



SPINAL CORD INJURY RESEARCH BOARD

Regular Business Meeting

September 21, 2015

1:00 PM to 5:00 PM

MINUTES

Locations

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

SCIRB Members Present

Anthony Caggiano, M.D., Ph.D.
Donald Faber, Ph.D.
Michael E. Goldberg, M.D.
Keith Gurgui
Bernice Grafstein, Ph.D.
Nancy Lieberman
Lorne Mendell, Ph.D.
Fraser Sim, Ph.D.
Mark Menniti Stecker, M.D., Ph.D.
Adam Stein, M.D.

SCIRB Members Absent

Thomas N. Bryce, M.D.
David A. Carmel
Gary D. Paige, M.D., Ph.D.

NYS DOH Staff Present

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

Guests

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 member Anthony Caggiano, M.D., Ph.D. was introduced and welcomed. Dr. Mendell noted that Jeffrey Ehmann's service had concluded and thanked him for his service.

Consideration of June 25, 2015 Meeting Minutes

Dr. Mendell asked the SCIRB members to consider Exhibit 1, the minutes from the June 25, 2015 meeting. No changes were suggested and no comments were offered.

ACTION

Bernice Grafstein, 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 (9-0), excluding a vote from Dr. Caggiano.

Program Update

Victoria Derbyshire, Ph.D., Deputy Director of the Wadsworth Center, provided an update regarding program activities. DOH staff have been working diligently on the following items:

- Providing technical assistance to the "Collaborations to Accelerate Research Translation (CART) and Innovative, Developmental or Exploratory Activities (IDEA)" awardees for the development of their contracts,

- Providing support for the “Individual Predoctoral & Postdoctoral Fellowships in Spinal Cord Injury Research” (Fellowships) Request for Applications (RFA),
- Providing support for the Translational Research Projects in Spinal Cord Injury (Translational) RFA, and
- Providing direction to the 19 organizations for this year’s Institutional Support Round 5 awards.

Dr. Derbyshire noted that the critiques for the six Fellowship applications to be considered by the Board were sent to the SCIRB for consideration in advance of the meeting. She stated DOH staff received five Translational applications and the SCIRB will make award recommendations at the December 2, 2015 meeting. She said responses to “Institutional Support for Spinal Cord Injury Research Round 5” solicitation of interest were due on September 2, 2015. She announced upon receipt of the necessary approvals and budgets, each of the 19 organizations was able to apply for up to \$337,412 (an equal share of the \$6.4 million yet to be unallocated from the current state fiscal year (FY) appropriation). DOH staff distributed a list of the eligible organizations (see page 7). The contract term is anticipated to be February 1, 2016 to August 31, 2016.

Charles Burns gave an update on the early planning stages for a scientific meeting. He said Dr. Mendell, Dr. Grafstein and Dr. Faber have volunteered to start the program committee, which will be charged with developing the format/content of the symposium, securing guest speakers, as well as selecting presentations/posters from SCIRB funded researchers to be showcased at the meeting.

Dr. Mendell asked when the Institutional Support Round 5 budgets were due. Dr. Derbyshire reported they are due on September 25, 2015. Nancy A. Lieberman proposed using another funding mechanism if these organizations did not apply and budget for the full amount of \$337,218.

ACTION

Ms. Lieberman made a motion that if any one of these institutions does not submit appropriate documentation, the balance left unspent is equally divided among those who did not apply for the full amount.

The Board discussed and offered the following suggestions for expending any leftover funds. Following discussion, Dr. Mendell seconded and subsumed Ms. Lieberman’s motion by making the following amendment:

Should a significant amount (≥\$100,000) not be applied for, a process should be put in motion to allow institutions that did apply for the full amount of \$337,218, to get a share of the overage of the extra funds in an equal way.

Dr. Derbyshire said DOH staff would investigate the options and take appropriate measures.

Dr. Mendell further added, a budget must be provided for the additional amount and contract timing should be the same (February 1, 2016 to August 31, 2016).

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

Carlene Van Patten, Associate Director of Administration for the Wadsworth Center, explained the contents of Exhibit 2. She reviewed the cash disbursements and projected cash disbursements of FY 13/14 through

18/19. Dr. Derbyshire noted that DOH would provide 25% advances for the “Institutional Support for Spinal Cord Injury Research Round 5” awards in attempt to expend as much funding as possible in FY 15/16.

Consideration of Applications for Funding

Dr. Derbyshire gave an overview of the RFA for Fellowships as well as the peer review and scoring process used. She stated the RFA made up to \$4 million available for award. She reviewed the SCIRB set a cutoff score at 3.9, meaning the applications scoring in the range of 4.0-9 and those that were triaged would not be considered for award.

Dr. Faber inquired about the triaged critiques and if they were going to receive these. Dr. Derbyshire confirmed the Board would receive these after the meeting.

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 applications, the SCIRB reconvened in Public Session.

Award Recommendations

Dr. Mendell began the process of considering each of the eligible six 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 six Fellowships awards (four Predoctoral and two Postdoctoral). Dr. Derbyshire announced the SCIRB recommended a total of \$812,879 in Fellowships awards. Details are provided on page 8.

RFA Development

DOH staff provided Exhibit 4 for this discussion. Dr. Mendell read the definition of a cure from the Institute of Medicine, Spinal Cord Injury strategic plan commissioned by the SCIRB. Additionally, he reviewed the historical summary of the SCIRB activities to date. Dr. Derbyshire explained the funds for future RFAs would come from the SCIRB FY 17/18 and 18/19 budgets.

The Board discussed the mechanism(s) SCIRB may want to utilize for support. Topics discussed amongst members included:

- Clinical studies to establish spinal cord injury (SCI) trauma treatment protocols
- CART/IDEA
- Translational awards
- Smaller investigative awards

ACTION

Dr. Mendell motioned to re-issue a CART/IDEA RFA. Adam Stein, M.D. seconded.

Dr. Grafstein asked if these mechanisms could be issued separately. Ms. Brautigam explained in the past both funding mechanisms, CART and IDEA, were issued in a single RFA. Some members recommended removing

the word collaboration from the RFA. Some members thought removing the requirement for inter-disciplinary collaborations (15% evaluation criteria) from the review criteria would be constructive.

WITHDRAWN

Dr. Mendell withdrew the previous motion after discussion.

ACTION

Dr. Stein motioned for a CART/IDEA RFA, deemphasizing the requirement for collaborations, removing the 15% review criteria titled “Inter-Disciplinary Nature of the Research Team” and adding that 15% to the “Research Plan” criterion. Ms. Lieberman seconded.

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

Ms. Lieberman distributed a list of draft resolutions of SCIRB. This document was used for framing conversations surrounding review procedures and scoring. The SCIRB discussed several of the draft resolutions and passed the following motions:

ACTION

Ms. Lieberman motioned that all applications submitted for funding be scored on a scale of 1 to 9, and accordingly, no applications shall be triaged out of the scoring process at the peer review level. Mark Menniti Stecker, M.D., Ph.D. seconded.

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

ACTION

Ms. Lieberman motioned that to the extent the DOH is able, any funds available in any given year have not otherwise been allocated and/or dispersed by the SCIRB, so that the maximum funds available in any particular FY shall not have been spent by the end of any FY, then such remaining funds (excess funds) shall be evenly distributed and dispersed amongst all New York State institutions having at least one active SCI research project. Dr. Stein seconded.

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

ACTION

Dr. Mendell motioned that each three-member scientific review panel considering applications for funding shall consist of at least a majority of “senior review scientists.” A “senior review scientist” is defined as someone who has served as a PI or Co-PI on more than one previously funded scientific research project. Dr. Stein seconded.

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

Mr. Keith Gurgui left the meeting.

ACTION

Ms. Lieberman motioned that in scoring the “Budget” criterion of any research application, a scientific review panel shall be instructed to determine whether the budget requested exceeds the proposed research to be conducted, provided that if the scientific review panel determines that any meaningful

portion of the budget should be categorized as having a non-research purpose it shall state the amount of such excess and the reason for such determination. Dr. Mendell seconded.

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

ACTION

Ms. Lieberman motioned that in addition to any New York State law governing conflicts of interest applicable to scientific reviewers participation in review panels, a scientific reviewer is considered to be in conflict with an applicant and his investigative colleagues if such scientific reviewer (1) has a long-standing scientific or personal disagreement with an applicant or such applicant's investigative colleagues, or (2) feels he cannot provide an objective review of such application.

She further resolved, that all SCIRB RFA's going forward shall contain the following text:

"Review Exclusions:

The SCIRB aims to conduct a review process that is rigorous and impartial. All participants in a review (including scientific reviewers, DOH staff members and members of the SCIRB) are required to disclose financial interests and declare all conflicts that meet relevant SCIRB and State New York conflict of interest regulations.

In addition, the SCIRB understands that even strict policies may not account for every perceived conflict. Therefore, all applicants seeking funding may identify up to three individuals (excluding SCIRB members and employees) and/or for-profit organizations that that such applicant believes could be biased whether for personal, professional, or competitive reasons (e.g., a company that is a direct competitor with respect to the applicant's proposed research or product). Individuals, and current employees, board members, and consultants (working on potentially competing research or product) of companies, identified by applicants pursuant to this screening mechanism will not be permitted to participate in the review of such applicant's application.

1st Exclusion

Type (Individual/Company/Other Entity) (circle or check one)

Name:

2nd Exclusion

Type (Individual/Company/Other Entity) (circle or check one)

Name:

3rd Exclusion

Type (Individual/Company/Other Entity) (circle or check one)

Name: "

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

Future Meetings

The Translational RFA applications will be considered at the SCIRB meeting on December 2, 2015. As much as \$12 million for approximately two awards may be recommended for funding. This funding would span across five FY's, beginning FY 16/17.

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

Public Comment

Nurit Kalderone, Ph.D. spoke to a National Institutes of Health procedure in which certain meritorious applications are brought forward and presented by the scientist to the council for consideration regardless of score. She said members of the council may choose to recommend the award for funding after the scientific presentation. She offered her opinion in favor of both rehabilitation and cellular regeneration therapeutics research and asserted rehabilitation research costs more.

Adjournment

The Board unanimously voted to adjourn and the meeting ended at 5:23 p.m.

Institutional Support for Spinal Cord Injury Research, Round 5

<i>Institution Name</i>	<i>Maximum Award</i>
Albany Research Institute, Inc. - Albany Stratton VA Medical Center	\$337,218
Bronx Veterans Medical Research Foundation - James J. Peters VA Medical Center	\$337,218
Columbia University	\$337,218
COM Affiliation, Inc. - Albert Einstein College of Medicine	\$337,218
Cornell University	\$337,218
Health Research, Inc. - Wadsworth Center	\$337,218
Icahn School of Medicine at Mount Sinai	\$337,218
Regenerative Research Foundation	\$337,218
Research Corporation of Long Island, Inc. - Northport VA Medical Center	\$337,218
Research Foundation of CUNY - City College	\$337,218
Research Foundation of CUNY - Staten Island	\$337,218
Research Foundation of SUNY - Albany	\$337,218
Research Foundation of SUNY - Downstate Medical Center	\$337,218
Research Foundation of SUNY - Stony Brook	\$337,218
Sloan-Kettering Institute for Cancer Research	\$337,218
Syracuse University	\$337,218
The Feinstein Institute for Medical Research	\$337,218
University of Rochester	\$337,218
WM Burke Medical Research Institute	\$337,218
Total (19 Institutions)	\$6,407,144

2015 Fellowships Recommendations for Award

Application Number	Organization Name	Investigators	Funding Mechanism	Project Title	Votes (Y-N)	Recommended Award
DOH01-FELLOW-2015-00002	Rensselaer Polytechnic Institute	Ryan Gilbert, Ph.D. Christopher Johnson, D.L., B.S. Diana-Andra Borca-Tasiuc, Ph.D. Lee Lignon, Ph.D.	Predoc	Magnetic Alignment of Electrospun Fibers for Treatment of Acute Spinal Cord Contusive Injury	10-0	\$135,600
DOH01-FELLOW-2015-00006	Research Foundation for SUNY, University at Albany	Ben Szaro, Ph.D. Rupa Choudhary, M.S. Melinda Larsen, Ph.D. Gregory Lnenicka, Ph.D. Kurt Gibbs, Ph.D. Cara Pager, Ph.D.	Predoc	Intracellular Modulations of Cytokine Signaling Leading to Successful CNS Axon Regeneration in a Vertebrate Model	10-0	\$85,585
DOH01-FELLOW-2015-00014	The Research Foundation of CUNY obo City College of New York	John Martin, Ph.D. Alzahraa Amer, M.S.	Predoc	Modulating Spinal Cord Neural Activity to Promote Recovery of Motor Function After SCI	10-0	\$138,120
DOH01-FELLOW-2015-00018	The Trustees of Columbia University in the City of New York	Ulrich Hengst, Ph.D. Jose C. Martínez	Predoc	Control of the Transcriptome in Regenerating Axons through mRNA Degradation	9-0 Goldberg recused	\$127,500
DOH01-FELLOW-2015-00012	Winifred Masterson Burke Medical Research Institute	Jason Carmel, M.D., Ph.D. Caitlin Hill, Ph.D. Hongguen Park, Ph.D.	Postdoc	Dissecting and Strengthening Corticospinal Connections After Spinal Cord Injury Using Advanced Neuroscience Methods	8-0 Caggiano & Grafstein recused	\$172,118
DOH01-FELLOW-2015-00003	Winifred Masterson Burke Medical Research Institute	Jian Zhong, Ph.D. Mariel Voutounou, Ph.D. Francesco Boato, Ph.D.	Postdoc	Promoting Intrinsic Growth Competency of Injured Neurons Using Genetic and Small Molecule Approaches	8-0 Caggiano & Grafstein recused	\$165,354