



**SPINAL CORD INJURY RESEARCH BOARD**

Regular Business Meeting

January 23, 2015

9:00 AM to 12:00 PM

MINUTES

**Locations**

**Albany:** NYS DOH David Axelrod Institute, Executive Conference Room, 120 New Scotland Ave

**New York City:** NYS DOH Metropolitan Area Regional Office, 90 Church St, Conference Room 4 C

**Board Members Present**

David A. Carmel  
Donald Faber, PhD  
Michael E. Goldberg, MD  
Keith Gurgui  
Nancy A. Lieberman  
Lorne Mendell, PhD  
Paul Richter  
Mark Menniti Stecker, MD, PhD  
Jonathan R. Wolpaw, MD

**DOH Staff Present**

Ellen Anderson  
Bonnie Jo Brautigam  
Charles Burns  
Victoria Derbyshire, PhD  
Jeannine Tusch  
Carlene Van Patten  
Diana Yang, JD

**Board Members Absent**

Thomas N. Bryce, MD  
Jeffrey Ehmann  
Gary D. Paige, MD, PhD  
Adam Stein, MD

**Call to Order and Opening Remarks of the Chair**

The meeting was called to order at 9:05 a.m. with a welcome by Chair, Lorne Mendell, PhD. Spinal Cord Injury Research Board (SCIRB) members and Department of Health (DOH) staff introduced themselves. New member Mark Menniti Stecker, M.D., Ph.D. was introduced and welcomed.

**Consideration of October 1, 2014 Meeting Minutes**

Dr. Mendell asked SCIRB to consider Exhibit 1, the minutes from the November 24, 2014 meeting. No changes were suggested and no comments were offered.

**ACTION**

Michael E. Goldberg, MD made a motion to approve the minutes as presented. Donald Faber, PhD seconded. A roll call vote was taken and the motion was unanimously approved (7-0), excluding a vote from Dr. Stecker. David A. Carmel was not present for this vote.

**Program Update**

Ms. Brautigam presented Exhibit 2, Spinal Cord Injury Research Funding Encumbrances (State Fiscal Year 2013-14 and State Fiscal Year 2014-15), a list of contracts executed from April 2013 to present (including the rounds of Institutional Support and Peer Review contract) that encumbered \$9,191,703. She explained the term for the most recent Institutional Support contracts was extended until August 31, 2015, although contractors were urged to spend and voucher for funding by March 31, 2015. SCIRB commended DOH staff on its efforts to get funding into the hands of the spinal cord injury (SCI) research community.

Mr. Carmel joined the meeting.

Ms. Brautigam informed SCIRB that the competitive Collaborations to Accelerate Research Translation (CART) and Innovative, Developmental or Exploratory Activities (IDEA) Request for Application (RFA) had been released on Tuesday, January 20, 2015. She reminded members that this RFA includes the one-time-use funds language to make additional funding available in Year 1 so that researchers have the opportunity to “jump start” and enhance the proposed research program. She noted that applications are due on March 5, 2015 (by 6:00 p.m.) and reminded all SCIRB members, visitors and listeners of the importance of the use of the New York State Grants Gateway website, to seek training and immediately registering to apply for funding. She also announced the Individual Predoctoral and Postdoctoral Fellowships in Spinal Cord Injury Research (Fellowships) RFA will be released in the coming weeks.

Ms. Brautigam reported that the peer review contractor, the American Institute of Biological Sciences (AIBS) was able to start work on January 1, 2015. She estimated that with the assistance of AIBS, SCIRB should be able to meet in July to review critiques for the CART/IDEA awards.

### **DOH Proposal for Distribution of Fiscal Year 2015-16**

Ellen Anderson announced the Fiscal Year (FY) 2015-16 Executive Budget included \$7 million for SCI research in a special revenue account, specifically designated for that purpose. She explained that spending as much as possible in the current FY helps to facilitate the roll over option into the next FY, putting the funds in the hands of the SCI research community for the people of the state of New York.

### **Consideration of RFA's for Release in 2015**

Dr. Mendell noted DOH staff has recommended SCIRB to first reach agreement on the essential elements of the RFA through discussion of the concept papers and then authorize staff to move directly to RFA development and issuance. He recommended that no votes be taken until both of the concept papers had been discussed because SCIRB would also need to set some funding priorities.

Ms. Anderson described a simplified outline of the RFA development process, noting that the essential discussions and decisions to be made by SCIRB in the development and approval of an RFA are of “who, what, where, when, why and how much,” as outlined in the concept papers provided to SCIRB. Following input from the SCIRB on these decisions, the DOH incorporates program history and other required language.

Ms. Brautigam confirmed for the SCIRB that it has the ability to recommend applications for funding regardless of the score based on programmatic balance and other factors. The rationale for recommending applications out of score order must be approved by the Office of the State Comptroller (OSC).

Ms. Brautigam emphasized that the discussion of each concept paper should incorporate priorities for funding, because if the State budget stays at the proposed \$7 million per year, there will not be sufficient funds to support the size and number of awards projected in the concept papers. She noted that adjustments to RFA amounts can be made before issuance and at time of award recommendation. She observed that:

1. Issuing RFAs for more funding than can reasonably be expected to be awarded “ties up” the funds until after the Office of the State Comptroller approves the procurement process and outcomes/award recommendations. This leads to a delay in issuing future RFAs.
2. Adding funding to an RFA after it has been issued (at time of award recommendation) may increase the amount of time it takes for approvals to issue letters of award.

Staff handed out a brief list of points to be covered during discussion of the concept papers and noted that as a starting point, each concept paper included text from similar NIH RFAs and past SCIRB RFAs. Dr. Mendell added that during discussion of the two concept papers, if the SCIRB identified need for different funding mechanisms those would also be explored. SCIRB began discussion of the two concept papers:

- Partnerships for Commercialization of SCI Research Discoveries
- Translational Program Projects in SCI

Early in the discussion the SCIRB merged the elements of both concept papers into one translational research RFA and eliminated requirements specific to Program Project-style applications (e.g., interdisciplinary approach to a single problem, three to five projects). The following summarizes the general consensus of the discussion:

- a five year translational award of up to \$1 million per year plus indirect costs of up to 20% to allow flexibility in the size of applications and awards – anticipating two awards
- ability for for-profit and out-of-state participation (though the applicant must be a not-for-profit or governmental organization in NYS)
- need for clear expectations stipulating that the application:
  - be based on demonstrated proof-of-principle
  - does not contain hypothesis driven research
  - perhaps includes Phase I or Phase II clinical trials
  - clearly geared to the statutory mandate to find cures for SCI
- a high bar so that a limited number of awards would be made only to applications with high probability of clinical application
- the SCIRB will review all critiques (i.e., no cutoff score for consideration of funding)
- independent expert peer review using a score of 1 to 9
- revise evaluation criteria and use the following weights:
  - Innovativeness and Approach, 25%
  - Feasibility and Translational/Clinical Potential, 40%
  - Investigators & Environment, 15%
  - Budget, 20%.

### **Fiscal Year 2015-16 and Future Fiscal Year Spending**

The SCIRB continued to discuss the current and future FY SCIRB budgets, with an emphasis on the need to expend available cash each year. Dr. Mendell recommended reducing the Fellowships RFA from \$6 million to \$4 million before issuance.

In terms of cash, Ms. Brautigam explained that staff is required to estimate cash expenditures and adjust those based on actual invoices. These projections are moving targets, so it is difficult to project how much cash will be spent in any given year. However, staff expect that the timing of RFAs and awards will not expend \$7 million in FY 15/16. Ms. Anderson reminded the SCIRB that whenever there is an influx of money for programs, there is a challenging start-up period before RFAs can be issued and contractors can invoice. She advised that until the program is stabilized, the SCIRB needs to come up with spending ideas and suggested that the program would benefit from additional one-time funding ideas.

Mr. Carmel recommended that the DOH initiate the non-competitive Institutional Support funding mechanism and expand the eligible organization list to include recipients of the upcoming CART/IDEA awards that are not already eligible. Ms. Brautigam clarified that this mechanism will only be used in the event that the CART/IDEA applications and awards are insufficient to utilize the full funding available. Dr. Faber commented that the SCIRB should anticipate the need to do this annually until the program is fully underway.

#### **ACTION**

Dr. Mendell made a motion that the SCIRB authorize staff to develop a single, translational RFA that would incorporate today's discussion (the details of which would be included in the meeting minutes) and that if the DOH is satisfied that the RFA is clear based on the discussion, it issue that RFA without further input from the SCIRB. Ms. Lieberman seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

#### **ACTION**

Dr. Mendell made a motion to reduce the Pre/Postdoctoral Fellowship RFA from \$6 million to \$4 million. Dr. Faber seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

Dr. Faber left the meeting.

### **ACTION**

Mr. Carmel made a motion to use the non-competitive Institutional Support funding mechanism, prorating any unencumbered funds for FY 15/16 to the eligible institutions determined in FY 14/15 plus institutions that receive CART/IDEA awards that are not already eligible. Ms. Lieberman seconded. A roll call vote was taken and the motion was unanimously approved (8-0).

### **Discussion Regarding Board Resolution of 11/24/14**

Ms. Brautigam stated that at its last meeting, the SCIRB unanimously voted to have a discussion of the legislative history and the complete statute. She noted that this resolution was the outcome of Ms. Lieberman's comments about the source and the amount of funding available to the program. Dr. Mendell invited DOH staff to address the Board.

Diana Yang, JD noted that the DOH provided the SCIRB with the legislation and bill jacket via e-mail before the meeting. She stated the DOH position that the FY 2014-15 funding level is consistent with statute, which states that the program be funded in amounts up to \$8.5 million.

Ms. Anderson stated that, consistent with the statute, surcharges from traffic violations collected are being transferred to the General Fund, and by the authority of Senate Finance Law §99-f, transferred to the Spinal Cord Injury Trust Fund. She explained the funding appears as Special Revenue-Other funds in the state budget, which is the designation given to single purpose accounts such as Spinal Cord Injury Trust Fund.

Ms. Lieberman handed out a document to the members assembled in New York City. Noting that italicized text represents inserted language and that bracketed [ ] text represents deleted language, her presentation of the handout included the following parts:

- Laws of New York, 1998, Public Health Law §251(4).
- Laws of New York, 1998, State Finance Law §99-f(2).
- New York State Senate Introducer's Memorandum in Support, Bill Number: S7287C.
- Laws of New York, 1999, Public Health Law §251(4)
- Laws of New York, 1999, State Finance Law §99-f(2).
- Budget Report on Bills, Session Year 1999. Senate No. 5328-B.
- LRS for Windows, Bill Number S5328B.

Ms. Lieberman stated that "simply restating the statute and not looking into any legislative history misses the point." She said the Laws of New York, 1998, State Finance Law §99-f (2), created ambiguity that was corrected in the Laws of New York, 1999. She reviewed the budget report and the bill summary from 1999 and concluded that "it is clear the language of \$8.5 million was meant as a floor." She provided additional copies of the handout to staff and asked that after the DOH had a chance to review the documents she presented today, it report at the next SCIRB meeting what the process is to acquire \$8.5 million.

Mr. Carmel asked staff to provide members with projections on both a cash and an encumbrance basis as well as the assumptions that inform those projections.

### **Public Comment**

No members of the public wished to comment.

### **Adjournment**

The Board unanimously voted to adjourn and the meeting ended at 12:08 p.m.