South Carolina Spinal Cord Injury Research Fund



Annual Report 2002/2003

2002/2003 ANNUAL REPORT SOUTH CAROLINA SPINAL CORD INJURY RESEARCH FUND

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Board of Directors



Charles L. Allen Mt. Pleasant, SC Spinal cord injury survivor, Charleston Municipal Court Judge and teaches at Trident Technical College. (Term: March 2003 - 2007)



Phanor L. Perot, Jr, M.D., PhD. Charleston, SC.

Board Certified in Neurological Surgery and Professor Emeritus of Neurosurgery at the Medical University of South Carolina and past Department Chairman.

(Term: March 2003 - 2007)



Brian G. Cuddy, M.D. Charleston, SC Board Certified Neurosurgeon in private practice, Clinical Associate Professor of Neurosurgery at MUSC, and directly involved in establishing

the Spinal Cord Injury Research Fund. (Term: March 2001 - 2004)



David Griesemer, M.D. Charleston, SC Board Certified in Neurology and serves as Chairman of the MUSC Department of Neurology and Associate Professor of Neurology and Pediatrics.

(Term: March 2003 - 2007)



Columbia, SC Mother of a family member with spinal cord injury and staff member of the Office of Minority Affairs of the SC Department of Health and Environmental

Terry Peacock

Control. (Term: March 2001 - 2005)



David L. Shallcross, M.D. Greenville, SC Board Certified in Physical Medicine and Rehabilitation and conducts a private practice, Upstate Medical Rehabilitation, as well as serves as Medical

Director of the inpatient rehabilitation unit at BonSecours St. Francis Health System in Greenville.

(Term: March 2001 - 2005)



W. Daniel Westerkam, M. D. Columbia, SC

Specialist in Physical Medicine and Rehabilitation who is Director of Rehabilitative Services at Palmetto Richland Memorial Hospital as well as

Associate Medical Director at HealthSouth Rehabilitation Hospital in Columbia. (Term: March 2001 - 2005)

State of South Carolina

Spinal Cord Injury Research Board

"Dum Spiro Spero - While I breathe I Hope"

Brian G. Cuddy, MD Chairman

Judge Charles L. Allen David Griesemer, MD Terry Peacock Phanor L. Perot, MD, PhD David L. Shallcross, MD W. Daniel Westerkam, MD

Dear Friends and Supporters,



J. Walker Coleman, III Fund Administrator

Medical University of South Carolina Administrative Building 171 Ashley Avenue, Suite 200A P.O. Box 250001 Charleston, SC 29425

October 2003

On behalf of the Board and staff of the South Carolina Spinal Cord Injury Research Fund, it is my privilege as well as pleasure to share the following second Annual Report of Fund activities.

The intense groundwork of our previous eighteen months started paying off in very real terms with the first set of eight research projects awarded funds in September and off and running almost immediately. Soon thereafter organizing Scientific Director, Dr. Peter Kalivas, passed the leadership baton along to the new scientific team of Dr. James Krause as Scientific Director and Dr. Mark Kindy as Associate Scientific Director. Our Fund was not only instrumental in attracting this nationally recognized spinal cord expertise to the state, but is directly benefiting as they continually update and administer our scientific review processes as well as promote the Fund to potential researchers throughout South Carolina while building an in-state spinal cord injury research infrastructure. I call particular attention to their reports in the text as well as to **Appendix 8** which includes an inspirational newspaper article about Dr. Krause.

Among the initial projects was a Conference put on by the Spinal Cord Injury Association which I helped keynote with both pride as well as deep respect and appreciation for the organizers. You can read more about this in the text that also includes informative summaries of all Round 01 projects which will be completing activity throughout the next Fiscal Year.

However, our work only was getting started. A Round 02 Request for Proposals resulted in twelve new project applications for which the follow-up formal scientific review and subsequent Board review resulted in approval for funding of ten. As the year ended, development of Round 02A and 03 RFPs was well underway. A Winter press conference was held to update on Fund progress as well as publicly thank our Fund legislative creators including Representative Chip Limehouse and Senator Arthur Ravenel as well as past Representative Ron Fleming. The Fund Web page went on line in April. It can be accessed at <u>www.scscirf.org</u> (see Appendix 7).

These highlights only touch upon the many achievements over the period which are presented in more detail throughout this Report. The Board would like to express its appreciation to all who are interested in and supportive of the Fund—particularly the S.C. Legislature, the Medical University of South Carolina, Clemson, and the University of South Carolina. We look forward to an even more productive FY 03—04.

Respectfully,

Brian G. Cuddy, M.D. Board Chair

~OVERVIEW OF FUND~

PURPOSE/CHARGE: Promoting research to develop better understanding of causes and effective treatment strategies for paralysis, sensory loss, and other consequences of spinal cord injury and disease.

LEGISLATIVE BACKGROUND: The South Carolina Spinal Cord Injury Research Fund (SCIRF) was established in 2000 by amendment (Bill S54 44-38-510) to Section 2, Chapter 38, Title 44 of the 1976 S.C. Code as signed by the Governor on July 20, 2000.

RATIONALE/NEED:

- Average annual SC incidence rate of TSCI is 67/1,000,000.
- Rate 22% higher than national average of 55/1,000,000.
- About 12% of the TSCI injuries have traumatic brain injury.
- 66% of the TSCI occur at prime of lives (age 20-54).
- 3/4th of injuries occur among males.
- All races are equally affected.
- Highest average acute care charge of \$85,256 is incurred by those with complete paralysis (ASIA=A).
- Lowest is \$ 27,248 incurred by those with recoverable TSCI (ASIA=E).
- Overall acute care charge of TSCI (acute care hospital fee) from 1990-2000 is \$111,409,136 which indicates an annual acute care charge of \$10,000,000 is expended for acute hospital care of TSCI only.
- Using the willingness-to-pay method of cost analysis, the total economic impact of TSCI in SC is estimated at \$ 25,765,812 per annum in 1997 dollar values.
- 58% of the TSCI are the result of motor vehicle injuries.

SOURCE OF FUNDS: A \$ 100 surcharge is levied on each Driving Under the Influence (DUI) conviction and transferred from the local municipalities to the Treasury Department which subsequently deposits this monthly in the Fund.

AMOUNT COLLECTED: The surcharges started on January 1, 2001. As of June 30 2003, the Fund had raised \$ 1,808,632.35. The average monthly amount collected over the first 33 months has ranged from \$69,000 to almost \$ 72,000. **Appendix 1** is a record of monthly collections through June 30.

GOVERNANCE: The Fund is governed by a freestanding seven-member State board appointed for staggered terms by the Governor based on recommendations of the President of the Medical University of South Carolina. **Appendix 2** presents detailed Board information. Current members are as follows:

- 2 Medical Doctors from MUSC: Phanor L. Perot, Jr., M.D., PhD., and David Griesemer, M.D.
- 2 Medical Doctors Specializing or Significantly Engaged in the Treatment of Spinal Cord Injuries in S. C.: David L. Shallcross, M.D. (Greenville) and W. Daniel Westerkam, M.D. (Columbia).
- 2 Members Who Have a Spinal Cord Injury or Have Family Members with an Injury: Judge Charles L. Allen (Charleston) and Terry Peacock (Columbia)
- 1 At Large Member Who is a Medical Doctor and a Member of the South Carolina Medical Association: Brian G. Cuddy, M.D. (Charleston) who is also the elected Board Chairman.

ADMINISTRATION: The Fund is attached to the Medical University of South Carolina for administrative purposes, and the Board has appointed three staff Members:

- <u>ADMINISTRATOR</u>: J. Walker Coleman III, MBA., (20%) who oversees day-to-day Fund operations.
- <u>SCIENTIFIC DIRECTOR</u>: James S. Krause, PhD., (10%) who oversees the Scientific Fund operations including setting priorities, web page, and promoting the Fund statewide.
- <u>ASSOCIATE SCIENTIFIC DIRECTOR</u>: Mark S. Kindy, PhD., (5%) who organizes and oversees the process of soliciting and review of all project applications to the Fund.

PRIMARY OBJECTIVES:

- Advance knowledge of SCI injury repair and regeneration within the SC research community by encouraging physicians and scientists to apply expertise to SCI field.
- Foster collaborative interdisciplinary approaches to SCI research among SC hospitals, rehabilitative centers, research universities, and interested organizations.
- Nurture next generation of SCI researchers through support of young scientists and post-doctoral fellows.
- Improve well being and quality of life of individuals with SCI by research programs that prevent or treat the secondary conditions and consequences of SCI.
- Set budgets and administer funds for SCI research as mandated by the SC Legislative Act, and assure highest quality of research and commitment by investigators.

INITIAL FUNDING PRIORITIES:

- Translating basic and pre-clinical findings into clinical applications.
- Studying strategies to promote growth and survival at cellular level.
- Assuring efficacy of drugs or other interventions to prevent or reduce secondary injury and to provide insight to the mechanisms causing this progressive damage.
- Exploring the role of tissue transplantation in restoration of spinal cord function.
- Studying other disorders of spinal cord or brain that are reasonably expected to produce new insight into the mechanism or treatment of dysfunction following spinal cord injury.
- Defining anatomical, pathophysiological, inflamatory, and neurochemical characteristics of spinal cord injury or disease in well defined animal models.
- Elucidating biological and physical mechanisms that improve functions compromised by spinal cord injury, including dysfunction, chronic pain, and uncontrolled spasticity.
- Developing strategies to prevent or treat secondary complications from injury or disease of the spinal cord.
- Developing innovative rehabilitative strategies, services, or priorities to promote recovery and function following spinal cord injury.
- Developing public education programs to help decrease the occurrence of spinal cord injury by safety education, better safety practices, and decreased alcohol use as a contributing factor.
- Developing education programs for the injured and their families.

REQUESTS FOR PROPOSALS (RFP): There have been two rounds completed to date with plans for implementation of two more underway.

- <u>ROUND 01</u>—RFP issued 12/15/01 with 3/15/02 deadline. Received 12 proposals. A copy of this RFP is included in Fund's 01/02 Annual Report.
- <u>ROUND 02</u>—RFP issued 02/01/03 with 5/13/03 deadline. Added were five Funding Mechanisms: Primary Research, Care Access/Delivery, Career Development, NIH Grand Seed, and Research Result Dissemination. Received 12 proposals. **Appendix 5** contains a full copy of this RFP.
- <u>ROUND 02A</u>—RFP target issue date of October 03 for two special initiatives: faculty recruitment, and a study of need/feasibility for additional acute care rehabilitation facilities in SC.
- <u>ROUND 03</u>—RFP target issue date of December 03 for "to be determined" priorities.

ROUND 01 PROJECTS:

A first round of eight (8) research projects were approved and awarded funds on 09/01/02 for periods ranging from 12 to 18 months. Most are currently in the final months of activity. Following is summary information on each. The summary progress reports on their first ten months of activity (as of June 30, 2003) are presented in the ANNUAL REPORTS OF THE FUND SCIENTIFIC DIRECTORS which follows later in this Report.

• SCIRF0202—<u>Gene Expression Profiling of CNS Regions Implicated in a Mouse Model of Spinal</u> Cord Injury {\$ 85,466 for 18 months}

P.I.: Jacqueline F. McGinty, PhD Professor, Physiology and Neuroscience

Medical University of South Carolina

GOALS: This project will use an animal model to determine the damage-related changes in expression of genes. Specific brain regions will be characterized for changes in gene expression that are related to spinal cord motor functions and the emotional responses to pain.

• SCIRF 0302—<u>Statewide Outcome Assessment for Spinal Cord Injury (SOASCI): Assessing the</u> <u>Implementation and Effectiveness of Methylprednisoleone Protocol and Other Outcomes of Spinal</u> <u>Cord Injury In South Carolina</u> {\$ 123,349 for 12 months}

P.I.: Stephen J. Haines, MD, Professor and Chair Department of Neurological Surgery Medical University of South Carolina

GOALS: This project will provide definitive analysis of the effectiveness in the use of methylprenisoleone in the treatment of spinal cord injury. This project will establish and manage an extensive patient database for citizens of South Carolina.

• SCIRF 0602—<u>Assessment and Treatment of Musculoskeletal Pain in the Shoulder Girdle in SCI</u> <u>Through Surface-Recorded EMG and EMG Biofeedback</u> {\$ 91,990 for 18 months}

P.I.: Susan J. Middaugh, PhD, PT, Professor

Department of Anesthesia and Perioperative Medicine Medical University of South Carolina

GOALS: This project will evaluate the use of shoulder girdles in the treatment of musculoskeletal pain. This instrument is widely used and by assessing involuntary physiological measures the researchers hope to provide more accurate evaluations of this instrument than have been previously obtained.

• SCIRF 0802—<u>Spinal Modulation of the Nociceptive Pressor Reflex</u> {\$ 87,978 for 18 months} P.I.: Britt Wilson, PhD

Associate Professor, Pharmacology and Physiology University of South Carolina School of Medicine

GOALS: This study will examine the underlying cellular physiology mediating nociceptive pressor reflexes that are modified by spinal cord injury.

SCIRF 1102—<u>An In Vitro Model of the Reflex Arc as Applied to Spinal Cord Injury </u>{\$ 100,252 for 18 months}

P.I.: James J. Hickman, PhD Hunter Endowed Chair of Biomaterials Department of Bioengineering Clemson University

GOALS: This study will culture neurons on materials that will permit the establishment of a spinal reflex arc. This project will establish the proper materials for directing spinal cell growth with the goal of determining the best materials to be used in vivo to promote reinervation of damaged spinal cord.

• SCIRF 1202—<u>Taking Charge of Your Life</u>"—<u>Statewide Conference for People With Spinal Core</u> Injuries {\$ 29,476 for 12 months}

P.I.: Kermit L. Short, Executive Director

South Carolina Spinal Cord Injury Association

GOALS: This conference will bring recent information on the existing and future treatments for people suffering spinal cord injury. In addition, it will highlight research generated by funding from this program.

• SCIRF 1302—<u>Recruitment Assistance for James S. Krause, PhD as Chair of the Department of</u> <u>Rehabilitative Sciences at MUSC and Scientific Director of the SCI Research Fund {</u>\$ 125,000 for 12 months}

P.I.: James S. Krause, PhD (& Danielle N. Ripich, PhD)

Chair, Department of Rehabilitative Sciences

College of Health Professions

Medical University of South Carolina

GOALS: Dr James Krause was recruited in part to be Scientific Director of the SCI program. Thus, he was awarded one-time monies to develop an administrative infrastructure and establish epidemiological databases for spinal cord injuries in South Carolina.

• SCIRF 1402—<u>Recruitment Assistance for Mark S. Kindy, PhD as The Admiral Pihl Endowed</u> <u>Chair of Neuroscience at MUSC and Associate Scientific Director of the SCI Research Fund</u> {\$ 75,000 for 12 months}

P.I.: Mark S. Kindy, PhD

Admiral Pihl Endowed Chair of Neuroscience

Department of Physiology/Neuroscience

Medical University of South Carolina

GOALS: Dr. Mark Kindy was recruited in part to be the Associate Scientific Director of the SCI program, and will manage the SCI research pilot program. For this purpose, he was awarded one-time monies to purchase equipment for general use by researchers to evaluate the neurobiology of spinal cord injury.

ROUND O2 PROJECTS:

A second round of ten (10) projects was approved on July 11, 2003 for periods ranging from 12 to 18 months and scheduled to be awarded funds on September 1, 2003 or shortly thereafter.

• SCIRF 0103—<u>"Taking Charge of Your Life"</u>—Continuing Education for People With Spinal Cord Injury {\$65,000 for 12 months}

 P. I.: Kermit Short Executive Director, SC Spinal Cord Injury Association
 TYPE APPLICATION: Educational Project
 GOALS: Proposes to develop by primary prevention for SCI targeted at 16-30 year olds and secondary prevention for individuals with spinal cord injury.

• SCIRF 0303—<u>Development of a Laser Cell Micropatterning System for In Vitro Investigation of</u> <u>Adult Stem Cell Spinal Cord Injury Treatment</u> {\$149,890 for 18 months}

P. I.: Bruce Z. Gao, PhD., Assistant Professor

Department of Bioengineering Clemson University

TYPE APPLICATION: Grant-in-Aid

GOALS: To develop a laser cell micropatterning system to study the effects of endogenous and exogenous factors on the biological properties of adult stem cells.

• SCIRF 0403—In Vitro System to Determine Factors Promote Survival and Regeneration of Principal Neurons of the Spinal Cord {\$ 74,892 for 18 months}

P. I.: Peter Molnar, PhD., Research Assistant Professor Department of Bioengineering Clemson University

TYPE APPLICATION: Career Development Award

GOALS: To use an in vitro system of spinal cord injury as a high-throughput screen for pharmacological compounds that may protect neurons from impaired function.

• SCIRF 0503—<u>Determination of Occurrence and Causes of Death Among South Carolina Residents</u> with Traumatic Spinal Cord Injury {\$ 145,000 for 18 months}

P. I.: Elisabeth Pickelsimer, DA, Research Assistant Professor Department of Biometry and Epidemiology/Rehabo;otative Sciences

Medical University of South Carolina

TYPE APPLICATION: Grant-in-aid (special)

GOALS: Proposes to identify the portion of deaths and causes of death among persons with traumatic spinal cord injury whose injuries occurred in 1997 and 1998, and to compare these with a similar population based cohort from Colorado.

• SCIRF 0603—<u>The Prevalence of Upper Quarter Pain Among Persons with Long-term Spinal Cord</u> Injury {\$ 75,000 for 18 months}

P. I.: David Morrisette, PT, ATC, MTC, PhD. Associate Professor, Physical Therapy Education Program Department of Rehabilitative Sciences, Medical University of South Carolina

TYPE APPLICATION: Career Development Award

GOALS: Proposes to measure upper quarter pain (i.e., head, neck,

upper back) related to musculoskeletal problems among persons with spinal cord injury.

• SCIRF 0703—<u>Frequency, Severity, ad Risk Factors for Falls and Fall-Related Injuries Sustained by</u> <u>Individuals with Incomplete Spinal Cord Injury</u> {\$ 75,000 for 18 months}

P. I.: Sandra S. Brotherton, PhD.

Assistant Professor, Department of Rehabilitative Sciences Medical University of South Carolina

TYPE APPLICATION: Career Development Award

GOALS: Proposes to investigate risk factors for falls among persons

with incomplete spinal cord injury who ambulate in order to identify risk models that may be used in subsequent clinical and laboratory studies of balance and gait.

• SCIRF 0803—Estrogen Therapy for Spinal Cord Injury {\$ 137,592 for 18 months}

P. I.: Swapan K. Ray, PhD.

Assistant Professor, Department of Neurology

Medical University of South Carolina

TYPE APPLICATION: Grant-in-Aid

GOALS: To examine the protective effects of estrogen on Inflammation following spinal cord injury.

• SCIRF 0903—Theraputic Use of Minocycline for Spinal Cord Injury {\$ 24,988 for 12 months}

P. I.: Narayan R. Bhat, PhD., Professsor Department of Neurology Medical University of South Carolina

TYPE APPLICATION: Senior Investigator Award

GOALS: Models of spinal cord injury will be examined to determine the beneficial effects of minocycline (neuroprotective and anti-inflammatory activity) on neuronal damage.

• SCIRF 1003—Project M.I.L.E. (Mobile Inclusion Life-Training Evaluation)

P. I.: Michael E Godkin, Director,

Disabilities Resource Center, North Charleston

TYPE APPLICATION: Educational/Special

GOALS: A special seed award of up to \$ 3,000 for 12 months to secure consultation in developing a subsequent proposal fully responsive to the terms of the February 1, 2003 Spinal Cord Injury Fund RFP.

- SCIRF 1103—Anti-inflammatory Approaches for Spinal Cord Injury {\$ 75,000 for 18 months}
- P. I.: Ernest Barbosa, MD, Associate Professor Departments of Neurology and Pediatrics Medical University of South Carolina

TYPE APPLICATION: Career Development Award

GOALS: To use models of spinal cord damage to determine the role of inflammation in injury and to evaluate the effectiveness of anti-inflammatory drugs in the protection from injury.

SUMMARY BUDGET INFORMATION:

Following is current information as of July 11, 2003 (date of final Board Meeting of Fiscal Year that took place several days after the year ended). **Appendix 4** contains much more detailed budget information and budgets are further discussed in the ANNUAL REPORT OF THE FUND ADMINISTRATOR as presented later in this Report.

- <u>INITIAL 18 MONTHS (01/01/01--06/30/02)</u> expended \$ 30,675 for initial organization and implementation.
- <u>FY 03 (07/01/02—6/30/03)</u> expended \$ 349,562 (\$ 27,624 for Program Administration; \$ 18,987 in Research Development; and \$ 302,951 for initial months of Round 01 Research Projects).
- <u>FY 04 (07/01/03---6/30/04)</u> initial budget estimate of \$ 1,333,110 (\$ 29,836 for Program Administration; \$ 54,352 for Research Development; \$ 418,560 for completion of Round 01 Research Projects; and \$ 830,362 in total commitments for Round 02 Research Projects). Assuming continued DUI collections at current levels, there would be approximately \$ 930,000 available by year end for Round 02A and 03 research projects as well as to start the following year's administrative and scientific components.

~ANNUAL REPORT OF FUND ADMINISTRATOR~

NARRATIVE HIGHLIGHTS: 2002/2003 witnessed a steady progression of activity, the highlights of which follow:

- September: Based upon approvals made at the May 31, 2002 Board meeting and subsequent mail approvals of June 21 and August 15, eight (8) Round 01 projects were awarded funds for periods of twelve to eighteen months and initiated activity. This was preceded by an intense two month period of activity with the MUSC Office of Research and Sponsored Programs as well Office of Grants Accounting instrumental in developing and implementing a fully accountable system for awarding, expending, and monitoring of all funds. These Offices are to be commended for the ongoing administrative support which has been donated at no charge.
- October: The first Fund ANNUAL REPORT was completed and distributed to a mailing list of 550 throughout South Carolina. Board Chair Cuddy made a presentation on the Fund at the annual meeting of the South Carolina Spine Society. Dr. Peter Kalivas resigned as Fund Scientific Director and the following scientific staff members assumed office as approved by the Board: Dr. James Krause, Scientific Director, and Dr. Mark Kindy, Associate Scientific Director (see Appendix 8 for information on both).
- November: Visit of Board Chair, Scientific Director, and Administrator with leaders of the South Carolina Department of Vocational Rehabilitation and the South Carolina Department of Disabilities and Special Needs. The purpose of such contact was informing others about the Fund as well as seeking input as to needed future Fund priorities. Both agencies emphasized the need for more acute care comprehensive inpatient rehabilitation facilities in the state, particularly now that MUSC had closed its unit.
- **December:** Fund Board met and approved Round 02 funding schedule and draft RFP as well as additional specifications for the scientific review process of proposals received. The formal review process was organized by the Scientific Directors and is fully presented in **Appendix 6**.
- February: RFP for Round 02 (see Appendix 5) projects approved by the Board and widely disseminated (basic mailing list of 90 augmented by email and hand distributions at the state research universities plus later posting on the Fund Web page as noted below). This added five specific "Funding Mechanisms" to facilitate greater interest and participation while directly furthering basic Fund goals: (1) Primary Research Grants; (2) Health Care Needs Grants; (3) Career Development Grants; (4) Small Pilot Incentive Grants; and (5) Results Dissemination Grants. Also a press conference was held in Charleston with two of the Fund's original legislative sponsors, Representative Chip Limehouse and Senator Arthur Ravenel. Its several purposes included public thanks to the Fund's legislative originators; providing the Press with latest information on Fund progress/status; introducing the two new scientific staff members; and announcing release of the Round 02 RFP. Finally in February, the Fund Board Chair gave a progress report to the MUSC President's Advisory Council which included a statement of appreciation for the extensive support from MUSC that had made possible the Fund's successful organization and initial implementation. This was followed by a meeting with potentially interested MUSC scientific investigators.

- April: Several months of development and formatting by the Scientific Director and colleagues resulted in launching of the Fund Web Page featuring the Round 02 RFP as its debut cover screen (Appendix 7 presents additional Web Page information).
- May: Successful statewide conference held with Fund support (South Carolina Statewide Conference for People with Spinal Cored Injury: "Taking Charge of Your Life"). Fund Chair Cuddy made welcoming remarks and both scientific directors attended. See following Annual Report of Fund Scientific Directors for additional details. Twelve(12) Round 02 project proposals were received by the RFP deadline, and the scientific review process activated. Each proposal received reviews by three independent reviewers plus summary reviews by the Scientific Director and Associate Director.
- June/July: Fund Chair Cuddy met with the MUSC Provost to discuss future Fund plans as well as MUSC support resources and mechanisms. Progress reports on all Round 01 projects were received. The Fund Board met and approved ten (10) Round 02 projects for funding; priorities and timeline for a Round 02A of projects to be issued in the Fall (faculty recruitment, and an acute care rehabilitation services need/feasibility study); set preliminary objectives timelines for a Round 03 RFP; and approved year end 03 budget as well as the proposed 04 budget (see Appendix 4).

BUDGET DISCUSSION: The FY 02-03 budget witnessed the first year of research project activity with final budget and expenditures as follows:

	BUDGET	EXPEND.
PROGRAM ADMINISTRATION	\$ 38,755	\$ 27,623.95
RESEARCH DEVELOPMENT	\$ 37,852	\$ 18,987.08
FUND ROUND 01 PROJECTS	\$ 720,511	\$ 302,951.23
SCIRF 0202 McGinty	\$ 85,466	\$ 46,685.30
SCIRF 0302 Haines	\$ 123,349	\$ 57,852.09
SCIRF 0602 Middaugh	\$ 91,990	\$ 46,671.89
SCIRF 0802 Wilson	\$ 89,978	\$ 10,745.24
SCIRF1102 Hickman	\$ 100,252	\$ 48,824.34
SCIRF 1202 Short	\$ 29,476	\$ 29,422.27
SCIRF 1302 Krause	\$ 125,000	\$ 9,315.59
SCIRF 1402 Kindy	\$ 75,000	\$ 53,434.51
FUND ROUND 02 PROJECTS	\$ 985,882	\$ 0.00
TOTAL 02-03 BUDGET/EXPEND.	\$1,783,000	\$ 349,562.26

The "Budget" column figures above include both expenditures and obligations (projects awarded or to be awarded funds). The "Expenditure" column presents actual final expenditure figures. Program Administration was able to save over \$ 10,000 through not hiring a part-time Staff Assistant thanks to the assistance volunteered by several offices of MUSC including the Office of the President, Research Office,

Grants Accounting, the MUSC Medical Center Marketing Department that coordinated the Annual Report and RFP statewide mailings, and the College of Health Professions which designed and implemented the Web page. Savings in the Research Development core were a combination of the two Scientific Director positions not coming on board until October as well as a decision not to hold scientific sessions at the Annual Conference this year as the Round 01 projects were just starting and would not be ready for meaningful reports until at least a full year of activity. None of the Round 01 projects actually were implemented until September at the earliest, and several of the twelve-month projects as well as most of the eighteen-month projects subsequently requested and received six-month extensions. The Round 02 project figures were obligated as soon as approved by the Board, but would not be actually awarded until September 2003 at the earliest. Any and all savings from any part of the budget are used to increase the amount of funds available for the next round of research projects.

The Board approved the following budget for FY 03-04 as well as the additional estimated amount available for Round 02A and 03 projects based upon a detailed cash analysis which exceeds the \$800,000 year end "Reserve Target" set by the Board to assure that sufficient funds are always available to fully meet Fund budget commitments. Given the constant variation of monthly totals received through DUI collection (so far ranging from averages of \$72,000 to \$69,000) the Board established the Reserve Target to assure full fiscal control and accountability.

PROGRAM	<u>A ADMINIS</u>	<u>TRATION</u>			<u>\$_29,836</u>
RESEARC	<u>\$ 54,352</u>				
ONGOING ROUND 01 PROJECTS					\$ 418,560
FUND RO	\$ 830,362				
	12 Month Pr	rojects		18 Month Projec	<u>ts</u>
1.	Short	65,000	3.	Gao	149,890
9.	Bhat	24,988	4.	Molinar	74,892
10.	Goodkin	3,000	5.	Pickelsimer	150,000
			6.	Morrisette	75,000
			7.	Brotherton	75.000
			8.	Rav	137.000
			11.	Barbosa	75.000
	TOTALS	92,988			737,374
EST. 03-04 SCI ANNUAL BUDGET: \$1,333,110					
EST. AVAIL. ROUND 02A & 03 PROJECTS \$					\$ 930,313

Appendix 4 contains more detailed information about FY 02-03 and FY 03-04 budgets as well as the complete Cash Analysis from Fund inception used as basis for the FY 03-04 budget.

GOALS FOR FY 03-04:

Among the goals set by the Fund Administrator for the upcoming year are:

- Set up appropriate fiscal administrative/oversight mechanisms and award all Round 02 projects.
- Provide ongoing fiscal monitoring and oversight of Round 01 projects.
- Continue series of meetings between Fund Board and State leaders, including Office of the Governor, for two-way information sharing.
- Complete and provide statewide distribution of the S. C. SPINAL CORD INJURY RESEARCH FUND ANNUAL REPORT— 2002/2003.
- Organize and convene a meeting of shareholders and statewide leaders to discuss need for additional acute care rehabilitation services with target of a possible Fund Round 02A RFP component inviting the S. C. research universities to formally study the need and develop possible implementation plans.
- Help the Scientific Directors complete Round 02A and Round 03 RFPs, followed by coordination of their statewide dissemination.
- Assist the Scientific Director with ongoing updating of the Fund Web page.
- Receive Round 02A and Round 03 projects and assist the Scientific Directors with the scientific review and dissemination of such findings to the Board.
- Convene at least two meetings of the Board during the year: the first of which will finalize the new RFPs, and the second will review resultant research project proposals.
- Continue monitoring of monthly DUI collections, working with the Board to make adjustments as may be necessary to insure ongoing fiscal solvency and oversight.
- Maintain updated power point and slide Fund overview presentations for use by the Board and staff at appropriate meetings and events.

~ANNUAL REPORT OF FUND SCIENTIFIC DIRECTORS~

REPORT OF SCIENTIFIC DIRECTOR:

As Scientific Director of the South Carolina Spinal Cord Injury Research Fund, it is with great pleasure that I am able to summarize the many accomplishments of the Fund activities over the past year. We have received progress reports for the first year projects. Exceptional progress is being made in both basic and applied science areas, with the highlight of the first year being a conference by the South Carolina Spinal Cord Injury Association on May 1, 2,003 in Columbia. This SCSCIRF supported conference was attended by 160 participants, a large portion of whom had a SCI or were family or friends of those with SCI.

Both the Scientific Director and Associate Scientific Director were recruited with assistance from the fund.

In order to better meet the needs of researchers, we have established five separate funding mechanisms. These mechanisms were intended to support a broad range of research activities and diverse researchers who are at different points in their careers. In additional to basic grants, new mechanisms were added to fund pilot studies for senior investigators, career development awards for new investigators, and educational projects. A special emphasis was placed on addressing the specific needs of people with SCI in the state of South Carolina.

We are pleased to not only have received applications in each area, but that there was at least one successful applicant applying for each type of grant. There was a balance between basic science and applied science and we again will be supporting the dissemination of information directly to consumers.

In the upcoming year we look forward to building upon the success of the Fund and establishing new priorities to meet additional needs. Two of the highest priorities are to increase the number of highly qualified spinal cord injury researchers in the state of south Carolina through assistance in recruitment efforts and the funding of a research special project that will address the needs for quality rehabilitative care within the state of South Carolina. This second priority will perform a needs assessment to identify the most feasible way of enhancing the quality of rehabilitation services for newly injured people with spinal cord injury.

As we look to these new challenges, we will continue our unwavering commitment to the well being of South Carolina citizens with spinal cord injury, their friends, and family members. In doing so we will continue to rely on the support of the citizens of the state of South Carolina, the many experts who have assisted us either by their participation on the Board of Directors or as scientific reviewers, and the people with spinal cord injury who live every day with the issues that the Fund was developed to address.

Thank you for your continued support and we move forward with great optimism that with each passing year the lives of citizens in South Carolina will be improved by virtue of the accomplishments of the work being done through the Fund.

REPORT OF ASSOCIATE SCIENTIFIC DIRECTOR:

The overall goal of the South Carolina Spinal Cord Injury Research Fund is to provide the necessary resources to develop both basic and applied science programs in South Carolina. The Fund was established in 2001 to promote the individual and collaborative studies on injuries to the spinal cord that result in paralysis or other loss of neurologic function. The charge of the Fund is to provide support in the discovery, translation and development of pharmacologic, gene or cellular therapeutic strategies to limit the amount of damage, stimulate repair mechanisms and promote regeneration and following spinal cord injury. In addition, other responsibilities are to identify biomarkers that can be used to track the pathophysiological process and the effectiveness of neuroprotective therapies in spinal cord injury. Finally, the identification of innovative clinical trial protocols, therapeutic parameters and improvement in rehabilitation strategies to assist in the recovery from spinal cord injury. The Fund has provided support to individuals around the state and has been instrumental in the recruitment of scientists to South Carolina institutions of higher education for the advancement of science in the area of spinal cord injury. Future development of these programs will have significant impact on the prevention and recovery from spinal cord injuries.

SUMMARY PROGRESS REPORTS OF ROUND 01 PROJECTS:

Following is information received on progress of the funded Round 01 projects as of July 30, 2003. All will complete their work in the upcoming Fiscal Year.

<u>SCIRF0202</u>—Gene Expression Profiling of CNS Regions Implicated in a Mouse Model of Spinal Cord Injury:

The specific hypothesis that is being examined in this proposal is that development of chronic pain after SCI involves activation of a variety of opioid-related genes and signaling pathways that leads to long-term changes in the medial pain system that perpetuate the dysesthetic qualities of SCI-induced neuropathic pain. Based on these changes, the longterm goal is to identify novel therapeutic targets to treat this debilitating condition. During the following 2 weeks, 40% of the mice injected with quisqualate exhibited spontaneous pain behaviors, i.e., excessive grooming directed at the site of injury. The tissue was frozen and sent to MUSC. The RNA was extracted and 3 samples were pooled in order to obtain adequate RNA per hybridization probe. The RNA quality was assessed by gel electrophoresis and on a Hewlett Packard Bioanalyzer. Good quality RNA was biotin-labeled in preparation for Affymetrix GeneChip hybridization and analysis which was performed in the MUSC Microarray Facility. To date, 2 arrays per group have been hybridized. We are awaiting the next shipment in order to bring the number of samples in each group to 4. At that time, Dr. Grier Page, formerly of the Biometry and Epidemilogy Dept at MUSC and now at U Alabama, Birmingham, and who is skilled in analysis of large microarray datasets, will perform a multiple comparison analysis of all the microarray samples. Therefore, at this time, we only have individual comparisons that are not a reliable index of changes in gene expression. Significance: Because the mechanisms of chronic pain in general, and in particular after SCI, are far from clear, the study of gene and protein expression in specific components of the CNS of animals that develop post-SCI pain will contribute to a better understanding of both the intrinsic mechanisms underlying chronic pain as well as to future development of novel therapeutic strategies to treat this debilitating condition. Plans: Finish array hybridizations for cingulate and retrosplenial cortex, perform array analyses, identify candidate genes and verify by in situ hybridization. Perform array procedures on all thalamic and periaqueductal gyra samples. Prepare data for presentation and publication.

SCIRF 0302—Statewide Outcome Assessment for Spinal Cord Injury (SOASCI): Assessing the Implementation and Effectiveness of Methylprednisoleone Protocol and Other Outcomes of Spinal Cord Injury In South Carolina:

The overarching goal of the Statewide Outcome Assessment for Spinal Cord Injury (SOASCI) is to improve the lives of persons with SCI in South Carolina. To attain this goal, determining the general health status, functional limitation, community reintegration, service utilization, and other related outcomes of persons with SCI is critical. By August 15, 2002, we had completed the telephone survey tool, however, the MUSC IRB restricted the recruitment and interview process. By October 31, 2002, the project had completed abstracting 90% of the records of persons with traumatic spinal cord injury (TSCI). The first interviews began in March of 2003. Of the 75 individuals there was information on, 56 were interviewed, 17 had died and 2 refused to participate. We are waiting of the information from 96 patients. We will make extra effort to identify the factors that contribute to a higher death rate within one year after discharge. Despite the challenges posed by the disallowance of verbal consent, the project continued to strive for higher participation rate by using various approaches including sending out multiple reminders, seeking the assistance of Department of Disabilities and Special Needs (DDSN) case managers, and seeking the support of advocacy organizations to encourage persons with TSCI to respond to the consent letter. SOASCI is organized to promote collaboration among the various researchers at MUSC. The two departments in the College of Medicine, Department of Neurological Surgery and Biometry/Epidemiology, have worked closely to improve the methodology of the proposed research and to identify alternative strategies to the challenges posed. The surveillance data, which have been incrementally developed since June 1992 under the auspices of the DDSN and the National Center of the Injury Prevention and Control, CDC, remain the key component of this research endeavor.

<u>SCIRF 0602—Assessment and Treatment of Musculoskeletal Pain in the Shoulder Girdle in SCI</u> <u>Through Surface-Recorded EMG and EMG Biofeedback:</u>

During the first year of the proposal, IRB protocols were submitted to the IRB for approval, equipment was ordered and extensively tested for performance. Intensive work was carried out with engineering consultants to: (1) complete major purchase of physiological signal analysis software and associated computer hardware; (2) configure and calibrate equipment; (3) carry out the extensive computer programming required for the study protocols; (4) select optimal parameters for multichannel surface EMG recording, analog to digital conversion and quantification. A technical job was created and the person was hired on January 6, 2003. Testing of the proposed study protocols was performed and written materials prepared. Major recruitment activities were initiated in April of 2003. A recruitment flyer was developed and approved by the IRB. An application was submitted to the MUSC IRB and Charleston VAMC to add the VAMC to the study as a recruitment site. Dr. T. Lynn McFall, Chief of Physical Medicine and Rehabilitation at the VA, was added as a co-investigator. On May 1, the PI and research technician attended the S.C. Spinal Cord Injury Conference in Columbia and presented a poster of the research study. On May 15th, the first study participant was entered into the study. To date, 4 individuals have entered the study. Other individuals are scheduled to start in July, and regular enrollment of the planned 1-2 new participants per week is not underway. Data entry and data analysis are being developed and implemented. Initial data has been collected on the EMG recordings from selected cervical and shoulder muscles and differences can be detected. Enrollment will continue and the study is progressing.

SCIRF 0802—Spinal Modulation of the Nociceptive Pressor Reflex:

The primary goal of this proposal is to establish a model to determine if reflex cardiovascular increases evoked by stimulation of somatic (skin and skeletal muscle) afferent neurons are altered by peripheral inflammation and/or injury. The long-range goal is to determine the mechanism(s) by which this aug-

mentation occurs. The model used is the decerebrated Guinea Pig. Using this model, the animals were subjected to a somatic heat stimulus (paw warming) and the reflex cardiovascular response was measured. These animals showed an increase in the mean arterial blood pressure (MAP) with increasing temperature. Females showed a smaller change, suggesting a gender difference in the reflex cardiovascular responses evoked by heat. A second study to examine the effects of inflammation of MAP. The Guinea Pig model demonstrated the reflex rise in MAP elicited by mechanical stimulus was elevated 60 minutes after ankle inflammation. More work is needed to confirm this initial observation, and also to determine if the reflex responses to non-noxious stimuli are augmented and whether or not a gender difference exists. Another set of experiments are underway to examine the effects of opiate peptide synthesis in dorsal root ganglion using viral vectors. It is hypothesized that increasing opiate synthesis will decrease the sensitivity of the animals to the stimuli. This may provide an important treatment strategy for conditions such as autonomic dyreflexia.

SCIRF 1102-An In Vitro Model of the Reflex Arc as Applied to Spinal Cord Injury:

The major hypothesis for this work is that by studying the development of neural circuitry in a minimalistic model, we can apply what we have learned to develop new paradigms to restore function in the damaged spinal cord. This model is composed of individually connected cells to determine when and where the synaptic connections occur and which cells are involved. We have developed the spinal cord isolation and purification procedures in the lab and grown spinal cord cells on various matricies. In addition, we have shown that embryonic dorsal root ganglion (DRG) cells can be cultured in our defined system. The DRGs can be co-cultured with muscle cells in a serum free defined media we have developed. Experiments are underway for muscle to DRG recordings. We have cultured both pure and mixed populations of motoneurons and muscle in a defined serum free media. In addition, both motoneurons and DRGs have been grown with muscle cells to provide us with the possibility of multiple model systems. Our next goal is to pattern the cells on DETA (trimethoxysilylpropyl-diethylenetriamine) and couple it in a MEMS (microelectromechanical system) chamber.

<u>SCIRF 1202</u>—<u>Taking Charge of Your Life</u>"—<u>Statewide Conference for People With Spinal Core</u> <u>Injuries</u>

The First Statewide Conference for people with Spinal Cord Injury and their "Circle of Friends" met at the Sheridan Convention Center on May 1, 2003 in Columbia, SC. It was indeed a historic occasion with 160 participants, 15 exhibitors and representatives from agencies and providers of SCI services throughout the state. The highlights of the conference were the enthusiastic individuals with spinal cord injury that "soaked up" invaluable information that educates and empowers our people to "Take Charge of Their Own Lives". A diverse group of individuals interested in learning about staying healthy and about prevention and methods of improving their lives was enthusiastically supported by the participants. Our future plans are to hold a conference on May 7, 2005 which will concentrate n Spinal Cord Injury Health Care and Research issues that are helping in improving the quality of life for the SCI.

<u>SCIRF 1302—Recruitment Assistance for James S. Krause, PhD as Chair of the Department of Rehabilitative Sciences at MUSC and Scientific Director of the SCI Research Fund:</u>

The first nine months of my tenure at MUSC and as Scientific Director of the Spinal Cord Injury Research Fund (SCSCIRF) have been almost solely committed to administrative activities, including those related to revising the request for proposals, types of award mechanisms, and facilitating the review process. These activities have been very successful as we have elicited and obtained in each of the five target areas. The majority of the start-up funds from the SCSCIRF were dedicated to the development of a motion analysis laboratory. Space for this laboratory has been secured in the new CHP complex which should be completed in about 20 months. However, we have not yet used the \$75,000 to purchase equipment, as we are hoping to find additional funds that will allow us to purchase more pieces of equipment. We are trying to raise matching funds for this purpose. Another activity was related to the development of the website, which has been competed. Work is underway to secure participants for research studies. We have established monthly work groups to address these issues. I attended the South Carolina Spinal Cord meeting in Columbia.

SCIRF 1402—Recruitment Assistance for Mark S. Kindy, PhD as The Admiral Pihl Endowed Chair of Neuroscience at MUSC and Associate Scientific Director of the SCI Research Fund:

Over the last 11 months of this project, the PI has established a Spinal Cord Research Facility at the Medical University of South Carolina. We have purchased a spinal cord impact machine that is the standard in spinal cord injury. In addition, we have purchased the instruments and reagents necessary for execution of the program. The PI has trained his personnel in the proper handling and surgical procedures for the spinal cord injury, and have begun studies on the role of INK pathway in spinal cord injury. The facility has begun to provide services to the MUSC and Clemson community. Dr. Banik in the Department of Neurology at MUSC has started to do work using the spinal cord impactor. In addition, we have started collaborative work with Dr. James Hickman at Clemson to study the role of JNK in spinal cord injury as well as in ALS and to develop an in vitro model of spinal cord injury using transgenic and gene knockout mice. This work has generated a proposal entitled "In vitro model of the Reflex Arc for Spinal Disorders" which was submitted to the NIH Biotechnology Research Partnership Program in January. The grant scored well and will most likely be funded in the next cycle. We have continued to work on the JNK pathway in spinal cord injury and have shown that JNK deficient mice have smaller damage to the spinal cord than wildtype mice. In addition, the use of SP600125, a non-specific inhibitor of the INKs, reduced damage to the spinal cord. These studies will continue to determine the mechanisms and upstream pathways that contribute to this protective effect. Additionally, Dr. Kindy has committed time to the South Carolina Spinal Cord Injury Fund to help coordinate the second round of request for applications.

APPENDIX 1—SCIRF 02/03 ANNUAL REPORT Cumulative DUI Collections

DUI FINE COLLECTIONS FOR THE SCIR FUND SINCE INCEPTION OF FUND {running total last updated 06/30/03}

	~2001~	~2002~
Jan.	\$ 4,285.00	43,035.45
Feb.	10,774.90	67,213.13
Mar.	26,570.32	110,797.84
Apr.	41,513.91	68,851.75
May	42,606.41	73,028.36
June	50,170.12	82,816.19
July	54,159.28	58,312.09
Aug.	62,635.31	76,064.34
Sept.	53,845.08	60,925.72
Oct.	61,642.97	67,764.04
Nov.	60,039.88	69,631.96
Dec.	<u>63,716.54</u>	<u>65,987.31</u>
	\$ <u>531,929.72</u>	\$ <u>849,428.11</u>
	~2003~	~Cumulative~
Jan.	56,063.61	1,437,421.44
Feb.	79,548.82	1,516,970.26
Mar.	75,621.55	1,592,591.81
Apr.	67,871.19	1,660,463.00
May	69,933.84	1,730,396.84
June	64,092.46	1,794,489.30
Extra(6/30/03)	14,143.05	\$1,808,632.35

APPENDIX 2—SCIRF 02/03 ANNUAL REPORT Detailed Board Member Information

(Individuals and Terms as initially appointed by Governor 03/08/01)

~2 MEDICAL DOCTORS FROM THE STAFF OR FACULTY OF THE MEDICAL UNIVERSITY OF SOUTH CAROLINA (both initially appointed for 2 year terms, subsequently 4 year terms).

- * <u>Phanor L. Perot, Jr, M.D., PhD.</u>, Charleston, SC—Board Certified in Neurological Surgery and Professor Emeritus of Neurosurgery at the Medical University of South Carolina and past Department Chairman. (*Term: March 08, 2003—2007*)
- * <u>David Griesemer, M.D.</u>, Charleston, SC—Board Certified in Neurology and serves as Chairman of the MUSC Department of Neurology and Associate Professor of Neurology and Pediatrics. (*Term: March* 08, 2003—2007)

~2 MEDICAL DOCTOR SPECIALIZING OR SIGNIFICANTLY ENGAGED IN THE TREATMENT OF SPINAL CORD INJURIES IN SOUTH CAROLINA (both appointed for 4 year terms).

- * <u>David L. Shallcross, M.D.</u>, Greenville, SC—Board Certified in Physical Medicine and Rehabilitation and conducts a private practice, Upstate Medical Rehabilitation, as well as serves as Medical Director of the inpatient rehabilitation unit at BonSecours St. Francis Health System in Greenville. (*Term: March 08, 2001—2005*)
- * <u>W. Daniel Westerkam, M. D.</u>, Columbia, SC—specialist in Physical Medicine and Rehabilitation who is Director of Rehabilitative Services at Palmetto Richland Memorial Hospital as well as Associate Medical Director at HealthSouth Rehabilitation Hospital in Columbia. (*Term: March 08*, 2001–2005)

~2 MEMBERS WHO HAVE A SPINAL CORD INJURY OR WHO HAVE A FAMILY MEMBER WITH A SPINAL CORD INJURY (4 year terms, one will serve only 2 years for the first term).

- * <u>Charles L. Allen</u>, Mt. Pleasant, SC—spinal cord injury survivor, Charleston Municipal Court Judge and teaches at Trident Technical College. (*Term: March 08, 2003—2007*)
- * <u>Terry Peacock</u>, Columbia, SC—mother of a spinal cord injury victim who works for the Office of Minority Affairs of the SC Department of Health and Environmental Control. (*Term: March 08*, 2001—2005)

~1 AT LARGE MEMBER WHO IS A MEDICAL DOCTOR AND A MEMBER OF THE SOUTH CAROLINA MEDICAL ASSOCIATION (initial term of 3 years, 4 year terms thereafter).

* <u>Brian G. Cuddy, M.D</u>., Charleston, SC—Board Certified Neurosurgeon in private practice, Clinical Associate Professor of Neurosurgery at MUSC, and directly involved in establishing the Spinal Cord Injury Research Fund. (*Term: March 08, 2001—2004*)

APPENDIX 3—SCIRF 02/03 ANNUAL REPORT Board Meeting Agendas

~AGENDA~ SPINAL CORD INJURY RESEARCH FUND BOARD 2:00 pm Friday December 6, 2002—University Board Room 2nd Floor Administration/Library Building MUSC

Roll Call

Approval of Minutes

Report of Chairman-11/21/02 Visit with State Leaders

Report of Fund Administrator-Annual Reports, Budget Update, Press Conference

Report of Scientific Director—Progress Report (Including Plans for Participation in May 03 Conference), Web Site, Proposed Round 02 Priorities, Adjustments to Position Description Approved on 03/22/02

Report of Associate Scientific Director

Recommended Round 02 Review Process/Procedures, Recommended Round 02 Review Process Timetable, Draft Position Description for Associate Scientific Director

Other Old Business

New Business

Date of Next Meeting Other New Business

Adjourn

~AGENDA~ SPINAL CORD INJURY RESEARCH FUND BOARD 1:00pm Friday July 11, 2003—University Board Room 2nd Floor Administration/Library Building MUSC

1. Roll Call

2. Group Photograph

2. Approval of Minutes of 12/06/02 Meeting

3. Formal Endorsement of Board Actions Since 12/06/02

- * Round 02 Request for Proposals (RFP) as Issued February 15 and amended
- * Revision to 03 Budget Estimate
- * Revised Application Timeline with RFP Clarification
- * Review Process/Procedures/Lists of Approved Scientific Reviewers
- * Fund Web Page

4. Report of Chairman

- * Presentation at S. C. Spine Society Annual Meeting
- * Press Conference (February 21)
- * Presentation to MUSC President's Council and Meeting with MUSC Researchers (February 26)
- * Presentation at Spinal Cord Injury Conference (May 1)
- * Meeting with MUSC Provost (June 20)
- * Meeting with Politicians & State Leaders
- * Meeting to Discuss Need for Additional Rehabilitation Unit
- * Board Member Appointment Recommendations
- Plans/priorities/proposed timelines for Round 03 Projects & Possible Mid-Year Recruitment initiatives
- * Plans for Scientific Session to Present Round 01 Accomplishments

5. Report of Fund Administrator

- * Update on Fund Collections Through 6/30/03
- * Year End 03 Budget
- * Proposed 04 Budget
- * Extension Requests For Round 01 Projects
- * Proposed Policy for Projects Extensions with Carryover Funds
- * Proposed Format for Annual Report
- * Proposed Financial Audit

6. Report of Scientific Directors

- * Completion and Issuing Round 02 RFP
- * Further Refining the Scientific Review Process and Recommending Additional Scientific Reviewers
- * Formatting, Implementing (April), and Ongoing Oversight of Fund WEB Page
- * Revised Position Descriptions for Scientific Director and Associate Scientific Director
- * Progress Reports Received For Round 01 Projects
- * Receiving 12 Round 02 Project Proposals
- * Organizing and Conducting the Round 02 Scientific Review Process
- * Plans for Statewide Research Promotion and Grant Solicitation
- * Other Activities/Accomplishments in Advancing the Fund

7. Review of Round 02 Project Proposals (Executive Session)

- * Basic Science Projects-Dr. Mark Kindy
 - 3. Gao PI-Clemson
 - 4. Molnar PI—Clemson
 - 8. Ray PI—MUSC
 - 9. Bhat PI—MUSC
 - 11. Barbosa PI-MUSC
 - 12. Banik PI—MUSC
- * Applied Science Projects-Dr. James Krause
 - 1. Short PI-Spinal Cord Injury Assoc.
 - 2. Denkaus PI-MUSC
 - 5. Picklesimer PI-MUSC
 - 6. Morrisette PI-MUSC
 - 7. Brotherton PI—MUSC
 - 10. Godkin PI—Disabilities Resource Ctr.

8. Finalizing Timeline/Process/Priority Development for Round 03 Projects

9. Date of Next Meeting

10. New Business

11. Adjourn

APPENDIX 4—SCIRF 02/03 ANNUAL REPORT Fund Budgets

~FISCAL YEAR 02-03 BUDGET/EXPENDITURES SCI RESEARCH FUND {actual final expenditures}~

			BUDGET	EXPEND.
I.	PROGRAM ADMINISTRATION	\$	<u>38,755</u>	\$ <u>27,623.95</u>
	PERSONNEL (Incl. F. B. at 26.6%)		34,355	
	Fund Administrator (20%) and Staff Assistant (20%) BOARD MEETING TRAVEL/MEALS/REFRESHMENTS Avg. 3 Board 300 mi. three times year @ .345 mi= \$ 300 Meals at official meetings and while traveling (\$20x3x3)=\$180	5	900	
	Meals/Refreshments for Board Meetings (\$14x10peoplex3)=\$4 OTHER	20	3,500	
	Printing stationery/envelopes (second run of 2,500)= \$ 500 Printing letters, RFPs, Guidelines, insert card, report= \$200 Printing first Annual Report=\$ 1,500 Mail processing (Target Mail)/Postage of any major mailouts=\$	5200		
	Other mailing throughout the year (RFPs, reports)= \$ 100 Meeting support materials (visuals/photos)= \$ 500 Photocopy and basic office supplies=\$ 500			
II.	RESEARCH DEVELOPMENT	\$	<u>37,852</u>	\$ <u>18,987.08</u>
	PERSONNEL (Incl. F. B. at 26.6%)		27,852	
	Scientific Director (10.1%) and Assoc. Dir (5%) ANNUAL CONFERENCE SCIENTIFIC SESSIONS		10,000	
III	.FUND ROUND 1 PROJECTS	\$	<u>720,511</u>	\$ <u>302,951.23</u>
	SCIRE 0202 McGinty		85.466	\$ 46.685.30
	SCIRF 0302 Haines		123,349	\$ 57,852.09
	SCIRF 0602 Middaugh		91,990	\$ 46,671.89
	SCIRF 0802 Wilson		89,978	\$ 10,745.24
	SCIRF1102 Hickman		100,252	\$ 48,824.34
	SCIRF 1202 Short		29,476	\$ 29,422.27
	SCIRF 1302 Krause		125,000	\$ 9,315.59
	SCIRF 1402 Kindy		75,000	\$ 53,434.51
V.	FUND ROUND 2 PROJECTS	\$	<u>985,882</u>	\$ <u>0.00</u> *
T	DTAL 02-03 SCI ANNUAL BUDGET:	\$	1,783,000	\$ <u>349,562.26</u>

*NOTE: Round 02 Project not approved (07/11/03) or awarded (09/01/03) until following FY.

~FISCAL YEAR 03-04 BUDGET, SCI RESEARCH FUND~

{approved 07/11/03 BOARD MEETING and subsequently adjusted to reflect actual FY 02/03 year end expenditures}

I. <u>PROGRAM ADMINISTRATION</u> PERSONNEL (Incl. F. B. at 26.6%) Fund Administrator (20%)			<u>\$</u>	<u>29,836</u> 25,436
BOARD MEETING TRAVEL/MEALS/RE Avg. 3 Board 300 mi. three times year @ \$.345 mi= Meals at official meetings and while traveling (\$20) Meals/Refreshments for Board Meetings (\$14x10pe	BOARD MEETING TRAVEL/MEALS/REFRESHMENTS Avg. 3 Board 300 mi. three times year @ \$.345 mi= \$ 300 Meals at official meetings and while traveling (\$20x3x3)=\$180			
OTHER Printing stationery/envelopes (second run of 2,500) Printing letters, RFPs, Guidelines, insert card, repor Printing Second Annual Report=\$ 1,500 Mail processing (Target Mail)/Postage of any major Other mailing throughout the year (RFPs, reports)= Meeting support materials (visuals/photos)= \$ 500 Photocopy and basic office supplies=\$ 500	Meals/Refreshments for Board Meetings (\$14x10peoplex3)=\$420 OTHER Printing stationery/envelopes (second run of 2,500)= \$ 500 Printing letters, RFPs, Guidelines, insert card, report= \$200 Printing Second Annual Report=\$ 1,500 Mail processing (Target Mail)/Postage of any major mailouts=\$200 Other mailing throughout the year (RFPs, reports)= \$ 100 Meeting support materials (visuals/photos)= \$ 500 Photocopy and basic office supplies=\$ 500			
II. <u>RESEARCH DEVELOPMENT</u> PERSONNEL (Incl. F. B. at 26.6%) Scientific Director (10.1%) and Assoc. Dir (5%)	\$	54,352 27,852		
ANNUAL CONFERENCE SCIENTIFIC SESS TRAVEL (Fund Promotion) REVIEW PROCESS		10,000 10,000		
Stipends(\$1,000), Travel(\$2,000), Meetings(\$3,000		6,500		
III. <u>ONGOING ROUND 01 PROJECTS</u>			<u>\$</u>	<u>418,560</u>
IV. FUND ROUND 02 RESEARCH PROJEC	<u>TS</u>		<u>\$</u>	<u>830,362</u>
<u>12 Month Projects</u> 1. Short 65,000 9. Bhat 24,988 10. Goodkin 3,000 TOTALS 92,988				
EST. 03-04 SCI ANNUAL BUDGET:				1,333,110
V. EST. AVAIL. ROUND 02A & 03 PROJECTS				930,313 ¹

1 Amount will be available for both possible rounds which will probably not be actually awarded funds until early FY 04/05 (July 1, 2004).

~FY 2003/2004~ COMPOSITE BUDGET SPINAL CORD INJURY RESEARCH FUND (Revised after 07/11/03 SCIRF Board Meeting)

	<u>Base</u>	<u>F.B. (26.6%)</u>	<u>Sub-Totals</u>	TOTALS
SALARIES/WAGES				\$ 53,288
FUND ADMIN.				
Fund Administrator (20%)	20,092	5,344	25,436	
RESEARCH DEVEL.				
Scientific Direct.(10.1%)	15,000	3,990	18,990	
Assoc. Sci. Direct. (5%)	7,000	1,862	8,862	
(Res. Dev. Sub-Total)	(22,000)	(5,852)	(27,852)	
S/W Sub-Totals	42,092	11,196		
TRAVEL(Staff/Board)				10,900
Admin. Core (Board)			900	
Research Development			10,000	
OTHER				20,000
Admin. Core			3,500	
Research Development			16,500	
SUBGRANTS				1,248,922
Round 1 Projects			418,560	
Round 2 Projects			830,362	
TOTAL				<u>\$ 1,333,110</u>

~SC SPINAL CORD INJURY RESEARCH FUND CASH ANALYSIS~ {Prepared for 07/11/03 Board Meeting and adjusted using final FY 02/03expenditures}

INITIAL 18 MONTHS (01/01/01-06/30/02)		
Iotal Collections	977,703	
Total Expenditures	<u>30,675</u>	
YEAR END BALANCE		947,028
FY 03 (07/01/02-06/30/03)		
Carryover from Prior Period	947,028	
DUI Collections through 06/30/03	<u>825,957</u>	
TOTAL CASH	1,772,985	
Program Admin. Core Expenditures	27,624	
Program Scientific Core Expenditures	18,987	
Round 01 Projects First 12 Mos. Expenditures	<u>301,951</u>	
TOTAL EXPENDITURES	349,562	
YEAR END BALANCE		1,423,423
FY 04 (07/01/03-06/30/04)		
Carryover from Prior Period	1,423,423	
Additional Collections through 06/30/04 (est)*	<u>840,000</u>	
TOTAL CASH	2,263,423	
Program Admin. Core Budget	29,836	
Program Scientific Core Budget	54,352	
Round 01 Projects Last 6 Mos. Budget	418,560	
Round 02 Projects (18 month commitment)	830,362	
COMMITTED BUDGET	1,333,110	
YEAR END BALANCE (estimate)		930,313**

NOTES:

* DUI collections estimated at \$ 70,000 per month

****** Exceeds the minimum year end Board Reserve Target of \$ 800,000

APPENDIX 5—SCIRF 02/03 ANNUAL REPORT RFP for Round 02 Projects

RESEARCH ON SPINAL CORD INJURY (SCI) Request For Proposals (RFP) Issued by the Spinal Cord Injury Research Fund Board Judge Charles L. Allen, Brian G. Cuddy, MD(Chair), David Griesemer, MD, Terry Peacock, Phanor L. Perot, MD, PhD, David L. Shallcross, MD, and W. Daniel Westerkam, MD

Administered by the Medical University of South Carolina (MUSC)

Date of Release: February 1, 2003 Deadline for Submission: April 15, 2003 (extended to May 15)

Background: Amendment (Bill S54 44-38-510) to Section 2, Chapter 38, Title 44 of the 1976 S.C. Code was ratified on July 20, 2000 and authorized the new South Carolina Spinal Cord Injury Research Fund provided from a \$100 surcharge on each Driving Under the Influence (DUI) conviction. The Fund is administered by new Spinal Cord Injury Research Board appointed by the Governor, and was attached to MUSC for staff and administrative purposes. The law authorizes Fund use to cover basic operating and administrative costs, but directed that the balance be provided for spinal cord injury research projects.

The Board set the following **primary Fund objectives**: 1). Advance knowledge of SCI injury repair and regeneration within the SC research community by encouraging physicians and scientists to apply expertise to SCI field. 2). Foster collaborative interdisciplinary approaches to SCI research among SC hospitals, rehabilitative centers, research universities, and interested organizations. 3). Nurture next generation of SCI researchers through support of young scientists and post-doctoral fellows. 4). Improve well-being and quality of life of individuals with SCI by research programs that prevent or treat the secondary conditions and consequences of SCI. 5). Set budgets and administer funds for SCI research as mandated by the SC Legislative Act, and assure highest quality of research and commitment by investigators.

It also set **initial research funding priorities** and focus: 1). Translating basic and preclinical findings into clinical applications. 2). Studying strategies to promote growth and survival at cellular level. 3). Assuring efficacy of drugs or other interventions to prevent or reduce secondary injury and to provide insight to the mechanisms causing this progressive damage. 4). Exploring the role of tissue transplantation in restoration of spinal cord function. 5). Defining anatomical, pathophysiological, inflammatory, and neurochemical characteristics of spinal cord injury or disease in well-defined animal models. 6). Elucidating biological and physical mechanisms that improve functions compromised by spinal cord injury, including dysfunction, chronic pain, and uncontrolled spasticity. 7). Developing innovative rehabilitative strategies, services, or priorities to promote recovery and function following spinal cord injury. 8). Developing public education programs to help decrease the occurrence of spinal cord injury by safety education, better safety practices, and decreased alcohol use as a contributing factor. 9). Developing education programs for the injured and their families.

Request For Proposals: The South Carolina Spinal Cord Injury Research Board invites grant and contract applications for research on all aspects of spinal cord injury (SCI) in an effort to develop better understanding and ultimately treatment for paralysis and other consequences of spinal cord injury and disease. This is the second annual call for grants that outline innovative and potentially groundbreaking research. It is estimated that \$1,000,000 will be available for projects funded in response to this request.

SCI is a serious and seldom reversible cause of disability. Often traumatic in origin, it may also result from inflammatory, neoplastic, developmental, or rarely infectious causes. The consequences of SCI are legion, including paralysis of legs and arms, even muscles of respiration; loss of sensation and autonomic control; chronic pain; impairment of bowel, bladder, and sexual dysfunction; metabolic disorders such as hypercalcemia; muscle spasticity with contractures of joints, fractures, and heterotopic ossification; complications such as decubitus ulcers, uncontrolled blood pressure, and frequent infections. Victims of SCI typically lose the ability to function productively in society because of extraordinary demands of their medical care, limitations in rehabilitation resources after profound loss of mobility, and psychosocial difficulties associated with their severe impairment and total dependency upon others. The loss to spouses and children of SCI victims is substantial and the cost of care to families and the residents of South Carolina is extraordinary and ongoing. The long-term goal of this research initiative is to minimize the risk and incidence of SCI, interrupt or reverse the process of SCI, and improve the quality of life for residents of South Carolina with SCI.

Areas of potential research interest include: basic neurobiology, including regeneration of cells and axons, modulation of inflammatory and destructive processes, prevention of injury-induced neurotoxicity or secondary injury; pre-clinical studies, including refinement of animal models of SCI; translation of pre-clinical findings into treatment, including pharmacological trials, surgical approaches, and previously unexplored treatments; clinical issues, including diagnostic assessment and monitoring, relationship to other spinal cord disorders and psychological disorders; outcomes of rehabilitation, including therapies (prosthetic, physical, occupational, speech/language, recreational), quality of life (technological solutions, functional improvement), and attendant care; epidemiology, including factors affecting incidence, availability and quality of SCI care in South Carolina; education and prevention, including education curriculum for patients and families in appropriate and adequate SCI care (classroom, career), community (prevention of alcohol-related injury, opportunities for therapy and rehabilitation), and health care providers (curriculum at South Carolina colleges and universities, professional education).

Research Guidelines: A broad range of applications is encouraged. Examples of development and research programs that will be considered include:

- (1) Pilot Projects. Obtaining significant extramural funding for creative, high-impact research or treatments may be hampered by lack of resources to obtain the preliminary data or products necessary to demonstrate the value of the hypotheses. Grants will be made available to fund such novel and innovative research that significant extramural funding and/or product development is subsequently probable.
- (2) Collaborative Projects. Proposals requiring cooperation between professionals, specialties, laboratories, or institutions may require additional resources for larger projects or coordination of effort. Grants will be made available to fund such collaborative efforts if innovative efforts or productive new relationships develop.
- (3) Research of High Value to the Citizens of South Carolina. Certain research projects may be of demographic or cultural value specific to the State of South Carolina and may not be easily justified on a national research agenda. Proposals of such unique benefit to South Carolina will be considered.

(4) Assist in Recruiting Clinicians, Educators, or Researchers into the State of South Carolina. Under exceptional circumstances monies may be made available to assist in attracting nationally recognized clinicians, educators or researchers in the field of SCI into state institutions.

Eligibility and Terms of Support: Applications will be accepted from clinicians, therapists, educators, and scientists in South Carolina who have a terminal professional degree in their field and, in the case of research involving human subjects, have access to an Institutional Review Board. This includes, but is not limited to, faculty members of research and educational institutions throughout the state. All applicants will be required to submit a two-page progress report within 60 days of the termination of the award period. In addition, all applicants will be required to present their research at a Spinal Cord Injury Research Fund meeting and to have prepared a research proposal on SCI to be submitted within 6 months of the termination of the award.

Funding: Grant or contract support will be awarded initially for 18 months, with no guarantee of renewal. Further funding will depend on progress reports at 6-month intervals that include evidence of productivity, with consideration for renewal of projects that show progress or significant promise on resubmission. Reasonable amount of funds for support of the Principal Investigator's salary will be considered, but should not exceed 20% of the total requested budget (except for Career Development applications where it shall not exceed 50%). Grant or contract fund uses for equipment are not encouraged, but minor items will be considered provided they are clearly justified as absolutely essential to the successfully conduct of proposed research. Requests for travel should be focused on development of networking necessary for the conduct of research. The Spinal Cord Injury Research Fund does not provide support for indirect costs and any such related costs essential to the proposed research should be included in the direct cost budget request.

Timeframes: There will be at least one call for proposals annually. The review of all proposals will be completed within 60 days following the grant submission deadline. The deadline for applications in response to this Request for Proposals is **Tuesday, April 15, 2003, at 5:00 PM.** The South Carolina SCI Research Board will make money available within 30 days following a recommendation for funding by the Review Committee and approval.

Funding Mechanisms

- 1. Primary research grants will not exceed \$150,000 over an 18-month period. These will support research activities of junior faculty (usually within 1 to 5 years of their first faculty position) that range from basic science to applied science. Anticipated are three to four awards, with no more than a 2:1 ratio in either basic versus applied science. The primary goal of these research grants will be to perform studies that lay the foundation for larger projects that may being federal funds into the state of South Carolina.
- 2. One grant, not to exceed \$150,000 over an 18-month period will be awarded for a project that specifically addresses issues related to access to care or the health care delivery in the state of South Carolina. This project should address one or more of the following priorities: attendant care, access to primary rehabilitation, access to follow-up services, availability of physicians and other health care professions, the efficacy of existing programs, or outcomes associated with the quality of existing or pilot programs. The successful applicant must demonstrate that individuals in South Carolina are disadvantaged in terms of having access to a particular type of resource, or that there are particular shortcomings in the health care delivery system, then go on to investigate the impact of this

disadvantage on important outcomes such as secondary health conditions, function, and quality of life. For instance, there is only one CARF certified rehabilitation center that handles SCI rehabilitation in South Carolina which means that many citizens with SCI must go out of state for inpatient rehabilitation, and a substantial portion of people with SCI receive no inpatient rehabilitation at all. Therefore, a researcher may choose to investigate to role of primary rehabilitation after the onset of an SCI on the development of secondary conditions. This mechanism is specifically intended to identify shortcomings in the health care service delivery system and their impact on the lives of people with SCI in South Carolina. The results of the study should lay a foundation for the development of either programs or legislation that will intervene to improve the quality of life in people with SCI in this state.

- 3. Career development awards will be utilized to support new investigators in the field of spinal cord injury, or to support the work of individuals crossing over to spinal cord injury research from other areas. A maximum of \$75,000 will be granted over an 18-month period. The primary goals of this mechanism will be to increase the likelihood that a researcher will be able to successfully compete for a federally funded K grant or other federally funded career development award upon completion of the project. The proposed award will give new investigators set-aside time from their other activities to focus on research, not to exceed 50% FTE, and lay the foundation for them to obtain awards. These awards may reflect either basic science projects or applied projects.
- 4. Small pilot grant funds of \$20,000-\$25,000 will be available for single year projects. The goal of this award is specifically to support investigators who need to collect a modest amount of pilot data or purchase equipment necessary to position themselves for NIH grants. This mechanism will support the work of senior investigators. Three to five such awards per year are anticipated as funding levels permit. This mechanism also will have a second midyear cycle in which proposal may come directly to the Scientific Director or Associate Scientific Director who will set up a review from an external panel and then submit recommendations to the Board regarding approval.
- 5. Up to \$50,000 will be set aside for projects that disseminate the results of research to the citizens in South Carolina with spinal cord injury. This dissemination component is of great importance to the mission of the SCI Research Fund, as the information derived from the research studies must reach those individuals who can utilize it. Three types of activities will be supported under this mechanism: development of annual conference, generation of educational materials for consumers that may be directly disseminated to them (e.g., pamphlets), and funds for the continuation and updating of the website.

Review Process: Proposals will be reviewed by committees of reviewers approved by the Spinal Cord Injury Research Fund Board as drawn from a list of volunteers as well as those recommended by knowledgeable peers. One review committee will consider basic science or pre-clinical proposals, and another review committee will consider applied or clinical proposals. Investigators will be asked to submit the names of two (2) reviewers qualified to review their proposals, and these individuals may be selected as ad hoc reviewers. Each member of the Review Committees will have or have had a national competitive research award. Grants will be scored in a manner similar to an NIH grant review committee where 100 is the best possible score and 500 is the lowest score. Two reviewers will be assigned to each grant and all members of the appropriate review committee present for the review will have an opportunity to vote on each proposal. The Board will consider these reviews and scores in making all final award decisions. **Submission Address:** Grant applications should be submitted to Mark S. Kindy, PhD, Associate Scientific Director, South Carolina Spinal Cord Injury Research Fund, c/o Fund Administrator, Office of the President, Medical University of South Carolina, 171 Ashley Avenue, Suite 200-A, PO Box 250001, Charleston, SC 29425.

Application Format: The proposal must not exceed 12 pages in length, including the biosketch of the Principal Investigator. Pilot proposals should not exceed 5 pages. *Proposals not adhering to page limitation may be refused*. The format is similar to that of a National Institutes of Health (NIH) research proposal. Specific elements that should be included are:

- I. Face page (name, position, department, proposal title, abstract)
- II. Response to previous critique (only for renewal applications or resubmission of a previously unfunded proposal – maximum of 1 extra page)
- III. Specific aims
- IV. Value to the State of South Carolina (benefit to the people of the State and/or plans for obtaining extramural funding and/or compatibility with Fund's primary objectives and initial priorities. This section is particularly important to those applying for set aside funds for a project that specifically addresses the health care needs of individuals with SCI in South Carolina.)
- V. Background and rationale (Career Development applications should focus on their rationale on how the proposed activities will facilitate the applicant's research career development and how the award will assist the applicant in successfully competing for a federally funded career development award. Applicants should clearly specify which award(s) for which they intend on submitting an application).
- VI. Methods
- VII. Evaluation strategy (with measurable goals)
- VIII. References
- IX. Detailed Budget (with narrative justification)
- X. Biosketch (abridged NIH format, additional biosketches for each co-investigator should be included, adjusting page limit to accommodate more than one)

Please submit the original and six copies.

Review Criteria: Proposals will be reviewed by the Review Committees according to the following criteria:

- 1. Originality and significance of the hypothesis or product.
- 2. Feasibility and adequacy of the proposed research or product.
- 3. Qualifications and experience of the Principal Investigator and other key personnel. Special consideration will be given to new faculty and individuals less familiar with the extramural funding process. Career Development Awards will be reviewed based on the quality and clarity of the overall career development plan and how the current award will enhance the qualifications of the investigator.
- 4. Likelihood of the project ultimately receiving extramural support and/or benefiting the people of the State of South Carolina.
- 5. Availability of adequate facilities to conduct the proposed project
- 6. Appropriateness of the budget.
- 7. Relevance to the Fund's primary objectives and initial priorities as presented in the Background section of this RFP.

Awarding of Funds: Projects will be awarded by grant or contract based upon applicable South Carolina policies, procedures, and laws concerning the expenditure of State funds.

For Questions or Additional Information: Potential applicants should contact Dr. James Krause, Scientific Director or Dr. Mark S. Kindy, Associate Director, South Carolina Spinal Cord Injury Research Fund. Procedural and basic science questions should be addressed to Dr. Kindy. Questions regarding applied or clinical research, the set aside funds for special needs of people with SCI in South Carolina, career development awards, or consumer education should be addressed to Dr. Krause.

James S. Krause, Ph.D. Krause@musc.edu 843-792-1337

Mark S. Kindy, Ph.D. kindyms@musc.edu 843-792-0808

APPENDIX 6—SCIRF 02/03 ANNUAL REPORT Round 02 Project Review Information

Review Process for South Carolina Spinal Cord Injury Fund (Submitted April 29, 2003 for Board Consideration and subsequently approved)

I.PROPOSED PROCESS/PROCEDURES

Receipt of Project Applications

Applications will be received by May 15, 2003 and the review process will begin immediately on May 16, 2003.

Reviewer Pool and Final Reviewer Assignments

The proposals will be separated into two groups for Scientific Review, and corresponding Review

Committees appointed:

- a). <u>Basic Sciences Projects/Committee</u> (overseen and Chaired by Dr. Kindy).
- b). <u>Applied Science Projects/Committee</u> (overseen and Chaired by Dr. Krause).

There will be two types of reviewers assigned to each project:

- a). <u>Internal Reviewers</u> (i. e, all from South Carolina) who will be the members of the two Committees and, after being assigned their own projects to review, will meet to discuss their reviews as well as the written ones of the Outside Reviewers (see below)
- b). <u>Outside Reviewers</u> (i.e., from the region and Nation) who will be asked to submit written reviews of the proposals. Several of these may be invited to attend the meetings of the Committees if a need arises, particularly with respect to proposals in areas where there may not be adequate South Carolina (i.e., Internal Reviewer) scientific expertise available.

Reviewers for each project will be selected by the Scientific Directors from the pool of SCIRF Board approved reviewers. Every effort will be made to assign the reviewers with the most appropriate back-ground/expertise relative to each project; however, final specific reviewer assignments can not be made until the actual proposals are received on May 15 and analyzed by the Scientific Directors. Final reviewers will also be dependent on those who are able to accept and complete the assignments within the proposed review timelines. There will be at least one Internal and one Outside Reviewer assigned to each proposal.

Once all reviews have been completed, the two Committees (i.e., Basic Sciences and Applied Sciences) will meet to critique each proposal based on the criteria below and make recommendations to the Board for their final decisions. On each proposal, the assigned Internal Reviewer(s) would present their critiques as well as the written critiques of the External Reviewer(s). Then the whole Committee would vote for the final project score using the scoring scale below.

These findings/recommendations will be mailed out to the SCIRF Board along with the proposals, and the Board will subsequently meet to discuss and make final decisions. At that meeting, both Dr. Kindy and Dr. Krause will be available to clarify any questions about any aspect of the review process and its findings/ recommendations.

This whole scientific review process is modeled upon the peer review process developed by the National Institutes of Health.

Project Review Criteria

The following will be the criteria used in review of each application.

- 1. Scientific Significance and Approach
 - a. scientific excellence of the research proposal, including originality of ideas;
 - b. projected scientific impact, soundness or approach;
 - c. innovative and distinct nature of proposal;
 - d. logical organization of proposal;
 - e. applicant's familiarity with pertinent literature and work of other investigators in the field.
- 2. Investigator
 - a. qualifications of the applicant and relevant experience;
 - b. productivity of the applicant;
 - c. amount and quality of independent publications;*
 - d. evidence of scientific independence.*
 *<u>NOTE</u>: These two scoring criteria are not applicable for the investigators of proposed Career Development Awards. Instead they should be replaced by e. below:
 - e. quality of the career plan.
- 3. Resources and environment
 - a. adequacy of available facilities;
 - b. equipment and other resources necessary to the project.
- 4. Any other considerations

Scoring

- 1.0-1.4 Outstanding
- 1.5-1.9 Excellent
- 2.0-2.4 Above Average
- 2.5-2.9 Average
- 3.0-3.4 Below Average
- 3.5-3.9 Poor
- 4.0-4.5 Marginal
- 4.6-5.0 Scientific or Ethical Disapproval

APPENDIX 7—SCIRF 02/03 ANNUAL REPORT Web Page Information



APPENDIX 8—SCIRF 02/03 ANNUAL REPORT Information on Scientific Directors

BACKGROUND OF JAMES KRAUSE

Dr. James Krause obtained his Ph.D. from the Department of Psychology of the University of Minnesota in 1990. After spending the next 4 years as a rehabilitation psychologist, he embarked on a full-time career in long-term outcomes research after spinal cord injury and disability, combining work as a behavioral scientist and rehabilitation consultant. Dr. Krause has served as principal investigator on 11 federally funded research grants and spent two years as a visiting scientist at the Centers for Disease Control in Atlanta, Georgia. He currently serves as principal investigator on four federally funded studies of spinal cord injury related to aging, mortality, stability of interests, and community integration. Dr. Krause also serves as a consultant on three federally funded projects including the Model Spinal Cord Injury Systems at the Shepherd Center in Atlanta, Georgia, a Rehabilitation Research and Training Center at Rancho Los Amigos National Rehabilitation Center in Downy, California, and a collaborative study of aging after spinal cord injury at the Craig Hospital in Englewood Colorado. He has served as a consultant and expert witness in numerous spinal cord injury cases in litigation, utilizing his research on employment, aging, and mortality to assist in clarifying life care planning issues. Dr. Krause has over 60 publications in refereed journals, has made nearly 100 presentations at national conferences, and is a coauthor on a new book on life care planning. His awards include the Switzer fellowship from the Department of Education,



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the ARCA Award for outstanding vocational rehabilitation article in 1992, and the first ever Early Career Award from Division 22 of the American Psychological Association. He currently serves as Associate Dean for Clinical Research in the College of Health Professions at the Medical University of South Carolina, as well as holding a joint research appointment with the Veterans Administration and serving as the Scientific Director for the South Carolina Spinal Cord Injury Fund.

New chairman

WILL from Pare 1G

es. He knows what it's like to face life in a wheelchair, to need ther-apy, to be told life's challenges are too difficult for someone like

His secretary, Terri Bozz comes in and holds up a Pepsi bottle so he can take a swig. His wife, Laura, stops by and helps him eat a bologna sandwich. He's paralyzed below his shoulders and depends on an assistant for many daily living activities.

The same man brought with him \$750,000 in research grants and has applied for another \$1 million since he got to MUSC this fall. His move here began with a phone call from Dr. Ronald T. Brown, associate dean for research in the College of Health Professions. In truth, Krause was n't familiar with MUSC and had never even been to Charleston. But he'd heard about the history and the beauty of the midsized city.

And, oh, the water

And, ch, the water. Water all over, just like his hometown in Mianessta where he grew up, where he loved to swim and fish and where he came clos-er to death than most folks realized.

Brown explained that MUSC was earching for a new chairman Would Krause be interested It would mean leaving his re search job at a large catastrophic care hospital in Atlanta. And it would mean uprooting his wife Laura from her job as director for the rehab m licine center at nt Hospital. They'd love to

"I never really felt at home in Atlanta," he recalls. "I didn't like the traffic. And it was away from the water.

One fall night a few weeks ago Krause rode home on a clear evening when the full moon reflected on the smooth water he low. It reminded him of Ottertail Lake.

ON THE WATER

At best, Krause was an average high school student. A muscular weight-lifter, he liked to bully other kids, especially with headlocks and other wrestling moves he saw on TV

He grew up in Wadena, home to about 4,000 people, an area de-fined by lakes where Krause and nost everyone else loved to swim nd fish. Especially on Ottertail most ev Lake.

And that's exactly what he was doing one July day in 1971. Krause, his brother and cousins were running along the banks, splashing in the shallows, diving out into the deeper spots. He knew the roll of the lake floor well, knew how to dive with his head back a bit so he wouldn't strape up his face. But be didn't know that in that

spot, the property owners had been dredging. Krause ran a stretch, dove in

and smacked dirt. He doesn't re call it being an especially hard hit, but it must have been exactly wrong.

His cousin spotted him and hauled him out. Paramedics rushed him to a lo

cal medical center for a quick



Laura Krause laughs during a mishap while buckling husband James after a shapping stop in West Ashley

stop. Then he spent 90 minutes, awake, in the back of a speeding, wailing ambulance escorted by a highway patrolman along the route to Fargo, N.D., home to the nearest hospital that could handle his injuries. When he arrived, a doctor

warned Krause he needed to be put in something called tong trac-tion: "We're going to drill in your head. It sounds worse than it will feel Not true

Krause was under local anesthe sia when the doctor drilled two holes in the back of his skull and bolted his head to a weight. It would immobilize him and help his bones fuse. Even today, 31 years later, Krause cringes a sound of a dentist's drill or to s at the imagine that sensation, not so much of nam but the eerie feel of

At one point I was swimming Two hours later, they're taking my clothes off and drilling in my he recalls. Then he key there. For a long,

long time. His mother rented an apartment

in Fargo to be near him. Humphrey, a fellow Minnesotan and then-presidential hopeful, got Krause's brother furloughed and eventually discharged from his Army station in Germany Krause spent three and a half months in the ICU, lived 10 months with a tracheotomy tube In his throat. One day someone wheeled him past his ventilator, and he spotted his reflection. He'd shrunk from 160 pounds to 90. He looked like a concentration camp victim.

"I was probably closer to dying han I ever realized," he says. Every morning, Krause awoke than I et in a sleepy fog, fresh from dreams of running or fishing. He never woke up thinking he was in the hospital bed. "The hardest thing with an injury is waking up

every day," he says. If someone sat down and told him he'd never walk again, Krause doesn't remember it. But soon enough, it became

clear. He woke each day expecting to be in the hospital. And for 18 months of the next two years, he was. He underwent skin surgeries. kldney stone surgeries and treatments for respiratory problems. It took five months to stabilize him. Then he was sent to a chil-

dren's hospital in St. Paul. He was 17, surrounded by sick children. "It was weird, but it made me tough," he recalls.

The injury also became big news in his hometown. His parents owned a downtown business, and his family was well-known. The and local newspaper ran front-page stories. The town held a fund-rais-er for Jim Krause Day. They hung a banner over Main Street, and the Minnesota Vikings came

They raised \$10,000, a buge sum in the early 1970s. But when Krause returned to

Wadena between hospital stays, it had become too hig of a deal. When he ventured out to eat or shop, strangers approached him. He began to stay home, to him-Next he moved to a rehab insti-

tute in Minneapolis, where his old-er sister lived. Josie, a 28-year-old away from home, took her little brother out every night. She never seemed put out. Years later, she admitted, "I didn't always want to et. Det Edit you to go home and be satisfied."

And be wasn't. At the institute, Krause scored high on intelli gence tests, enjoyed a social life with Josie and focused on pursu-ing a medical career.

"It was really a turning point for me," he says. "That was the point when I found a sense of purpose in my life for the first time since

the injury." Yet it was 1974, when few place were wheelchair-friendly. Krause heard of Southwest Minnesota State University, which prided It-

self on being accessible. He figured it would be perfect for him

The school approved him aca-demically. Then be met with the rehab services staff. They rejected him. A counselor ent him the infamous letter and sent him the infamous letter sug-gesting he find something useful to do - from his house.

"Here was the most accessible place in the country, and they thought I couldn't make it," he recalls But Krause had no intention of

going home

HITTING THE BOOKS

He quickly applied to the Univer-sity of Minnesota in the heart of Minneapolis-St. Paul and was accepted. But the school was three hours from his parents' home. He'd need

a place in the Twin Cities that could help him with daily living activities while he went to

school. At 19, Krause moved into a nursing borne. For two years he lived among fragile people he knew were misknew we treated. At

lights. "People re beaten there were prob-lems," he recalls "It was a tough place, it really

tension courses and, the next year, enroll as a full-time student Then he moved to a transitional living home where he stayed gh his undergraduate work throw in the honors program. The man told to stay home grad-

uated summa cum laude. Then he fulfilled the dreams of many young people. At 25, he moved to California with his best friend

His buddy was Tony Lebahn, a man born with no arms or legs, from a low-income background "an extraordinary person who did it all on pure will." Tony didn't have the family support Krause enjoyed, wasn't especially good-

ooking or smart. But Tony was determined. One day, Krause wheeled around a corner and saw Tony leaning chest-deep into the fridge, grab bing a drink with his teeth. He ed a lot from Tony, and to gether they created ways to get through everyday life.

Kra e still recalls one night when Tony went out. Krause chose to stay home, alone for the first time since the injury nine mars earlier

He turned on the stereo and just sank in the feeling of solitude. Seven months later. Krause decided to return to school. Tony stayed behind. He'd met his future wife and eventually had three kids, coached Little League and was active in his church. Tony

was active in his church. died a couple of years ago Krause moved in with a friend and a paid, live-in assistant and began his graduate work. In 1989, the man told to stay

arned his Ph.D. in psychol-OEV

SHEPHERD CENTER Krause landed a job at Shepheri Center in Atlanta, a catastrophic care hospital that treats more than 200 new solnal cord injuries

a year. He split his time between treating patients with new spinal cord injuries and working on re-search projects. He often worked with assess-

ment teams to figure out patients unique needs. For instance, many spinal cord injuries occur in drunken driving wrecks or alcohol-related incidents and violence Many patients needed treatment for alcohol abuse that could burt their recoveries and shorten their

The work led Krause to his too research interest: studying how a person's characteristics can pre-dict mortality and other outcomes. The idea is to better focus limited resources, a huge insue as insurers and government pro-grams search for ways to cut costs.

Krause became a full-time sci-entist and landed several compet-itive, federally funded research rts

One day, he was flying to a pro One day, he was hying to a pro-feesional conference when a spunky blonde spotted him on the plane. It was Laura Cheney's first day as Shepherd's social work di-rector, and she was headed to the same conference where both

would be presenting. On her way down the plane aisle, "I noticed this good-looking guy with beautiful blue eyes." The plan landed, and passengers

filed off. "Then I noticed he wasn't getting off the plane," she recalls. They met at the conference, but Krause was dating someone else. Several months passed before she heard he was planning to ask her out. She consulted with a hospital colleague: What should she expect?

She shouldn't have worried. "He never presents neediness. It was very comfortable," Laura recalls. They fell in love and married in 1993. Her father built a folding stool so she could walk down the aisle and sit beside her new

Nine years later. Krause still gushes over Laura's beauty, her energy, her intelligence. His gus er Okie Krause laughs, "Laumoth ra has a mind of her own. Nobody pushes her around, and that's good for him!

RETURN TO THE WATER Ronald Brown chaired MUSC's search for a new head of rehab sciences.

He wanted someone who would promote research, so he scoured medical journals to find the

hottest scientists "Krause's name kept appearing," Brown says. "He does seminal work in spinal cord injuries, and I was looking for a very strong, na-

tionally recognized person in research So Brown picked up the phone. He had no idea about Krause's in-jury. Sure, the man used a speak-

er phone. Lots of people do. It wasn't until they arranged to fly Krause to Charleston that it ecame apparent. "And it didn't matter either,"

Brown adds. From his end. Krause wasn't

looking for a new job. A few times a year be took calls like this one

But this one intrigued him Maybe it was the chance to di-rect about 20 full-time faculty and a range of adjuncts with 284

Or maybe it was the chance to Or maybe it was the chance to take his grant-writing skills to South Carolina, a tough place for people with spinal cord injuries to get help. MUSC recently closed its inpatient rehab unit, the state's inpatient rehab unit, the state's only residency program, in part due to finances. Today, newly injured people often are stabilized and then released without sup-

People go straight home. Krause says. "I can't overstate it. It's just terrible." Or maybe it was the chance to

serve as scientific director of the new S.C. Spinal Cord Injury Research Fund.

Search Fund. Drunken driving offenders pay \$100 into the fund, which should raise \$1 million a year for spinal cord injury research.

The money will be used largely to begin research projects that have trouble getting funding from traditional sources and then build those projects enough to land bigger dollars.

"I want to get resources into the hands of people who need it," Krause says. And then there's what Krause

achieves without trying, the lesons he teaches those around him about overcoming mundane hurdies each day with peace.

"He is an amazing guy. He is an inspiration to me," says James Kuykendall, one of Krause's two personal assistants, who's also an personal assistants, who's also an occupational therapy student. "His approach to life is truly posi-tive. He does everything he

AT THE SPOT

Even as his career leaps ahead in Charleston, Krause still owns a cabin op Ottertail Lake where a single dive so many years ago could have derailed his ambitions. His stronger memories of the lake are those of days spent fishing with his grandfather, father

and brothers. He still boats by that spot, could figure out exactly where it haped if he wanted

But he doesn't bother. "I don't really think about it," he avs casually. "I look at where the says casually. "I k fish will be biting."

Jonnifer Berry Hawes write feature stories. Contact her at 937-5489 or at jhanes@postandcourier

nights, the staff often didn't an-swer his call

WHEN. Krome endured life there be-cause it meant he could take er-

BACKGROUND OF MARK KINDY

Mark S. Kindy, Ph.D. Admiral Pihl Chair and Professor Interim Director, Neuroscience Institute Director, Stroke Program Associate Director, Center on Aging Associate Director, Spinal Cord Injury Research Center

Dr. Kindy started his academic research career as an Assistant Professor in the Department of Biochemistry at the University of Kentucky (UK) Medical Center in 1989. In addition, he joined as an Associate member of the Center on Aging. Dr. Kindy was promoted to Associate Professor with tenure in 1994 and rapidly gained the respect and acknowledgement as a leader in the area of stroke and Alzheimer's disease. Dr. Kindy was appointed the Associate Director of the Stroke Program at UK in 1996 and help to build a strong basic science program in the mechanisms of neurodegeneration. Dr. Kindy was promoted to a Full Professor.

Dr. Kindy was recruited to the Medical University of South Carolina as the Admiral Pihl Endowed Chair of the Neuroscience Institute, Director of the Stroke Program and Associate Director of the Center on Aging and Spinal Cord Injury Research Fund in August of 2002. He was recruited into the Department of Physiology and Neuroscience at MUSC to bring a strong research program in both stroke and Alzheimer's disease (AD). Dr. Kindy has made significant contributions to the areas of stroke and AD by helping to define the mechanisms involved in the development and progression of the diseases. In April of 2003, Dr. Kindy was appointed the Interim Director of the Neuroscience Institute to enhance the programs in translational neuroscience research and biotechnology. Dr. Kindy has been funded by the National Institutes of Health (National Institute on Aging, National Institute of Neurological Disease and Stroke, National Institute of Diabetes and Digestive and Kidney Diseases), the Veterans Administration (VA), and numerous private foundations. Dr. Kindy is a Research Career Scientist of the VA. Currently, Dr. Kindy brings in almost \$800,000/year in research dollars.

Dr. Kindy serves on the Editorial Board of several journals, is a member of the NIH Pathology A study section and American Heart Association Brain 1 study section and serves as an advisor to several biotechnology corporations.

Dr. Kindy received his bachelor's degree from the University of Massachusetts, Amherst, and his Ph.D. from Boston University School of Medicine and received post-doctoral training at the Salk Institute in La Jolla, CA.

Dr. Kindy is married to Lisa Zokas Kindy an attorney and Director of Clinical Risk Management for the Medical University of South Carolina. Lisa and Mark have two children.