

SPINAL CORD INJURY RESEARCH BOARD

Regular Business Meeting June 25, 2015 1:00 PM to 5:00 PM MINUTES

Locations

NYS DOH Wadsworth Center, Biggs Laboratory, Sturman Conference Room, Empire State Plaza, Albany, NY NYS DOH Metropolitan Area Regional Office, Conference Room 4C, 90 Church Street, New York, NY

SCIRB Members Present

Thomas N. Bryce, M.D.
Donald Faber, Ph.D.
Keith Gurgui
Bernice Grafstein, Ph.D.
Nancy Lieberman
Lorne Mendell, Ph.D.
Gary D. Paige, M.D., Ph.D.
Fraser Sim, Ph.D.
Mark Menniti Stecker, M.D., Ph.D.
Adam Stein, M.D.

SCIRB Members Absent

David A. Carmel Jeffrey Ehmann Michael E. Goldberg, M.D.

NYS DOH Staff Present

Teresa Ascienzo
Guthrie S. Birkhead, M.D.
Bonnie Jo Brautigam
Charles Burns
Victoria Derbyshire, Ph.D.
Jeannine Tusch
Carlene Van Patten
Diana Yang, J.D.

Guests

Paul Richter Jonathan R. Wolpaw, M.D. Nurit Kalderone, Ph.D. Tracy Tress

Call to Order and Opening Remarks of the Chair

The meeting was called to order at 1:03 p.m. with a welcome by Chair, Lorne Mendell, Ph.D. followed by introductions of Spinal Cord Injury Research Board (SCIRB or Board) members and the New York State Department of Health (DOH) staff. New board members Fraser Sim, Ph.D. and Bernice Grafstein, Ph.D. were introduced and welcomed. Dr. Mendell announced that the SCIRB now has a fully seated board of 13 voting members.

Presentation to Paul Richter

Dr. Mendell introduced Guthrie S. Birkhead, M.D., Deputy Commissioner of the Office of Public Health for the New York State Department of Health. Dr. Birkhead presented a plaque to Paul Richter, founding member of the Board that read: "With gratitude for your dedication and service to the people of New York State and the Spinal Cord Injury Research Board."

Dr. Birkhead thanked Mr. Richter for his 17 years of service (1998-2015) to the New York State Spinal Cord Injury Research Program, SCIRB, the scientific community and those who suffer from spinal cord injuries. Mr. Richter said it was a pleasure and honor to serve on the Board with so many wonderful, caring, dedicated and intelligent people. He thanked the DOH staff and SCIRB members for volunteering their time to this important program. Dr. Mendell thanked him for his efforts and warm felt words on behalf of SCIRB.

Consideration of January 23, 2015 Meeting Minutes

Dr. Mendell asked SCIRB members to consider Exhibit 1, the minutes from the January 23, 2015 meeting. No changes were suggested and no comments were offered.

ACTION

Mark Menniti Stecker, M.D., Ph.D. made a motion to approve the minutes as presented. Donald Faber, Ph.D. seconded. A roll call vote was taken and the motion was unanimously approved (8-0), excluding votes from Dr. Sim and Dr. Grafstein.

Consideration of CART & IDEA Applications for Funding

Bonnie Jo Brautigam gave an overview of the Request for Applications (RFA) for "Collaborations to Accelerate Research Translation (CART) and Innovative, Developmental or Exploratory Activities (IDEA) in Spinal Cord Injury Research" as well as the peer review and scoring process used.

Ms. Brautigam noted that the critiques for the 14 applications that could be considered by the Board were sent to the SCIRB for consideration in advance of the meeting. She stated that the funding requests for these applications totaled \$9.3 million, exceeding the RFA designated amount of \$6.9 million. She advised SCIRB to decide, in public session and before recusals, whether it wanted the flexibility to consider exceeding the \$6.9 million amount if the discussion of individual applications led the Board to that result. She reminded SCIRB of the following:

- SCIRB may choose to reduce the number and/or the amount of one-time-use funds to any or all
 applications, and
- SCIRB may elect, at its discretion, to continue making recommendations for possible funding of proposals beyond the amount available for the funding mechanism and the RFA.

Nancy Lieberman requested an explanation of the impact of this decision on the amount of funding available in future years. Ms. Brautigam explained that expenditures for these two and three year awards would come from both current and future fiscal years funding and that the SCIRB's decision to use the Institutional Support funding mechanism would encumber the remainder of current fiscal year funds. Amounts of funding in subsequent years will determine the availability of future years of research funding for RFAs already issued as well as others yet to be developed.

ACTION

Ms. Lieberman made a motion asking that in the future, DOH staff provide a chart that lists the grantee that's selected, whether it's CART or IDEA, and the maximum amount of money that would go out each fiscal year. Dr. Faber seconded.

Ms. Brautigam stated that members will receive a Spinal Cord Injury Research Program Report (Exhibit 3) in advance of future meetings. She clarified that the Board should vote on whether it wanted the flexibility to exceed \$6.9 million in CART & IDEA awards now so that if necessary after consideration of the eligible applications, staff could request additional funding for this RFA.

After discussion, a roll call vote was taken and the motion was unanimously approved (10-0).

Dr. Grafstein asked if there is any downside to recommending awards in an amount of \$9.3 million. Ms. Brautigam said there was not.

Gary D. Paige, M.D., Ph.D. asked if there will be rollover of unspent funds from this fiscal year to next year. Teresa Ascienzo said SCIRB should never anticipate rollover of previous year funding.

ACTION

Dr. Paige made a motion to consider the possibility of raising the \$6.9 million for this RFA up to \$9.3 million to be determined soon (for CART & IDEA awards). Dr. Adam Stein seconded. A roll call vote was taken and the motion was unanimously approved (10-0).

SCIRB unanimously voted to adjourn into Executive Session for the purpose of considering applications for research funding. Members of the public and non-essential staff were asked to leave the room. After discussing applications, SCIRB reconvened in Open Session.

Application Votes

Dr. Mendell began the process of considering each of the eligible 14 applications, noting that the final award amounts will be contingent on correction of any arithmetic errors. He explained the final recommendations will be forwarded to the Commissioner of Health and upon his acceptance, the contract process will be initiated.

The SCIRB recommended nine awards (three CART and six IDEA) and six requests for one-time-use funds. Ms. Ascienzo announced SCIRB recommended a total of \$5,719,548 in CART & IDEA awards and one-time allowable funds. Details are provided on pages 5 and 6.

ACTION

Ms. Lieberman made a motion for DOH staff to provide the SCIRB with evaluations and scores of all applications that scored 4.0 or worse for this and future RFAs for transparency of the peer review process and formulation of future RFAs. Dr. Paige seconded.

Dr. Mendell reminded everyone that these are confidential documents and may not be shared beyond the review of the SCIRB members.

A roll call vote was taken and the motion was approved (10-0).

Program Update

Ms. Brautigam provided a brief overview of the current funding opportunities released in FY 2015-2016:

- Individual Predoctoral & Postdoctoral Fellowships in Spinal Cord Injury Research RFA
 - o \$4 million
 - 12 applications were received
 - No award will exceed \$100,000 per year (\$300,000 per award)
 - SCIRB will make recommendations at its meeting on September 21, 2015
- Translational Research Projects in Spinal Cord Injury RFA
 - \$12 million (in anticipation of two awards)
 - Applications are due on July 22, 2015
 - SCIRB will make recommendations at a meeting in November or early December 2015

Ms. Ascienzo noted that based on today's recommendations, approximately \$6.5 million will be available for the upcoming Institutional Support awards (Round 5). Ms. Brautigam reiterated the Board's decision to issue these non-competitive awards utilizing the Round 4 eligibility criteria. Ms. Brautigam reminded the SCIRB that spending under these awards must occur before February 28, 2016.

ACTION

Ms. Lieberman made a motion to expand the eligibility for Institutional Support Round 5 to any New York based spinal cord injury researcher or team of researchers who received funds from any state, local, federal or governmental agency, or any funding from a 501(c)(3) organization or international charitable organization. Dr. Mendell clarified that the award would go to the University. Dr. Adam Stein seconded. A roll call vote was taken and the motion was approved (9-1).

Next, Ms. Brautigam referred to Exhibit 3, the Spinal Cord Injury Research Program Report. This exhibit provides metrics for SCIRB to assess how the program is doing overall. Ms. Brautigam explained the report and answered questions. She clarified that the peer review contract is a five year contract in an amount that exceeds anticipated expenditures so as not to limit the number of procurements that can be peer reviewed in that time.

DOH staff then distributed a sample cash disbursement/encumbrance projection chart as requested by SCIRB at the last meeting. Ms. Brautigam reminded members that projections are constantly monitored and adjusted and are dependent on a number of factors (i.e. realistic application budgets and workplans, timely RFAs, board recommendations and execution of contracts, timely and accurate progress reporting and vouchering by contractors). She reviewed planned procurements, including the anticipated CRER Institutional Support 5 awards (contract 8/1/15-2/28/16) and noted the total amount has changed based on today's estimates to \$6.5 million. She asked that members contact her with any questions about this handout.

Future Meetings

Dr. Stecker suggested developing an RFA focusing on acute clinical patient care at the next SCIRB meeting. Ms. Lieberman asked for an extra hour to be added to major meeting agendas.

Public Comment

No members of the public wished to comment.

Adjournment

The Board unanimously voted to adjourn and the meeting ended at 5:05 p.m.

2015 CART/IDEA Recommendations for Award

Application Number	Organization Name	Principal Investigator	Funding Mechanism	Project Title	Base Award Votes (Y-N)	One Time Use Funds Request	One Time Award Votes (Y-N)	Recommended Award
DOH01- CARTID- 2015-00055	Health Research Incorporated, Wadsworth Center	Johnathan Carp, Ph.D.	IDEA	Role of Abnormal Urethral Sphincter Motoneuron Properties in Urinary Tract Dysfunction after Spinal Cord Injury	10-0	Yes	10-0	\$442,373
DOH01- CARTID- 2015-00070	CUNY City College of New York	John Martin, Ph.D.	CART	Repairing the Damaged Corticospinal Tract after Cervical Spinal Cord Injury	8-2	No	N/A	\$990,000
DOH01- CARTID- 2015-00042	Regenerative Research Foundation	Sally Temple, Ph.D.	CART	Sustained Delivery of IL10 and SHH to Promote Spinal Cord regeneration After Injury	9-0 Mendell recused	Yes	9-0 Mendell recused	\$1,097,684
DOH01- CARTID- 2015-00036	University at Stony Brook	Irene Solomon, Ph.D.	IDEA	Intermittent Hypoxia Induced Plasticity to Improve Lower Urinary Tract Function following Spinal Cord Injury	3-6 Mendell recused	Yes	3-6 Mendell recused	\$0
DOH01- CARTID- 2015-00041	Albert Einstein College of Medicine, Yeshiva University	David Sharp, Ph.D.	CART	Harnessing Microtubules to Enhance Urological Function after Spinal Cord Injury	9-0 Faber recused	Yes	9-0 Faber recused	\$1,197,182
DOH01- CARTID- 2015-00061	Burke Medical Research Institute	Dianna Willis, Ph.D.	IDEA	Alterations in Extracellular Vesicle Communication as a Cause of NMJ Dysfunction after SCI	7-3	Yes	7-3	\$448,978
DOH01- CARTID- 2015-00009	Burke Medical Research Institute	Jason Carmel, M.D., Ph.D.	IDEA	Delayed Versus Immediate Motor Training Following Brain Stimulation to Enhance Recovery in Rats with Chronic Corticospinal Tract Injury	9-0 Grafstein recused	Yes	9-0 Grafstein recused	\$450,419
DOH01- CARTID- 2015-00037	Icahn School of Medicine at Mount Sinai	Noam Harel, M.D., Ph.D.	IDEA	Augmenting Hand Muscle Control in Cervical SCI through Paired Cortical and Cervical Stimulation	9-0 Bryce recused	Yes	9-0 Bryce recused	\$391,353

Application Number	Organization Name	Principal Investigator	Funding Mechanism	Project Title	Base Award Votes (Y-N)	*One Time Use Funds Request	One Time Award Votes (Y-N)	Recommended Award
DOH01- CARTID- 2015-00054	SUNY Downstate Medical Center	Joseph Francis, Ph.D.	IDEA	24/7 Use of Fully Integrated Bi-Directional Autonomous Brain Machine Interface in Non-Human-Primates	8-2	No	N/A	\$341,559
DOH01- CARTID- 2015-00065	Icahn School of Medicine at Mount Sinai	Hongyan Zou, M.D., Ph.D.	IDEA	The Role of HDAC3 in the Epigenetic Regulation of Functional Polarization of Microglia and Macrophages after Spinal Cord Injury	7-2 Bryce recused	Yes	6-3 Bryce recused	\$360,000
DOH01- CARTID- 2015-00015	Burke Medical Research Institute	Jason Carmel, M.D., Ph.D.	CART	Paired Motor Cortex and Cervical Spinal Cord Stimulation to Promote CST Connections and Functional Recovery after Spinal Cord Injury	1-8 Grafstein recused	Yes	1-8 Grafstein recused	\$0
DOH01- CARTID- 2015-00005	Sloan-Kettering Institute for Cancer Research	Dimitar Nikolov, Ph.D.	IDEA	Regulation of NgR1/Lingo/P75 Signaling by A-Secretase in Spinal Cord Injury	1-9	No	N/A	\$0
DOH01- CARTID- 2015-00079	Columbia University	Sunil Agrawal, Ph.D.	IDEA	A Virtual-reality Test-bed with a Cable- driven Leg Exoskeleton and Pelvic Perturbations for Gait Rehab and SCI Patients	1-8 Bryce recused	Yes	1-8 Bryce recused	\$0
DOH01- CARTID- 2015-00008	Health Research Incorporated, Wadsworth Center	Xiang Yang Chen, Ph.D.	CART	Operant Conditioning of Corticospinal Motor Evoked Potential to Improve Gait after SCI	0-10	Yes	0-10	\$0