



SPINAL CORD INJURY RESEARCH BOARD

Regular Business Meeting

December 2, 2015

12:00 PM to 4:00 PM

MINUTES

Locations

NYS DOH Metropolitan Area Regional Office, Conference Room 4C, 90 Church Street, New York, NY

NYS DOH David Axelrod Institute, Executive Conference Room, 120 New Scotland Avenue, Albany, NY

SCIRB Members Present

Thomas N. Bryce, M.D.

Donald Faber, Ph.D.

Michael E. Goldberg, M.D.

Keith Gurgui

Nancy Lieberman

Lorne Mendell, Ph.D.

Fraser Sim, Ph.D.

Mark Menniti Stecker, M.D., Ph.D.

Adam Stein, M.D.

NYS DOH Staff Present

Teresa Ascienzo

Charles Burns

Kathy Chou, Ph.D.

Janet Cohn, J.D.

Matthew Kohn, Ph.D.

Victoria Derbyshire, Ph.D.

Marti McHugh

Jeannine Tusch

Carlene Van Patten

Diana Yang, J.D.

SCIRB Members Absent

Anthony Caggiano, M.D., Ph.D.

David A. Carmel

Bernice Grafstein, Ph.D.

Gary D. Paige, M.D., Ph.D.

Guests

Tracy Tress

Call to Order and Opening Remarks of the Chair

The meeting was called to order at 12:05 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.

Consideration of September 21, 2015 Meeting Minutes

Dr. Mendell asked the SCIRB members to consider Exhibit 1, the minutes from the September 21, 2015 meeting. No changes were suggested.

ACTION

Mark Menniti Stecker, M.D., Ph.D. made a motion to approve the minutes as presented. Michael E. Goldberg, M.D. seconded. A roll call vote was taken and the motion was approved (7-0), Thomas N. Bryce, M.D. recused himself from the vote.

SCI Research Opportunities

Dr. Mendell reviewed different funding scenarios for the Translational Research Projects (TRP) in Spinal Cord Injury (SCI) Request for Application (RFA). He explained how the SCIRB's decisions to fund, one, two or three translational awards would impact future funding opportunities:

- If the SCIRB recommends three translational awards for funding, DOH staff project that no Institutional Support rounds would need to be issued in the near future.
- If the SCIRB recommends one or two translational awards for funding, DOH staff project additional Institutional Support Round(s) would need to be issued.

Nancy Lieberman asked if there would be enough funding to issue another TRP in SCI RFA in January 2016 if the SCIRB decided to award three applications for consideration today. Victoria Derbyshire, Ph.D., Deputy Director of the Wadsworth Center recommended for the SCIRB to continuously make well-timed rolling RFA decisions to ensure \$8.5 million is spent every year on SCI research.

ACTION

Dr. Mendell made a motion to adjourn into Executive Session and Dr. Stecker seconded. The 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 the TRP in SCI applications, the SCIRB reconvened in Public Session.

Dr. Adam Stein joined the meeting.

Award Recommendations

Dr. Mendell began the process of considering each of the eligible five applications, noting that the final award amounts will be contingent on correction of any arithmetic errors and administrative issues. 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 two TRP awards for a total of \$8.7 million for five years, which are spread over six state fiscal year (FY) periods (6/1/16-6/30/21). Details are provided on page 6.

DOH staff project a small non-competitive Institutional Support round may need to be issued in FY 2017. DOH staff will continue to provide financial projections at future meetings.

Consideration of Annual Report

Dr. Mendell asked the SCIRB to consider the draft 2015 SCIRB Annual Report. The SCIRB agreed to make changes to Section V. Major Activities of the Board and Program.

ACTION

Dr. Mendell motioned to approve the draft 2015 SCIRB Annual Report as presented with clarification of multiple year awards and adding language that the SCIRB intends to expend \$8.5 million every year for SCI research. Dr. Stein seconded. A roll call vote was taken and the report was unanimously approved as to be amended (9-0).

RFA Discussion

The SCIRB discussed and revised a draft Request for Applications (RFA) for "Project to Accelerate Research Translation (PART) and Innovative, Developmental or Exploratory Activities (IDEA)." This draft included recommended changes from the SCIRB's previous meeting. The SCIRB had recommended deemphasizing collaborations so that it's not a requirement and the name of the RFA has changed (formerly CART/IDEA). Projected dates for the PART/IDEA RFA are:

- January 2016 – RFA release
- June 2016 – consideration of PART/IDEA applications
- January 2017 – contracts start

The SCIRB may choose to award up to 10 multiyear awards for a projected total of \$6 million for this RFA.

ACTION

Dr. Mendell motioned to approve the PART/IDEA RFA including revisions and all forthcoming resolutions approved by SCIRB will be subject to amendment in this RFA.

The following amendments to the draft PART/IDEA RFA subsumed in the motion are listed in detail below:

Section C. Available funds

- Approximately \$6 million is available to support these awards,
- PART – three year award, total direct costs per year will be capped at \$275,000, plus total indirect costs not to exceed 20%,
- IDEA – two year award, total direct costs per year will be capped at \$150,000, plus total indirect costs not to exceed 20%,

Section B. Purpose of the funds

- the phrase “inter-disciplinary and collaborative approaches to” will be removed,
- the phrase “as are the under-studied areas of bowel and bladder function” will be removed,

Section III. A. Project Narrative/Workplan Outcomes for PART

- second paragraph will be removed,

Section V. F. SCIRB Review

- the phrase “until available funds are exhausted” will be removed,
- the sentence, “Scoring ties will be resolved on the basis of the above and with consideration of the score for “Research Plan” and among those applications involved in the tie, ” will be removed.

Donald Faber, Ph.D. seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

Ms. Lieberman distributed a list of draft resolutions of SCIRB. This document was used for framing conversations surrounding review procedures and miscellaneous processes. This document mentions the New York Public Health Law § 250 – 251 (SCI Law). The SCIRB discussed several of the draft resolutions and passed the following motions:

1. EXPERIENCE OF SCIENTIFIC REVIEW PANEL MEMBERS

ACTION

Ms. Lieberman motioned that each three-member scientific review panel considering applications for funding under the SCI Law shall consist of at least 2 “senior review scientists,” and accordingly, not more than one junior review scientist shall participate on each three-member scientific review panels. A “senior review scientist” is hereby defined to be a scientific researcher who has been a primary investigator or co-primary investigator on more than one scientific research project which has been previously funded. Dr. Stein seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

2. COMPOSITION OF REVIEW PANELS AND PROCESSES

ACTION

- a. Ms. Lieberman motioned that all applications submitted for funding under the SCI Law shall indicate whether the applicant categorizes such application as an application for “Rehabilitation (Rehabilitation)” research or “Cellular Regeneration & Therapeutics (Cellular Regeneration)” research;

- b. She further resolved that all applications submitted for funding under the category of Cellular Regeneration research shall be reviewed and scored by a panel of independent scientists/researchers, expert in the field of Cellular Regeneration, who are members of the Cellular Regeneration scientific review panel;
- c. She further resolved that all applications submitted for funding under the category of Rehabilitation research shall be reviewed and scored by a panel of independent scientists/researchers who are members of the Rehabilitation scientific review panel;
- d. She further resolved that within each of the Rehabilitation and Cellular Regeneration panels, applications shall initially be reviewed and scored by the respective three-member subpanels and thereafter, shall be reviewed and scored separately by each of the entire Rehabilitation or entire Cellular Regeneration panels;
- e. She further resolved that the SCIRB shall be provided with each score given by each member of the entire scientific review panel (either Rehabilitation or Cellular Regeneration panel, as the case may be) considering an application for funding under the SCI Law as well as any written review prepared, provided that the identify of each such scientific review panel member providing a score and/or written review shall not be disclosed to the SCIRB;
- f. She further resolved that the SCIRB shall be provided with respect to each of scoring done by the Rehabilitation panel and the Cellular Regeneration panel a graph chart whereby the X-Axis (horizontal line) lists the average score accorded each application by the applicable scientific panel (Rehabilitation or Cellular Regeneration), and the Y-Axis (vertical line) lists the number of applications with a particular average score;
- g. She further resolved that the SCIRB shall also be provided with graphs that display the mean score (i.e. the numerical average of all applications within each of the Rehabilitation applications and the Cellular Regeneration applications) and the median score (i.e. the score at which half of the number of applications in a particular category (either Rehabilitation or Cellular Regeneration) are higher and half of the number of applications in a particular category (either Rehabilitation or Cellular Regeneration) are lower.

The SCIRB made the following amendments to the above language:

- Sections (2b.-2d.) are qualified with the understanding that if the applications submitted were a small number then the panel will be combined.
- The reference to the “horizontal line” and “vertical line” has been removed (from Section 2f.).

Dr. Mendel seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

3. VOTING

ACTION

Ms. Lieberman motioned that the SCIRB shall have both the power to vote against any application which is recommended for funding by a scientific review panel and the power to vote in favor of any application submitted for funding under the SCI Law. Dr. Stein seconded. A roll call vote was taken and the motion was unanimously approved (8-0), excluding a vote from Dr. Stecker as he briefly left the room.

4. INTERRELATIONSHIP OF MISSION AND GOAL OF THE SCI LAW AND FUNDING PROCESS

The SCIRB discussed the interrelationship of mission and goal of the SCI law and funding process resolution prepared by Ms. Lieberman. After discussion, the SCIRB amended the approved PART/IDEA RFA, adding emphasis to the Section E. Review Criteria.

ACTION

Ms. Lieberman motioned to amend the language for the PART/IDEA RFA, Section IV. Review Criteria, with an addition of a bullet emphasizing the likelihood of the proposed research will have a high impact in curing SCI (will be first bullet point). She further motioned removing the reference to collaborative research and inter-disciplinary approach. Dr. Fraser Sim seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

5. MISCELLANEOUS

ACTION

Ms. Lieberman motioned that all RFA's prepared shall expressly state that on the final date applications for research grants are permitted to be submitted by applicants seeking funding, a member of the New York State Department of Health (DOH) staff shall be manning a specified telephone number during the 3 hour period to the deadline for submissions and a member of DOH staff shall be manning a computer at a specified email address, in each case, in order to address technical glitches or problems that applicants seeking funding may have in connection with the submission of their applications, provided that if such glitches or problems cannot be cured by the deadline for submission of applications, all reasonable efforts shall be made by the DOH staff to work with such applicant in order to reasonably resolve such glitch or problem so that the application will be deemed to have been submitted prior to the deadline. The presumption shall be given that if the applicant has sufficiently complied with the requirements of the RFA they shall be allowed to submit, which shall be brought back to our (NYS) procurement team. Dr. Goldberg seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

Other draft miscellaneous resolutions prepared by Ms. Lieberman were tabled and/or not discussed. The SCIRB may choose to discuss these topics at future meetings.

Future Meetings

At its next meeting in early 2016, the SCIRB plans to continue these types of discussions plus the possibility of issuing Individual Predoctoral & Postdoctoral Fellowships in Spinal Cord Injury Research" (Fellowships) RFA and Translational Research Projects in Spinal Cord Injury (Translational) RFA.

Public Comment

No members of the public wished to comment.

Adjournment

The Board unanimously voted to adjourn and the meeting ended at 4:00 p.m.

2015 Translational Research Projects (TRP) in Spinal Cord Injury (Round 1) Recommendations for Award

Application Number	Organization Name	Investigators	Project Title	Votes (Y-N)	Recommended Award
DOH01-2015-TRANS1-00013	RFCUNY obo The City College of NY/CUNY School of Medicine; Sub-applicant- Winifred Masterson Burke Medical Research Institute; Sub-applicant- Bronx Veterans Medical Research Foundation	John Martin, Ph.D. Jason B. Carmel, M.D., Ph.D. Noam Y. Harel, M.D., Ph.D.	Combined Motor Cortex and Spinal Cord Stimulation to Promote Arm and Hand Function After Chronic Cervical Spinal Cord Injury	8-0 Bryce recused	\$3,737,948.00
DOH01-2015-TRANS1-00011	Columbia University; Sub-applicant- University of Louisville Research Foundation	Sunil K. Agrawal, Ph.D. Susan J. Harkema, Ph.D.	Tethered Pelvic Assist Device (TPAD) and Epidural Stimulation for Recovery of Standing in SCI	8-0 Goldberg recused	\$5,033,354.00
DOH01-2015-TRANS1-00009	Burke Medical Research Institute; Sub-applicant- Columbia University; Sub-applicant- SUNY Downstate Medical School	David F. Putrino, P.T., Ph.D. Matei T. Ciocarlie, Ph.D. Joseph T. Francis, Ph.D.	Robust, Multimodal Control of Smart Robotic Manipulators for SCI Survivors: Learning, Shared Autonomy and Telemedicine	0-8 Goldberg recused	\$0
DOH01-2015-TRANS1-00002	Winifred Masterson Burke Medical Research Institute; Sub-applicant- Icahn School of Medicine at Mount Sinai	Jian Zhong, Ph.D. Hongyan Zou, Ph.D., M.D.	Small Molecule Modulators of HDACs and B-RAF Signaling to Promote Spinal Cord Axon Regeneration	1-7 Bryce recused	\$0
DOH01-2015-TRANS1-00003	Icahn School of Medicine at Mount Sinai; Sub-applicant- Bronx Veterans Medical Research Foundation; Sub-applicant- Kessler Foundation	Allan J. Kozlowski, Ph.D. Junqian Xu, Ph.D. Ann M. Spungen, Ed.D. Forrest F. Gail, Ph.D.	Translation of Walking into Rehabilitation and Community Life Following Spinal Cord Injury Using Exoskeleton Technology to Facilitate Neurological Recovery	0-8 Bryce recused	\$0