for grant award.

February 8, 2016 - June 30, 2017 Project funding interval.

(Funding interval starts with date of grant contract

encumbrance.)

Submit one original and three copies of the complete final proposal, stapled in the upper left corner. To conserve paper, please make copies two-sided. Do not place proposals in binders or covers. Hand deliver or mail complete copies of the final proposal to:

Nancy B. Walters, Ph.D., Program Manager Minnesota Office of Higher Education 1450 Energy Park Drive, Suite 350 St. Paul, MN 55108-5227

Proposals sent by U.S. mail should be sent with sufficient time to be processed and arrive by the deadline; the applicant is responsible for making sure the complete proposal arrives on time. Using a time-sensitive delivery service or hand delivery is recommended.

Note for hand-delivered applications: Directions to the Office of Higher Education can be found at: http://www.ohe.state.mn.us/mPg.cfm?pageID=1847. Use of the North building entrance (by the flag poles) is required.

All proposals must arrive by 4:30 p.m., December 7, 2015.

Any final proposal materials submitted late or by fax or e-mail will not be accepted.

All proposals will be acknowledged upon receipt. Each late or ineligible applicant will be notified that its application will not be considered.

X. APPENDIX A COPY OF STATUTE

LAWS OF MINNESOTA 2015

Ch. 69, art. 3

Sec. 13. [136A.901] SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM.

Subdivision 1. **Grant program.** The commissioner shall establish a grant program to award grants to institutions in Minnesota for research into spinal cord injuries and traumatic brain injuries. Grants shall be awarded to conduct research into new and innovative treatments and rehabilitative efforts for the functional improvement of people with spinal cord and traumatic brain injuries. Research topics may include, but are not limited to, pharmaceutical, medical device, brain stimulus, and rehabilitative approaches and techniques. The commissioner, in consultation with the advisory council established under section 136A.902, shall award 50 percent of the grant funds for research involving spinal cord injuries and 50 percent to research involving traumatic brain injuries. In addition to the amounts appropriated by law, the commissioner may accept additional funds from private and public sources. Amounts received from these sources are appropriated to the commissioner for the purposes of issuing grants under this section.

Subd. 2. **Report.** By January 15, 2016, and each January 15 thereafter, the commissioner shall submit a report to the chairs and ranking minority members of the senate and house of representatives committees having jurisdiction over the Office of Higher Education, specifying the institutions receiving grants under this section and the purposes for which the grant funds were used.

Sec. 14. [136A.902] SPINAL CORD AND TRAUMATIC BRAIN INJURY ADVISORY COUNCIL.

Subdivision 1. Membership. The commissioner shall appoint a 12-member advisory council consisting of:

- (1) one member representing the University of Minnesota Medical School;
- (2) one member representing the Mayo Medical School;
- (3) one member representing the Courage Kenney Rehabilitation Center;
- (4) one member representing Hennepin County Medical Center;
- (5) one member who is a neurosurgeon;
- (6) one member who has a spinal cord injury;
- (7) one member who is a family member of a person with a spinal cord injury;
- (8) one member who has a traumatic brain injury;
- (9) one member who is a veteran who has a spinal cord injury or a traumatic brain injury;
- (10) one member who is a family member of a person with a traumatic brain injury;
- (11) one member who is a physician specializing in the treatment of spinal cord injury representing Gillette Children's Specialty Healthcare; and
 - (12) one member who is a physician specializing in the treatment of traumatic brain injury.
- Subd. 2. **Organization.** The advisory council shall be organized and administered under section 15.059, except that subdivision 2 shall not apply. Except as provided in subdivision 4, the commissioner shall appoint council members to two-year terms and appoint one member as chair. The advisory council does not expire.
- Subd. 3. **First appointments and first meeting.** The commissioner shall appoint the first members of the council by September 1, 2015. The chair shall convene the first meeting by November 1, 2015.
- Subd. 4. **Terms of initial council members.** The commissioner shall designate six of the initial council members to serve one-year terms and six to serve two-year terms.
- Subd. 5. Conflict of interest. Council members must disclose in a written statement any financial interest in any organization that the council recommends to receive a grant. The written statement must accompany the grant recommendations and must explain the nature of the conflict. The council is not subject to policies developed by the commissioner of administration under section 16B.98.
 - Subd. 6. **Duties.** The advisory council shall:
 - (1) develop criteria for evaluating and awarding the research grants under section 136A.901;
- (2) review research proposals and make recommendations by January 15 of each year to the commissioner for purposes of awarding grants under section 136A.901; and
 - (3) perform other duties as authorized by the commissioner.

XI. APPENDIX B PROPOSAL COVER SHEET

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM 2015 PROPOSAL FOR FUNDING

PRINCIPAL INVESTIGATOR:				
RANK, DEPARTMENT, and SCHOOL, if appropriate:				
INSTITUTIONAL AFFILIATION:				
E-MAIL ADDRESS OF PRINCIPAL INVESTIGATOR:				
TITLE OF PROPOSAL:				
ADDRESS WHERE WORK WILL BE PERFORMED:				
PROJECT PERIOD: February 2016 to June 30, 2017				
AMOUNT REQUESTED: DIRECT \$				
DIRECT \$ (maximum 8%) TOTAL \$ (award request may not for the current project		\$125,00	0 in total	
	YES	NO	PROTOCOL#	APPROVAL DATE
RECOMBINANT DNA?				
HUMAN SUBJECTS?				
VERTEBRATE ANIMALS?				
DOES THIS PROJECT INVOLVE CLINICAL RESEARCH?				
AUTHORIZED REPRESENTATIVE INFORMATION				
To the best of my knowledge and belief, all data in this proposal are authorized by the governing body of the applicant.	re true and	correct	. The document h	as been duly
Institution's Authorized Representative for Approving Proposal Submissi				
Title:				
Phone: () E-mail Address				
Signature of Institution's Authorized Representative for Approving Propo	osal Submis	ssion:		
		Date		

XII. APPENDIX C PRINCIPAL INVESTIGATOR/INSTITUTIONAL ASSURANCE FORM

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

Principal Investigator/Institutional Assurance:

"The undersigned agrees to accept responsibility for the scientific and technic conduct of the research project and for provision of required progress reports grant is awarded as the result of this proposal."			
Date	Principal Investigator Signature		
Date	Institutional Official Signature		

XIII. APPENDIX D PROGRAM ABSTRACT

2015 PROGRAM ABSTRACT

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

PROJECT TITLE:
APPLICANT INSTITUTION:
BACKGROUND TO THE RESEARCH TOPIC:
THE QUESTION(S) OR CENTRAL HYPOTHESIS OF THE RESEARCH:
THE GENERAL METHODOLOGY TO BE USED:
INNOVATIVE ELEMENTS OF THE PROJECT:
IMPACT ON TREATMENTS AND REHABILITATIVE EFFORTS FOR FUNCTIONAL
IMPROVEMENT OF PEOPLE WITH SPINAL CORD OR TRAUMATIC BRAIN INJURIES:

XIV. APPENDIX E BUDGET AND BUDGET JUSTIFICATION

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

Principal Investigator (Last, First, Middle):

DETAILED B	UDGET FOR B	UDGET PE	CRIOD		From	Thro	ugh
PERSONNEL (Applicant organiza	ution only)	ТҮРЕ	%	INST.	DOLLAR	AMOUNT RE	EQUESTED
(FF	ROLE ON	APPT.	EFFORT	BASE	SALARY	FRINGE	
NAME	PROJECT	(months)	ON PROJ.	SALARY	REQUESTED	BENEFITS	TOTAL
	Principal Investigator			\$	\$	\$	\$
	Collaborator			\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
			SI	JBTOTALS	\$	\$	\$
CONSULTANT COSTS							\$
SUPPLIES							\$
PATIENT CARE COSTS							\$
OTHER EXPENSES							\$
OTHER EXPENSES							
OTHER EXPENSES							
TOTAL DIRECT COSTS FOR BU	JDGET PERIOD)					\$
INDIRECT COSTS (8% of Direct							\$
TOTAL COSTS	,						\$
		TOTAL DI	EUIEGAED	DECEADOU	GRANT PROGE	OAM ETINIDO	\$

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

BUDGET JUSTIFICATION:

XV. APPENDIX F SENIOR/KEY PERSONNEL REPORT

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

Principal Investigator (Last, First, I						
SENIOR/KEY	PERSONNEL REPO	DRT Project Titl	e:			
	All Sanjar/V av Parsonn	el for the budget period must be li	stad balow			
	All Sellol/Rey Personil			7.00 · 7		
Name	Degree(s)	Role on Project Institutional (e.g. Pl, Res. Assoc.) Affiliation		Effort Devoted to Proje Cal Acad S		roject Sum
			İ			

XVI. APPENDIX G

BIOGRAPHICAL SKETCH OF PRINCIPAL AND SENIOR/ KEY PERSONNEL

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

Principal Investigator (Last, First, Middle):							
BIOGRAPHICAL SKETCH Provide the following information for the <u>Principal Investigator and any key personnel</u> . <u>DO NOT EXCEED FOUR PAGES</u> .							
POSITION TITLE							
	ducation, such as n	ursing, and include postdoctoral training					
DEGREE (if applicable)	MM/YY	FIELD OF STUDY					
	GRAPHICAL SKE tigator and any key per POSITION ther initial professional e	GRAPHICAL SKETCH tigator and any key personnel. DO NOT POSITION TITLE ther initial professional education, such as not personnel.					

- A. Personal Statement
- B. Positions and Honors
- C. Selected Peer-reviewed Publications

XVII. APPENDIX H

OTHER GRANT SUPPORT FOR PRINCIPAL INVESTIGATOR AND SENIOR/KEY PERSONNEL

MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM

Principal Investigator (Last, First, Middle):		
OTHER GRANT SUPPORT: Provide active support Other Support includes all financial resources, whether in direct support of an individual's research endeavors, agreements, contracts, and/or institutional awards. Train	Federal, non-Federal, commerc including but not limited to rese	ial or institutional, available earch grants, cooperative
It is critical that the Other Support page be clear and de centers, joint grants, and other programs as well as the Both Active and Pending support should be listed.		
Include all information noted below for each proposal/a	ward:	
NAME OF INDIVIDUAL		
ACTIVE/PENDING		
Project Number	Dates of Project	Person Months (Cal/Academic/
Title Title	Annual Direct Cost	Summer)
Major Goals of Project		
Overlap		

XVIII. APPENDIX I INTENT TO SUBMIT FORM

2015 Intent to Submit Proposal for Minnesota Spinal Cord Injury and Traumatic Brain Injury Research Grant Program

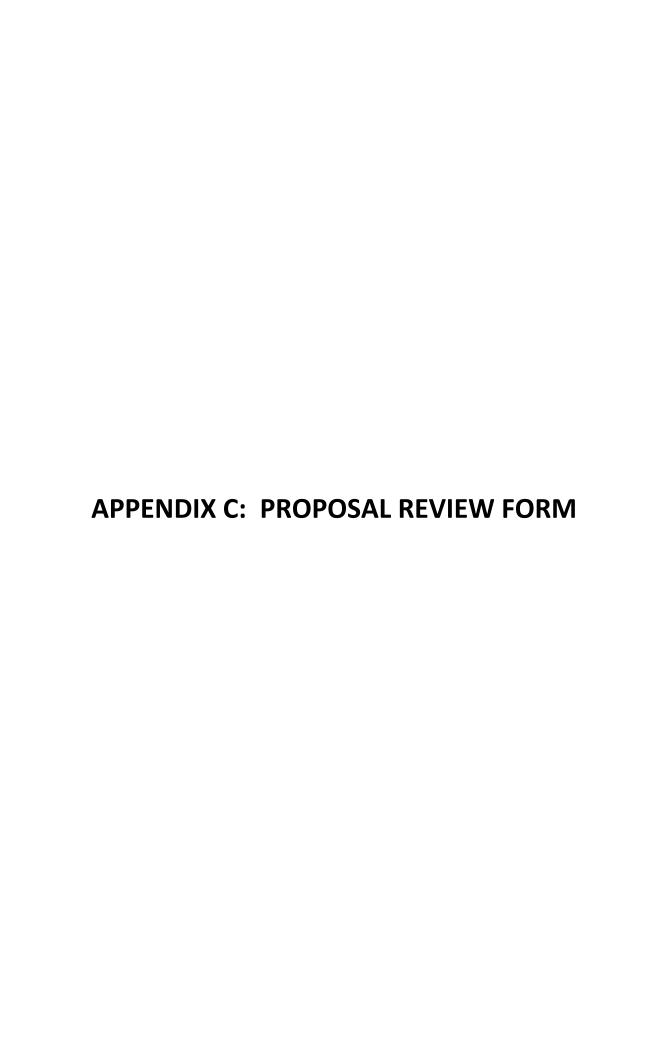
If your institution intends to apply for funding under the Spinal Cord Injury and Traumatic Brain Injury Research Grant Program, please provide the Office of Higher Education with the following information:

Name			
Institution/Organization			
Address			
Telephone () E-mail			
Check the blank as it applies to your proposal: () Research project for functional improvement of people with spinal cord injury () Research project for functional improvement of people with traumatic brain injury			
Please return this form by November 16, 2015, to:			
Kelly F. Gibson, Office & Administrative Assistant			
Competitive Grant Programs Minnesotre Office of Higher Education			
Minnesota Office of Higher Education 1450 Energy Park Drive, Suite 350			
St. Paul, MN 55108-5227			

Intent to Submit:

Responses may be sent by fax to (651) 642-0675 or by e-mail to kelly.gibson@state.mn.us

The Office of Higher Education (OHE) requests this information solely to help prepare for the proposal review process. Submission of an Intent to Submit form is not required for proposal submission. If you inform the OHE of your intent to apply, but subsequently decide not to do so, please notify the OHE accordingly.



MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY RESEARCH GRANT PROGRAM MINNESOTA OFFICE OF HIGHER EDUCATION 2015 PROPOSAL REVIEW FORM

Application No.	Reviewer No	Funding Requested:	
Principal Investigator(s)			
	OVERALL IMP	PACT	
the research field(s) involved, in o	impact score to reflect their assessment of the consideration of the following five scored revie to be judged likely to have major scientific im	w criteria, and additional review criteria. A	
Overall impact: Provide a paragr	aph summarizing the factors that informed you	r Overall Impact score. (Score: 1-9)	Score
	SCORED REVIEW (CRITERIA	
Reviewers will consider each of the each.	he five review criteria below in the determination	on of scientific and technical merit, and give	e a separate score for
1. Significance (Score: 1-9)			Score
Strengths			
Weaknesses			
2. Investigator(s) (Score: 1-9)			Score
Strengths			
Weaknesses			
3. <u>Innovation</u> (Score: 1-9)			Score
Strengths			
Weaknesses			
4. Approach (Score: 1-9)			Score
Strengths			
Weaknesses			
5. Environment (Score: 1-9)			Score
Strengths			
Weaknesses			