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January 17, 2017



Spinal Cord Injury and Traumatic Brain Injury Grant Program: January 17, 2017 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.

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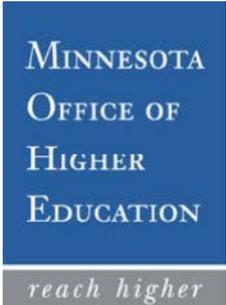
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Introduction

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.

Fiscal Year 2016 funds (\$500,000) were awarded, in entirety, for the four research projects listed below:

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 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 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 Title: Traumatic Brain Injury Classification and Outcome Assessment

Principal Investigator: Chad Richardson, MD

Institutional Affiliation: Hennepin County Medical Center

Grant Award: \$125,000

The progress reports/interim narrative reports for the Fiscal Year 2016 projects are found in Appendix B.

Funds for Fiscal Year 2017 Grant Program Purposes

For the Fiscal Year 2017 grant period, \$15,000 was retained by the Office of Higher Education for program administration, and \$485,000 was made available for research grants. 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 was added to the grant funds made available for the spinal cord injury research grants. A total of \$12,785 was added to the \$242,500 available for Fiscal Year 2017 spinal cord injury research grants. This leaves \$2,215 in donated funds that will be carried over to Fiscal Year 2018.

Schedule for Fiscal Year 2017 Proposal Solicitation and Proposals Received

To support research projects with fiscal year 2017 program funding, the following timeline was used to solicit proposals and award grant funds:

April 1, 2016	Request for Proposals available to applicants.
May 9, 2016	Deadline for receipt of intent to submit forms.
4:30 p.m., May 23, 2016	Deadline for receipt of proposals.
June 15, 2016	Notification of recommendation for grant award.
July 1, 2016 – June 30, 2017	Project funding interval.

A copy of the Fiscal Year 2017 Request for Proposals for the Minnesota Spinal Cord Injury and Traumatic Brain Injury Research Grant Program is provided in Appendix C. Three proposals were received that requested funding as Spinal Cord Injury Research Grants. Listed below are the three proposals with budget requests totaling \$381,342.

Proposal #	Title and Applicant	Amount Requested
SCI-1	Regents of the University of Minnesota Rozina Bhimani, PhD, DNP, APRN-CNP, CNE The Development of Multidimensional Telehealth Communication Tool for the Management of Spasticity in Spinal Cord Injury: A Step Towards Shared Decision Making	\$126,004
SCI-2	Regents of the University of Minnesota William Durfee, PhD Muscle Powered Exoskeleton for Standing and Walking by People with Spinal Cord Injury	\$128,385
SCI-3	Minneapolis VA Health Care System David Balsler, MD Enhancing Rehabilitation with Neuromodulation for Veterans with Spinal Cord Injury	\$126,900
TOTAL AMOUNT REQUESTED		\$381,342

Two proposals were received that requested funding as Traumatic Brain Injury Research Grants. Listed below are the two proposals with budget requests totaling \$242,500.

Proposal #	Title and Applicant	Amount Requested
TBI-1	Minneapolis VA Health Care System Tasha Nienow, PhD TDCS as an Intervention for Patients with Traumatic Brain Injury	\$121,250
TBI-2	Hennepin County Medical Center Molly Hubbard, MD Vagus Nerve Stimulation to Augment Recovery from Traumatic Brain Injury; Evaluation of Patients with Moderate Injury	\$121,250
TOTAL AMOUNT REQUESTED		\$242,500

2017 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 in 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 Rodreck	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

At the June 13, 2016 meeting, the council members completed their reviews of the five submitted research proposals and recommended four proposals for funding as Fiscal Year 2017 research grant proposals.

To complete this task, review panels of Advisory Council members was established for each specialty area (Traumatic Brain Injury and Spinal Cord Injury). Each proposal was reviewed and scored by members of the specialty area review panel reflective of the proposal’s research focus. 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 June 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.

Fiscal Year 2017 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 Appendix D. The four fiscal year 2017 projects recommended and funded were:

Project Title: Transcranial Direct Current Stimulation (tDCS) as an Intervention for Patients with Traumatic Brain Injury

Principal Investigators: Tasha Nienow, PhD

Institutional Affiliation: Minnesota Veterans Medical Research and Education Foundation

Grant Award: \$121,250

Project Purpose: This study aims to assess the magnitude of tDCS-induced cognitive and functional change in patients with mild traumatic brain injury to increase understanding of the mechanisms through which tDCS alters cognitive function and to evaluate the feasibility and acceptability of offering tDCS as an intervention. Cognitive dysfunction associated with traumatic brain injury is a strong predictor of community functioning. Present approaches to cognitive rehabilitation have had modest success in enhancing cognitive and functional performance, and there is a strong interest in developing more effective and efficient approaches to intervention. tDCS is a neuromodulatory technique that has been found to facilitate learning and to enhance cognitive performance. This study will examine the efficacy of tDCS to improve working memory performance and related cognitive functions in patients with mild TBI.

Project Title: Vagus Nerve Stimulation to Augment Recovery from Traumatic Brain Injury: Evaluation of Patients with Moderate Injury

Principal Investigator: Molly Hubbard, MD

Institutional Affiliation: Minneapolis Medical Research Foundation

Grant Award: \$120,323

Project Purpose: The purpose of this study is to provide initial evidence for the use of the non-invasive vagus nerve stimulator for treatment of patients recovering from moderate traumatic brain injury. The safety and effectiveness of an active nerve stimulator will be compared to sham treatment. Vagus nerve stimulation has been used since 1938 when researchers found that stimulating the nerve in animal models caused cortical EEG changes. Further research showed that vagal nerve stimulation was able to

reduce seizures and has been used in humans to treat intractable seizures since 1988. Gaining knowledge about the cognitive and functional improvements in subjects with a moderate TBI, using a device which has been approved by the FDA for treatment of migraines, will provide data which cannot be obtained in animal models.

Project Title: Muscle Powered Exoskeleton for Standing and Walking by People with Spinal Cord Injury

Principal Investigator: William Durfee, PhD

Institutional Affiliation: Regents of the University of Minnesota

Grant Award: \$128,385

Project Purpose: Through this project, a new concept is proposed that uses just one channel of stimulation combined with a lightweight, passive energy storing exoskeleton to provide short-range walking for a user with spinal cord injury (SCI). While there are several types of powered exoskeletons for walking, there remains a need for a solution that allows a user with SCI to stand and walk under the power of their own legs. In prior work, the research team has developed several versions of standing and walking systems that use surface electrical stimulation of the paralyzed muscle combined with an exoskeleton. This approach combines electrical stimulation and an exoskeleton in a novel way that really simplifies the electrical stimulation because only one muscle is stimulated and uses a passive exoskeleton that is projected to be much lighter than the current muscle powered exoskeleton.

Project Title: Enhancing Rehabilitation with Neuromodulation for Veterans with Spinal Cord Injury

Principal Investigator: David Balsler, MD

Institutional Affiliation: Minnesota Veterans Medical Research and Education Foundation

Grant Award: \$126,900

Project Purpose: Motor paralysis has an extreme functional, financial and emotional cost to veterans, their families and care providers. Recently, a small study using an epidural neuromodulation implant in the spine showed potential in helping persons with motor paralysis regain voluntary movement and stand. Additional data with epidural stimulation in motor complete spinal cord injury veterans is needed to know if these patients can benefit from standing and walking therapies. This pilot study provides the first step in determining whether robot exoskeleton rehabilitative resources can be useful for motor complete, as well as, motor incomplete spinal cord injury veterans. For this study, participants will have an epidural neuromodulator placed at L1-S1 followed by a year of monthly training to determine if this provides assistance in regaining voluntary movement and the ability to stand.

Project Timeline and Anticipated Outcomes

The project directors for Fiscal Year 2017 projects have a time period of July 1, 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.

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.

APPENDIX B: FISCAL YEAR 2016 PROGRESS REPORTS

2016-2017 Interim Narrative Reports

Submitted: October 17, 2016

Project Title: Oligodendrocyte progenitor cells and scar ablation for the treatment of chronic spinal cord injury

Principal Investigator (PI) Name, Title, Contact Information (e-mail and phone number):

Dr. Ann M. Parr, Assistant Professor, Department of Neurosurgery - University of Minnesota
amparr@umn.edu

Phone: 612-624-6666

Identify the innovative focus of the funded research project.

The innovative focus of the project is based on a combination of two novel technologies. The first is a method for neatly ablating glial scar tissue using a rose Bengal-based phototoxic approach in chronic spinal cord injury (SCI). It has been suggested that development of the glial scar acts as a major physical barrier to regenerating axons after SCI. We are refining this technique by modifying the rose-Bengal to test photo-ablative toxicity and diffusional efficiency. The second technology is a novel protocol to generate a consistent, reproducible supply of autologous human OPCs using iPSCs derived from dermal fibroblasts. Previously published methods to generate OPCs from iPSCs have proven to be difficult to reproduce and are unsuitable for the clinic. We hypothesize that a combination of the scar ablation technique with optimized cells for transplantation will prevent host astrocytes from re-forming a glial scar and will create a more favorable environment by eliminating a barrier for axonal regeneration.

Identify how treatment or rehabilitative services will be changed as a result of the funded research project.

Human spinal cord injury (SCI) currently has no effective treatment and any new effective treatments would have a huge impact on public health. Our goal is to bring a successful cell transplantation therapy from bench to bedside. It is important to note that a successful therapy may not require complete resolution of all of the detrimental consequences of SCI, but even small gains, for example in bowel and bladder function may be significant. While many groups have focused on therapies for subacute SCI, chronic SCI remains an unmet need, with an estimated 250,000 people currently living with chronic SCI in the US. Globally, many patients with chronic SCI have participated in stem cell therapies in attempts to improve their function and quality of life, some with negative consequences. Many cell types have been utilized, including mesenchymal stromal cells, Schwann cells, olfactory ensheathing cells, and neural stem cells and their progenitors. Despite the prevalence of these treatments, their efficacy remains largely unproven, and very little is understood about the mechanisms of action. This proposal will help improve our understanding of the glial scar as well as the effects of cell transplantation.

Describe the current status of the SCI/TBI research grant activities.

We have finished two out of three studies to address Aim 1 which is to investigate the time and intensity dependent photo-ablative characteristics of rose-Bengal and two of its derivatives in a model of chronic SCI. Rose-Bengal and one of the analogs have been injected and the rats have had their tissues harvested for further examination. The third analog study will start in the near future. Data analysis of the one of the three rose-Bengal derivatives is discussed below and

shows interesting results. In the next year we hope to determine the optimal rose-Bengal derivative and investigate the effects and mechanisms of locomotor recovery following transplantation of hiPSC-derived OPCs in combination with this derivative.

Are there any early project successes that you want to report on at this time?

Preliminary data suggests that there is a reduction in the glial scar with rose-Bengal based on astrocytic GFAP staining in our animal model of chronic spinal cord injury (Figure 1). There is no significant change in the number of other neural cell types including oligodendrocytes and neurons between controls indicating that specificity towards the glial scar and the scar ablation technique not being detrimental towards other cell types in the spinal cord.

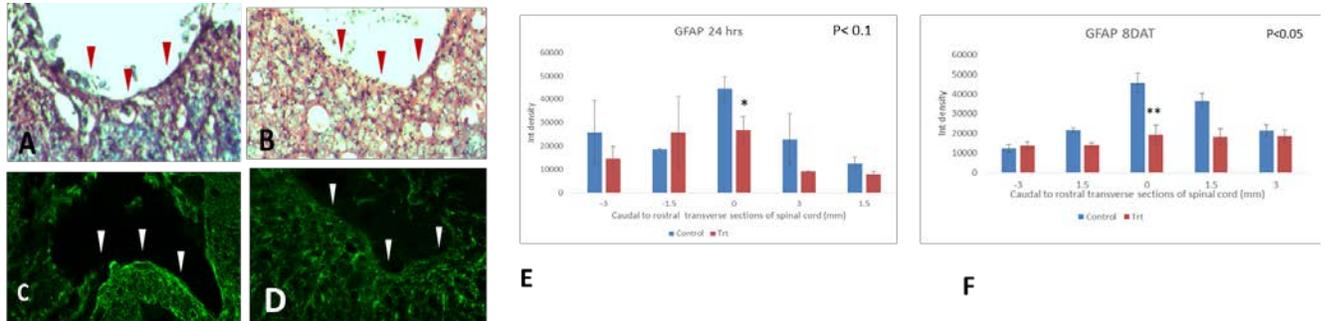


Figure 1: Scar ablation and GFAP. Spinal cord at 5 weeks after injury with saline treatment (A ,C). Spinal cord with Rose Bengal Derivative 1(RBD1) treatment 5 days post operative (B ,D). H &E staining (A, B) and GFAP immunostaining (C,D). The thick glial scar with smooth surface is pointed by arrows (A) and the disappearance of smooth surface after scar ablation (arrowheads; B). A continuous belt of GFAP immunoreactivity indicate congregation of astrocytes around the cavity (arrowheads; C) while decreased density of GFAP after scar ablation is depicted (arrowheads; D) . Scale bar=200um

The GFAP Integrated density of glial scar tissue was quantified using Image J. The average density of GFAP around the cavity is compared between control group (injured, saline treatment, n=3) and scar ablation group (injured, treated with Rose Bengal, n=3). The results show that the GFAP immunoreactivity is significantly reduced at 24 hours and 8 days post treatment ($P < 0.1$ and $P < 0.05$ respectively) after scar ablation compared to control group (E and F)

Project Title: Traumatic Brain Injury Classification and Outcome Assessment

Principal Investigator (PI) Name, Title, Contact Information (e-mail and phone number):

Chad Richardson, MD, Trauma Medical Director

chad.richardson@hcmcd.org

612-873-2810

Identify the innovative focus of the funded research project.

The goal of this research is to create an objective, multimodal classification scheme and outcome assessment for TBI based on radiographic measures, eye tracking, and blood-based biomarkers. The failure of current clinical assessment at both onset and long-term follow-up to classify brain injuries based on subtle pathology is a major barrier in the field's ability to move forward in testing novel therapeutics and prophylactics. Because of this barrier, over 30 clinical trials have failed in the last 25 years. By establishing a classification scheme that can capture each patients' underlying pathology more specifically, clinical trials will be able to stratify patients into more homogenous experimental groups, and clinical outcomes will be able to be predicted more accurately and targeted in novel treatments.

An additional significance of this study is the use of the eye tracking algorithm to assess brain injury. The opportunity to associate this type of eye tracking with radiographic measures may result in less patient exposure to dangerous radiation from brain imaging methods as well as faster and less invasive brain injury assessment. No other study of traumatic brain injury currently being conducted elsewhere combines eye tracking, blood-based biomarkers, and radiographic assessments.

Identify how treatment or rehabilitative services will be changed as a result of the funded research project.

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, analysis of blood-based biomarkers, combined with radiographic measures provide a more specific and objective measures of classifying TBI and assessing its outcome, but still require validation. The purpose of this prospective, observational clinical study is to create a classification scheme and develop outcome assessments for brain injury that will enable successful clinical trials and improve the quality of healthcare for patients suffering from a TBI.

Describe the current status of the SCI/TBI research grant activities.

At this time, the research project has successfully established a custom database management system that captures a variety of patient information. The database management system provides unique interfaces for electronic data capture for each aspect of the research, namely, radiographic measures, eye tracking, blood-based biomarkers, and standardized assessment. Along with these interfaces, there are a variety of tools and resources that provide the means for high-level data integrity. This system also provides

mechanisms to monitor study progress and provide a unified source for data analysis. Lastly, the system only allows access via role-based access with password protections while also incorporating encryption on data transfer and storage.

With the appropriate infrastructure in place, we have successfully screened over 600 patients and enrolled almost 170 patients. Based on the data kept at HCMC for head trauma admissions from previous years, we expect to screen about 9000 trauma patients and enroll about 1200 throughout the course of 15 months. With these patients recruited, we have been able to identify candidates for radiographic analysis by assessing clinically indicated MRI and CT scans. Therefore, we are well on our way to achieving our goals for recruitment.

Using these initial patients, we have been assessing the standard of care in radiographic imaging while also investigating the use of state-of-the-art methods. With this, we have been actively working towards establishing the most effective protocol for MRI sequences to assess TBI. We aim to finalize these sequences by the end of this month and begin recruitment into this section of the research project.

Are there any early project successes that you want to report on at this time?

We have constructed a unified data management platform that will provide a central location for data collection, which will allow us to integrate data from different measures to successfully achieve our goal of creating an objective, multimodal classification scheme and outcome assessment for TBI.

Project Title: Neuroimaging and Neurovision Rehabilitation of Oculomotor Dysfunction in Mild Traumatic Brain Injury (mTBI)

Principal Investigator (PI) Name, Title, Contact Information (e-mail and phone number):

Sarah B. Rockswold, MD

sarah.rockswold@hcmec.org

612-873-8700

Identify the innovative focus of the funded research project.

Too many trials in traumatic brain injury (TBI) have only studied the structural pathology following injury rather than treatment effects. This combined approach using state of the art imaging and a robust clinical model of post-traumatic oculomotor dysfunction (OMD), with successful neuro vision rehabilitation (NVR) intervention, will provide the basis for establishing biomarkers in TBI.

Identify how treatment or rehabilitative services will be changed as a result of the funded research project.

Mild traumatic brain injury (mTBI) is a significant cause of disability especially when symptoms become chronic. In HCMC's experience, this chronicity is often linked to OMD. Oculomotor dysfunction will continue until properly identified and treated, especially with NVR. However, there is a controversy in the ophthalmology community which tends to undermine the fact that NVR is not only effective but essential in the full recovery of OMD. Our pilot data demonstrate decreased activation in the precuneus, occipital cortex, superior temporal gyrus, and superior colliculus that control visual information and eye movement as well as auditory processing (which is also something patients with OMD find challenging). The goals of this research study are to better understand cerebral structural and metabolic changes associated with as well as the effectiveness of NVR on post traumatic OMD by utilizing resting state and task functional MRI and diffusion tensor imaging. A positive outcome will have a significant impact on the diagnosis and care of the considerable numbers of mTBI patients suffering from OMD, especially because NVR will be more accepted and utilized by the medical community. In turn, the overall functional outcomes after mTBI will improve, greatly relieving the suffering and disability for these patients. In addition, this combined approach using state of the art imaging and a clinical model of post-traumatic OMD, with successful NVR intervention, will provide the basis for establishing biomarkers in TBI.

Describe the current status of the SCI/TBI research grant activities.

We obtained IRB approval for this study at Hennepin County Medical Center in early March 2016. Unfortunately, it was a very slow process with the IRB at the University of Minnesota because of their recent changes so that we did not get approval until mid-September 2016.

Since that time, we have made good progress with the study and have enrolled 3 subjects. The visual testing, MRI scanning and neurovision rehabilitation have all gone very smoothly with no difficulty. There have been no adverse events.

Are there any early project successes that you want to report on at this time?

Not at this time.

Project Title: Epidural Stimulation for Spinal Cord Injury

Principal Investigator (PI) Name, Title, Contact Information (e-mail and phone number):

David Darrow, MD MPH

214-564-0623

darro015@umn.edu

Uzma Samadani, MD, PhD

917-388-5740

uzma.samadani@hcmcd.org

Identify the innovative focus of the funded research project.

Epidural spinal cord stimulation for spinal cord injury is a nascent treatment modality with published results from only a single center. While the results are a dramatic shift in the context of 50 years of negative trials in spinal cord injury, the results have not been reproduced. Our approach is innovative in multiple ways, but our focus has been on removing barriers to delivery of the treatment to the population at large. The main barriers identified are reproducibility and programming.

Our aim was to power a clinical study that could corroborate the results of the original study while providing information about potential directions that could be taken to improve the lives of patients suffering complications of spinal cord injury, especially in the context of interest from the NIH toward improving autonomic function.

The second major barrier, understanding how to optimally programming the pulse generators, is a product of the large parameter space for neuromodulation. In general, devices have matured over time and can offer more programming options. While more parameters to program provides flexibility, providers who are tasked with programming must now select a single programming option from more than 34 million option. There is no possible way to test all of these options in every patient to find the best, so methods must be used to ascertain whether certain areas within this space work better than others. In order to do this for volitional movement, we developed a novel wireless home testing unit utilizing accelerometers and a tablet computer which can engage patients in testing different parameters. By carefully selecting sequences of settings to be used during home therapy for patients, it is possible to figure out where in the more than 34 million settings enclaves of useful settings may be populated. With every patient repeating the process, a probabilistic map of the parameter space can be created. As a result, a clinical tool can be created to help providers navigate the parameter space for patients in clinic.

In addition the platform through which this is performed can also apply to other outcomes beyond volitional movement, and this study will begin to evaluate the possibility of optimizing for hypotension as well with continuous home monitoring. This novel approach enables the what is becoming a large working group of researchers collaborating about this project between the University of Minnesota, HCMC, VA, and others to offer remote research capabilities, allowing patients from across the state to easily participate in long- term studies without burdensome transportation costs.

Identify how treatment or rehabilitative services will be changed as a result of the funded research project.

This project directly moves a new and novel treatment modality into the possibility of broad clinical use. There are currently no FDA approved therapies for chronic spinal cord injury, and this project is geared directly towards transitioning epidural spinal cord stimulation into a potentially effective therapy.

In addition, this grant has also opened key doors between partners in the twin cities and in Minnesota allowing collaboration not previously explored between the Department of Neurosurgery and rehabilitation at the University of Minnesota, HCMC, and the VA. International partners in Canada have been recruited to begin exploration of autonomic function and collaborations are beginning with leading researchers in Europe.

Describe the current status of the SCI/TBI research grant activities.

An active collaboration with St. Jude Medical was sought and through a fast-paced dialogue, the first six stimulators in addition to clinical trial support was secured. We have found St. Jude Medical to be very interested in a deeper collaboration, and this partnership is now in expansion to other areas of neuromodulation as a direct result of this trial, including for deep brain stimulation. In effect, St. Jude is contributing \$240,000 towards the trial thus far. We anticipate further contribution in the future.

The trial has been designed with significant contribution from experts in clinical trials, and we are currently waiting for FDA IDE approval to begin the study. The IDE is for 100 patients over five years, and the SCI/TBI will be completely responsible for seeding this initiative and clinical trial with tremendous potential. We hope to enroll two patients at a time and implant the first two by the end of the year.

Are there any early project successes that you want to report on at this time?

We have had great success and interest in our home rehabilitation program, and we hope to publish an article on this specific subproject soon for your review.

In addition, numerous collaborations have been formed to support the trial and future research including the following:

Department of Neurosurgery: University of Minnesota, HCMC, VA
Department of Neurology: University of Minnesota
Physical Medicine and Rehabilitation: University of Minnesota, VA
VA Spinal Cord Injury Rehabilitation Center
University of British Columbia

APPENDIX C: COPY OF REQUEST FOR PROPOSALS

OFFICE OF HIGHER EDUCATION
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**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 – May 9, 2016
Grant Proposal – May 23, 2016**

PROJECT PERIOD:

July 1, 2016 – June 30, 2017

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

**April 1, 2016
Minnesota Office of Higher Education**

I. OVERVIEW

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. Three percent of this appropriation will be used for program administration. The Commissioner of the Office of Higher Education, in consultation with the program's advisory council shall award 50 percent of the State 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. To supplement Fiscal Year 2017 funding for the spinal cord injury research grants, a \$15,000 donation was provided by the Get Up Stand Up to Cure Paralysis Foundation. 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, traumatic brain injury research proposals will be funded up to a maximum total request of \$121,250 for the Fiscal Year 2017 grant period, which includes indirect costs set at 8% of total direct costs. The spinal cord injury research proposals will be funded up to a maximum total request of \$128,750 for the Fiscal Year 2017 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 grant award period will be the 12 months from July 1, 2016 through June 30, 2017.

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

IV. PROPOSAL SUBMISSION

Proposals must be submitted by **Monday, May 23, 2016 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: Provide an explicit description of how the proposed research will meet the goals of the research grant program. 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 May 9, 2016.

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 advanced 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.

The assignment of points during the proposal review process will be reflective of National Institutes of Health guidelines.

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 June 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 in advance, 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

April 1, 2016	Request for Proposals available to applicants.
May 9, 2016	Deadline for receipt of intent to submit forms. (Submission of intent to submit forms is suggested but not required.)
<u>4:30 p.m., May 23, 2016</u>	<u>Deadline for receipt of proposals.</u>
June 15, 2016	Notification of recommendation for grant award.
July 1, 2016 - June 30, 2017	Project funding interval. (Funding interval starts with date of grant contract encumbrance.)

Two formats of proposal submission are required:

1. Submit the complete final proposal as a .pdf document to nancy.walters@state.mn.us.
2. 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., May 23, 2016.

Any final proposal materials submitted late 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 2016 PROPOSAL FOR FUNDING**

PRINCIPAL INVESTIGATOR: _____

RANK, DEPARTMENT, and SCHOOL, if appropriate: _____

INSTITUTIONAL AFFILIATION: _____

E-MAIL ADDRESS OF PRINCIPAL INVESTIGATOR: _____

PHONE NUMBER OF PRINCIPAL INVESTIGATOR: _____

ADDRESS OF PRINCIPAL INVESTIGATOR: _____

TITLE OF PROPOSAL: _____

PROJECT PERIOD: July 1, 2016 to June 30, 2017

AMOUNT REQUESTED:

DIRECT \$ _____

INDIRECT \$ _____ (Maximum 8%)

TOTAL \$ _____ (Award request may not exceed \$121,250 in total for traumatic brain injury projects and \$128,750 for spinal cord injury projects for the current project period.)

	YES	NO	PROTOCOL #	APPROVAL DATE
RECOMBINANT DNA?	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
HUMAN SUBJECTS?	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
VERTEBRATE ANIMALS?	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
DOES THIS PROJECT INVOLVE CLINICAL RESEARCH?	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

AUTHORIZED REPRESENTATIVE INFORMATION

To the best of my knowledge and belief, all data in this proposal are true and correct. The document has been duly authorized by the governing body of the applicant.

Institution's Authorized Representative for Approving Proposal Submission (*Please type or print name clearly*):

Title: _____

Phone: () _____ E-mail Address _____

Signature of Institution's Authorized Representative for Approving Proposal Submission:

_____ 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 technical conduct of the research project and for provision of required progress reports if a grant is awarded as the result of this proposal.”

Date

Principal Investigator Signature

Date

Institutional Official Signature

XIII. APPENDIX D
PROGRAM ABSTRACT

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:**

(Use of this form is required. Abstract is limited to one page.)

XIV. APPENDIX E
BUDGET AND BUDGET JUSTIFICATION

**MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY
FISCAL YEAR 2017 RESEARCH GRANT PROGRAM**

Principal Investigator (Last, First, Middle): _____

DETAILED BUDGET FOR BUDGET PERIOD					From	Through	
<i>PERSONNEL (Applicant organization only)</i>		TYPE APPT. <i>(months)</i>	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator			\$	\$	\$	\$
	Collaborator			\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
				\$	\$	\$	\$
SUBTOTALS					\$	\$	\$
CONSULTANT COSTS							\$
SUPPLIES							\$
PATIENT CARE COSTS							\$
OTHER EXPENSES							\$
OTHER EXPENSES							
OTHER EXPENSES							
TOTAL DIRECT COSTS FOR BUDGET PERIOD							\$
INDIRECT COSTS <i>(8% of Direct Costs)</i>							\$
TOTAL COSTS							\$
TOTAL REQUESTED RESEARCH GRANT PROGRAM FUNDS							\$

**MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY
RESEARCH GRANT PROGRAM**

BUDGET JUSTIFICATION:

XV. APPENDIX F
SENIOR/KEY PERSONNEL REPORT

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 **Principal Investigator and any key personnel**. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
------	----------------

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training and residency training, if applicable.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY

- 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 for the **Principal Investigator and any key personnel.** Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

It is critical that the Other Support page be clear and detailed, and include funding through program projects, centers, joint grants, and other programs as well as the role of the person in each grant and any potential overlap. Both Active and Pending support should be listed.

Include all information noted below for each proposal/award:

NAME OF INDIVIDUAL

ACTIVE/PENDING

Project Number	Dates of Project	Person Months (Cal/Academic/ Summer)
Source	Annual Direct Cost	
Title		

Major Goals of Project

Overlap

XVIII. APPENDIX I
INTENT TO SUBMIT FORM

**2016 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:

Principal Investigator's 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 May 9, 2016, to:

*Kelly F. Gibson, Office & Administrative Assistant
Competitive Grant Programs
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.

APPENDIX D: PROPOSAL REVIEW FORM

**MINNESOTA SPINAL CORD INJURY AND TRAUMATIC BRAIN INJURY
RESEARCH GRANT PROGRAM
MINNESOTA OFFICE OF HIGHER EDUCATION
PROPOSAL REVIEW FORM FOR FISCAL YEAR 2017**

Application No. _____	Reviewer No. _____	Funding Requested: _____
Principal Investigator(s) _____		
OVERALL IMPACT		
Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.		
<u>Overall impact</u> : Provide a paragraph summarizing the factors that informed your Overall Impact score. (Score: 1-9)		Score _____
SCORED REVIEW CRITERIA		
Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.		
1. <u>Significance</u> (Score: 1-9)		Score _____
Strengths		
Weaknesses		
2. <u>Investigator(s)</u> (Score: 1-9)		Score _____
Strengths		
Weaknesses		
3. <u>Innovation</u> (Score: 1-9)		Score _____
Strengths		
Weaknesses		
4. <u>Approach</u> (Score: 1-9)		Score _____
Strengths		
Weaknesses		
5. <u>Environment</u> (Score: 1-9)		Score _____
Strengths		
Weaknesses		