

SPINAL CORD INJURY RESEARCH BOARD

Regular Business Meeting May 11, 2022 9:00 AM to 3:00 PM

DRAFT AND UNADOPTED

Location

Virtual from the NYS DOH, Wadsworth Center, Biggs Laboratory, Sturman Conference Room, Albany, NY

SCIRB Members Present

Michael E. Goldberg, M.D.
Bernice Grafstein, Ph.D., D.Sc.(hon.)
Keith Gurgui
Lorne Mendell, Ph.D., Chair
Kristjan T. Ragnarsson, M.D.
Fraser J. Sim, Ph.D.
Adam B. Stein, M.D.

SCIRB Members Absent

Nancy A. Lieberman

NYS DOH Staff Present

Teresa Ascienzo
Alana Buscher, Executive Secretary
George Cotich, Jr.
Andrea Garavelli
Jonathan B. Karmel
Kerri Kluetzman, Ph.D.
Farrah M. O'Brien
Brian Rourke
Jeannine Tusch

Members of the Public

Chia (George) Hsu, Ph.D. Lynda Murray, Ph.D. Michelle Walsh (Tress Advisors) Yu-Kuang Wu, P.T., Ph.D.

Call to Order and Opening Remarks of the Chair

The meeting was called to *(unofficial)* order at 9:10 a.m. with a welcome by Chair, Lorne Mendell, Ph.D., followed by introductions of New York State Spinal Cord Injury Research Board (SCIRB) members and the New York State Department of Health (DOH) staff. Note, one (1) board member was absent and there is two (two) gubernatorial vacancies and three (3) vacancies to be filled by legislative leadership.

Carlene Van Patten

Board Membership Updates

Dr. Mendell said that the former Vice Chair of SCIRB, Dr. Donald S. Faber, Ph.D., Gary D. Paige, M.D., Ph.D., and Anthony O. Caggiano, M.D., Ph.D. resigned from the SCIRB and that the Commissioner of Health thanked them for their dedicated service over years, and the SCIRB wishes them all the best on their future endeavors.

Dr. Mendell said that he would be stepping down as Chair but will continue to serve as a member and named Adam B. Stein, M.D. to serve as Vice Chair.

DOH Staff Updates

Victoria Derbyshire, Ph.D. has retired, and Carlene Van Patten will be retiring soon. Alana Buscher will serve as the Executive Secretary to the Board.

Board Member Recruitment

Dr. Stein and Kristjan T. Ragnarsson, M.D. wanted to review the criteria to be considered for SCIRB membership. Andrea Garavelli stated to be considered for SCIRB membership, candidates need to be New York State residents. Ms. Garavelli noted that gender inclusion would be considered when selecting potential candidates and referenced the broad board

member statute that states members should include but not be limited to representatives of the following fields: neuroscience, neurology, neuro-surgery, neuro-pharmacology, and spinal cord rehabilitative medicine. Ms. Garavelli further explained that SCIRB members are prohibited during their tenure from applying for (e.g., a Principal Investigator (PI) or Co-PI Investigator) or receiving SCIRB funding (e.g., salary support). She further clarified SCIRB member roles in projects, e.g., if an applicant includes a SCIRB member in their SCI research project (as an unpaid mentor or unpaid collaborator) the SCIRB member would recuse themselves from considering the application during discussion and voting.

Dr. Mendell asked for further clarification regarding the SCIRB member roles in projects, specifically if they are allowed to be co-investigators that contribute to the scientific content on SCI research projects and wondered if a fellow lab member(s) is able to receive salary support. Dr. Mendell said it could be of benefit to know these specifics when recruiting potential members. Ms. Garavelli said the DOH staff would enquire with the DOH Ethics Officer on this.

SCIRB members shared potential candidate names with DOH staff for membership consideration.

Passing of Paul Richter, former member and advocate for the SCIRB

Keith Gurgui said a few words in honor of Paul Richter, former SCIRB member and advocate for the NYS spinal cord injury program and legislation, who passed on August 1, 2020. Mr. Gurgui and Dr. Mendell thoughtfully recognized the work Mr. Richter did to help create the SCIRB and he will be missed.

Michael E. Goldberg, M.D. joined the meeting for official order at 9:40 a.m. and Dr. Mendell briefly summarized the Chair updates for Dr. Goldberg. Dr. Mendell continued to follow the business agenda as quorum had been reached.

Consideration of January 24, 2020 Meeting Minutes

Dr. Mendell asked the SCIRB to consider Exhibit 1, the minutes from the January 24, 2020 meeting.

ACTION

Mr. Gurgui made a motion to approve the minutes as presented with edits. Bernice Grafstein, Ph.D., D.Sc.(hon.)

A roll call vote was taken, and the minutes were unanimously approved (7-0).

Translational Research Projects (TRP) in Spinal Cord Injury (Round 4) Request for Applications (RFA)

Ms. Garavelli provided an overview of the applications received in response to this RFA; the procurement timeline is bulleted below:

- Two (2) applications were submitted by the deadline
- The RFA made \$8 million available to fund approximately two (2) awards
- If the SCIRB recommends:
 - o the top scoring application then \$3.57 million would be programmed
 - o the top two (2) scoring applications then \$7.57 million would be programmed
- The contracts are expected to begin on October 1, 2022 for a term of five (5) years

Projects to Accelerate Research Translation (PART) and Innovative, Developmental or Exploratory Activities in Spinal Cord Injury (Round 5) RFA

Andrea Garavelli provided an overview of the applications received in response to this RFA; the procurement timeline is bulleted below:

- Twenty-nine (29) applications were submitted by the deadline, one (1) PI withdrew their application because they received funding elsewhere
- Scoring ties were resolved using the score for the "Research Plan" among those applications involved in the tie
- The RFA made \$5 million available to fund approximately 5-14 awards
- If the SCIRB recommends the top nine (9) scoring applications funding of \$5.75 million would be programmed
- The contracts are expected to begin on October 1, 2022 for a term of three (3) years for PART awards and two (2) years for IDEA awards

For both abovementioned RFAs, Ms. Garavelli said that the SCIRB may vote in favor or against any application submitted for funding, and if an application for which there are available funds is not recommended for funding, the SCIRB will fully justify why the application was not approved. She stated the SCIRB could approve, but not fund other meritorious applications due to limited resources, which could become recommended awards for funding, should there be any declinations.

The SCIRB adjourned into Executive Session for the purpose of considering applications for research funding and future RFAs at 9:50 a.m. Members of the public were placed in a virtual waiting room.

After discussing the research applications and future RFAs, the SCIRB reconvened in Public Session at 1:00 p.m.

SCIRB Recommends TRP (Round 4) and PART and IDEA (Round 5) applications
Dr. Mendell began the process of considering the applications in response to the TRP (Round 4) and PART and IDEA (Round 5) in Spinal Cord Injury RFAs. Ms. Garavelli announced the application number, organization, and principal investigator. A listing of the SCIRB's recommendations is provided on pages 7-8.

In summary, the SCIRB recommended funding of \$7.57 million in the form of two (2) TRP awards using the peer review results as the basis for the decision.

The SCIRB also recommended funding of \$5.75 million in the form of four (4) PART and five (5) IDEA awards using the peer review results as the basis for the decision.

Ms. Garavelli also said that the SCIRB could recommended to approve, but not fund other meritorious applications due to limited resources.

ACTION

Dr. Grafstein made a motion to approve but not fund due to limited resources one (1) IDEA application (DOH01-PART5-2022-00018) submitted by Jenny Hongyan Zou, M.D., Ph.D. at the Icahn School of Medicine at Mount and should there be any declinations, this application could be approved. Dr. Sim seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

Ms. Garavelli said the SCIRB's recommendations will be forwarded to the Commissioner of Health for approval.

Future RFA: Translational Research Projects (TRP) in Spinal Cord Injury (Round 5)

ACTION

Dr. Grafstein made a motion to approve a TRP (Round 5) RFA for release in 2022 with \$8 million available. Dr. Stein seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

Future Institutional Support (Round 7) Solicitation of Interest:

ACTION

Dr. Sim made a motion to approve a future Institutional Support (Round 7) Solicitation of Interest for release in 2022 with \$6 million available. Dr. Mendell seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

Future RFA: Projects to Accelerate Research Translation (PART) and Innovative, Developmental or Exploratory Activities in Spinal Cord Injury (Round 6)

ACTION

Dr. Stein made a motion to approve a PART & IDEA (Round 6) RFA for release in 2022 with \$5 million available. Dr. Mendell seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

Future RFA Changes

ACTION

Dr. Goldberg made a motion to include Workplan Narrative page limitations as a Pass/Fail item on all RFAs moving forward. Dr. Sim seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

ACTION

Dr. Mendell made a motion to include adding triage at a level of 5.0 for all future RFAs.

Dr. Stein seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

Consideration of SCIRB Reports

The SCIRB considered the draft SCIRB reports in their meeting materials. Ms. Garavelli noted that the final reports will be sent to the Commissioner of Health for approval, and then the reports will be provided to the Governor and Legislative leaders.

ACTION

Dr. Grafstein made a motion to approve the draft 2019 SCIRB Annual Report as presented. Dr. Stein seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

ACTION

Dr. Grafstein made a motion to approve the draft 2020-2021 SCIRB Report as presented. Dr. Stein seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

DOH Program Update

Ms. Garavelli provided an update on the status of other program activities and previously awarded contracts:

- One (1) contract from the TRP in Spinal Cord Injury (Round 2) ended in April 2022 and one (1) received a no-cost extension and will end in April 2023
- Three (3) of the PART awards from the PART and IDEA (Round 3) contracts are in their final year since they received no-cost extensions. These contracts will end in April 2023
- Five (5) Individual Pre- and Postdoctoral Fellowships (Round 4) contracts are in their final year and will end in July 2022
- The DOH peer review contract with the American Institute for Biological Sciences (AIBS) continues and ends in December 2024
- One (1) PART and seven (7) of the eight (8) IDEA (Round 4) contracts began in November 2021. These multi-year contracts will end in October 2023 (IDEA) and October 2024 (PART). One (1) of the eight (8) IDEA awardees from the Research Foundation of SUNY Albany, Dr. Ben Szaro declined his award and announced his retirement
- The Translational (Round 4) contracts are anticipated to begin in October 2022
- The PART & IDEA (Round 5) contracts are anticipated to begin in October 2022
- The Fellowships (Round 5) RFA was released in March and applications are due June 1, 2022. The Board will vote to approve meritorious applications for funding at their next Board meeting in the Fall of 2022

Future NYS SCI Research Symposium

Ms. Garavelli stated that the last Symposium was held in 2018 and planning the event took a little over a year. She said with the pandemic, the planning of the next Symposium in 2021 was put on hold and the SCIRB will discuss the planning at the next SCIRB meeting.

Public Comment

No members of the public provided a written statement and there was no public comment.

Open Meetings Law, SCIRB Resolution

Ms. Garavelli stated that it is likely the next SCIRB meeting will be in person and Public Officers Law, Open Meetings Law has been amended allowing flexibility for videoconferencing due to extraordinary circumstances. She stated, the SCIRB can adopt a resolution, allowing its members to participate and vote in extraordinary circumstances, as long as there is a quorum of members, gathered at a physical location or locations open to the public.

ACTION

Dr. Gurgui made a motion for the SCIRB Chair to use their discretion, and in their absence, the Vice-Chair, on behalf of the Board, to excuse the member's physical attendance if the reason for the extraordinary circumstance is communicated to the Board's Chair/Vice-Chair prior to a meeting. Dr. Grafstein seconded.

A roll call vote was taken, and the motion was unanimously approved (7-0).

Future Meeting & Adjournment

At its next meeting in Fall 2022, the SCIRB will consider applications for funding the Predoctoral and Postdoctoral Fellowships (Round 5) RFA. Dr. Mendell thanked members of the SCIRB, the public and DOH staff for attending. All members and DOH staff thanked Dr. Mendell for his service as Chair. The business meeting was adjourned at 1:43 p.m.

TRP in Spinal Cord Injury (Round 4)
\$7.57 million in the form of two (2) TRP awards were recommended. Projects are five-year awards.

Organization	Research Category	Project Title	PI	Recommended Funding	Votes (Y-N)
The Feinstein Institute for Medical Research	Rehabilitation	Constant and Cortically- Modulated Transcutaneous Spinal Cord Stimulation for the Treatment of Upper Extremity Impairment	Chad E. Bouton, M.S.	\$3,570,469	7-0
Columbia University	Rehabilitation	Improving balance after spinal cord injury using a robotic upright stand trainer	Sunil K. Agrawal, Ph.D.	\$3,995,925	

PART and IDEA (Round 5)
\$5.75 million in the form of four (4) PART and five (5) IDEA awards were recommended. Projects are three (3) years for PART awards and two (2) years for IDEA awards.

Organization	Funding Mechanism/ Research Category	Project Title	PI	Recommended Funding	Votes (Y-N)
Sloan Kettering Institute for Cancer Research	IDEA/ Cellular Regeneration & Therapeutics	Promoting neuronal regeneration by targeting the alpha secretase cleavage of p75 with monoclonal antibodies	Dimitar B. Nikolov, Ph.D.	\$360,000	7-0
Winifred Masterson Burke Medical Research Institute DBA Burke Neurological Institute	PART/ Rehabilitation	Enhancing nerve transfer surgery to restore hand and arm function in chronic tetraplegia	Edmund R. Hollis, Ph.D.	\$990,000	
Stony Brook University	PART/ Cellular Regeneration & Therapeutics	Therapeutic intermittent hypoxia to reduce detrusor overactivity and symptom severity in chronic incomplete SCI: translation and mechanisms	Irene C. Solomon, Ph.D.	\$986,610	
Winifred Masterson Burke Medical Research Institute DBA Brain and Mind Research Institute	IDEA/ Cellular Regeneration & Therapeutics	Mechanisms controlling early and segmentally distinct loss of long distance corticospinal axon regenerative ability	Vibhu V.Sahni, Ph.D.	\$360,000	
Icahn School of Medicine at Mount Sinai	PART/ Rehabilitation	Augmentation of Bladder Function by Transcutaneous Spinal Cord Stimulation after Conus Medullaris Injury in Primates	Leif A. Havton, M.D., Ph.D.	\$995,000	
Albany Research Institute, National Center for Adaptive Neurotechnologies	IDEA/ Rehabilitation	Operant Conditioning of Somatosensory Evoked Potentials to Improve Motor Function after SCI	Disha Gupta, Ph.D.	\$356,538	
The City College of New York	IDEA/ Cellular Regeneration & Therapeutics	Nucleolipid Signaling for Spinal Cord Regeneration	Ashiwel S. Undieh, Ph.D.	\$360,000	
The City College of New York	PART/ Rehabilitation	Leveraging LTP to promote CST axon sprouting in the spinal cord	John Martin, Ph.D.	\$982,800	
Winifred Masterson Burke Medical Research Institute DBA Burke Neurological Institute	IDEA/ Cellular Regeneration & Therapeutics	Role of SPARC in pathological wound healing after spinal cord injury	Edmund R. Hollis, Ph.D.	\$360,000	