



SPINAL CORD INJURY RESEARCH BOARD

Regular Business Meeting

January 20, 2016

12:00 PM to 4:00 PM

MINUTES

Locations

NYS DOH Metropolitan Area Regional Office, Conference Room 4A/B, 90 Church Street, New York, NY
NYS DOH David Axelrod Institute, Auditorium A&B, 120 New Scotland Avenue, Albany, NY

SCIRB Members Present

Thomas N. Bryce, M.D.
Anthony Caggiano, M.D., Ph.D.
Donald Faber, Ph.D.
Michael E. Goldberg, M.D.
Bernice Grafstein, Ph.D.
Keith Gurgui
Nancy Lieberman
Lorne Mendell, Ph.D.
Gary D. Paige, M.D., Ph.D.
Fraser Sim, Ph.D.
Mark Menniti Stecker, M.D., Ph.D.

SCIRB Members Absent

David A. Carmel
Adam Stein, M.D.

NYS DOH Staff Present

Teresa Ascienzo
Charles Burns
Kathy Chou, Ph.D.
Andrea Garavelli
Matthew Kohn, Ph.D.
Victoria Derbyshire, Ph.D.
Jeannine Tusch
Carlene Van Patten

Guests

Tracy Tress

Call to Order and Opening Remarks of the Chair

The meeting was called to order at 12:08 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 December 2, 2015 Meeting Minutes

Dr. Mendell asked the SCIRB to consider Exhibit 1, the minutes from the December 2, 2015 meeting.

Members of the SCIRB discussed peer review panel sizes, while referencing Section 2. Composition of Review Panels and Processes.

ACTION

Nancy Lieberman made a motion to revoke the understanding that if there were a small number of applications submitted then the panel will be combined. Gary D. Paige, M.D., Ph.D. seconded. A roll call vote was taken and was unanimously approved (11-0).

Ms. Lieberman provided edits for the December 2, SCIRB meeting minutes, Section 2. Composition of Review Panels and Processes. Proposed deletions are shown in ~~Strikeout~~ and additions are shown in Underline:

- 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,
- She further resolved that within each of the Rehabilitation and Cellular Regeneration panels, applications shall be 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 ~~as a whole~~.

ACTION

Donald Faber, Ph.D. made a motion to approve the minutes as presented subsuming the Section 2. Composition of Review Panels and Processes resolutions listed above. Ms. Lieberman seconded. A roll call vote was taken and the minutes were unanimously approved as to be amended (11-0).

Strategy for Disbursing SCI Research Funds Going Forward

Dr. Mendell introduced strategies for disbursing spinal cord injury (SCI) research funds going forward. During discussion, Victoria Derbyshire, Ph.D. reviewed the following:

- The SCIRB plans to expend \$8.5 million each year,
- projected disbursements for fiscal year (FY) April 1, 2016-March 31, 2017 are \$8.68 million, which include ongoing research contracts, peer review, and funding from the new Projects to Accelerate Research Translation (PART) and Innovative, Developmental or Exploratory Activities (IDEA) Request for Applications (RFA),
- the SCIRB's RFA decisions made today will impact FY April 1, 2017-March 31, 2018 disbursements because there is a one-year lag,
- the DOH staff project one (1) Institutional Support round (Round 6, proposed contract start date 1/1/17) may need to be issued, and
- SCIRB could consider offering multi-year Institutional Support contracts based on available funds.

Members of the SCIRB discussed evaluating the Institutional Support awards. Mark Menniti Stecker, M.D., Ph.D., requested for the SCIRB to receive and review the Institutional Support budgets in advance of future awards. Instead, Dr. Mendell suggested for the SCIRB to receive a report on the scientific impact. Ms. Lieberman specifically added for the SCIRB to receive one or two paragraphs on how the funding facilitated the scientific research. Dr. Paige explained the application funding process, which requires the institutions to submit detailed budget plans and a description on how the funding will be spent. Dr. Derbyshire stated that all research accomplishments will be described in the (2016) SCIRB annual report.

The DOH staff distributed a handout to provide sample options for RFA release strategies and funding levels listed on page 3. Dr. Mendell explained the SCIRB could explore other options as well.

- **Option A:**
 - PART/IDEA (\$6 million for approximately 10 awards with proposed contract start dates on 1/1/17, 1/1/18 and 1/1/19), and
 - Fellowships (\$1.5 million for approximately 6 awards with proposed contract start dates on 3/1/17, 3/1/18 and 3/1/19).

- **Option B:**
 - PART/IDEA (\$6 million for approximately 10 awards with proposed contract start dates on 1/1/17, 7/1/18, and 1/1/20), and
 - Translational (\$8 million for approximately 2 awards with proposed contract start dates on 1/1/17; \$5 million for approximately 1 award with proposed contract start dates on 1/1/18).

- **Option C:**
 - PART/IDEA (\$6 million for approximately 10 awards with proposed contracts start dates on 1/1/17 and 7/1/18),
 - Fellowships (\$1.5 million for approximately 6 awards with proposed contracts start dates on 3/1/17, 3/1/18 and 3/1/19), and
 - Translational (\$8 million for approximately 2 awards with proposed contract start dates on 1/1/18).

The SCIRB discussed matters related to the peer review process and reviewing applications. Dr. Mendell requested for the SCIRB to base application distinctions on programmatic relevance when reviewing applications.

The SCIRB discussed/reviewed a variety of standard processes:

1. Dr. Stecker requested for the SCIRB to receive a summary of funding options before considering applications for award.
2. The SCIRB discussed having one mechanism for all applications. Anthony Caggiano, M.D., Ph.D. said it would be unfair to compare applications for PART/IDEA to Translational applications and he recommended having designated funding amounts for each distinct mechanism.
3. Dr. Fraser Sim, Ph.D. reminded the SCIRB of their ability to “approve but not fund” applications. DOH staff said the SCIRB could certainly do that.
4. Mr. Keith Gurgui recommended to give all RFAs the same deadline, so that the SCIRB can make recommendations for awards at the same meeting. Ms. Lieberman thought that this idea would overwhelm everyone (including the applicant community, DOH staff, and the SCIRB).

ACTION

Dr. Mendell motioned that the SCIRB members wish to see all three mechanisms listed in Option C., PART/IDEA, Fellowships and Translational without specifying frequency and funding amounts. Dr. Faber seconded.

During discussion, Mr. Gurgui questioned if the Fellowships RFA fits the mission and goal to find a cure for SCI. Many SCIRB members spoke from previous experiences and agreed the RFA is a viable program for the mission and goal of the SCIRB.

Dr. Sim suggested having an additional funding mechanism, to encourage investigators to come to NYS, similar to a National Institutes of Health (NIH) K-99/R-00 mechanism. Long standing SCIRB members said the Board received a similar draft RFA which had problematic criteria. The Board may discuss this at a future meeting.

After discussion, a roll call vote was taken and the motion was unanimously approved (11-0).

ACTION

Dr. Faber motioned to solicit Translational awards every three years. Dr. Paige seconded.

The SCIRB discussed the frequency of offering the Translational RFA in different variations. Ultimately, Dr. Faber's motion was voted upon.

A roll call vote was taken and the motion was approved (9-2).

Members of the SCIRB agreed to take a short break. After they reconvened, the SCIRB discussed the following items:

1. PART/IDEA RFA
 - Anticipated release for Winter 2016 (January/February)
 - The DOH staff will provide scenarios in accordance with the allocations.
2. Fellowships RFA
 - Anticipated release for Spring 2016 (March)
 - The DOH staff will look into sending reminder emails to the applicant community to subscribe to receive SCIRB e-Alerts

ACTION

Dr. Mendell made a motion for the DOH staff to issue a Fellowships RFA to be issued in the very late winter/early spring and the SCIRB would act on these applications in September. Dr. Grafstein seconded. A roll call vote was taken and the motion was unanimously approved (11-0).

3. Multi-year Institutional Funding Awards
 - The SCIRB agreed to use the same eligibility criteria as in the previous round (Round 5). Note, the SCIRB inquired if the eligibility criteria included "approved but not funded" awards and Dr. Mendell discouraged the SCIRB from adding this to the criteria.
 - The DOH staff would have the ability to issue this funding mechanism, dependent upon if there are excess funds available.
 - Funds will be distributed evenly among the eligible institutions, as they were in previous rounds.

ACTION

Dr. Mendell made a motion granting DOH staff the authority to issue three-year Institutional Support awards as in the past (issuing the funding mechanism as needed and using the same eligibility criteria) with the proviso that the SCIRB sees what has been distributed. Ms. Lieberman seconded. A roll call vote was taken and the motion was approved (11-0).

4. Optional Conflict of Interest (COI) Form
 - The SCIRB considered implementing a due date, which would correspond with the letter of intent due date. Note, the letter of intent form would remain optional.

- Applicants may identify up to three individuals (excluding SCIRB members and employees). Note, there are COI policies and procedures in place for SCIRB members and staff.
- Prior to this meeting, the DOH staff had a conversation with the peer review contractor, American Institute of Biological Sciences, and they recommended having a deadline for this process.

ACTION

Dr. Mendell motioned for applicants who decide to submit a COI Form, must do so as part of the letter of intent by the same deadline. Applicants may use this COI Form to identify perceived conflicts with up to three individuals, excluding SCIRB members and employees. Ms. Lieberman seconded. A roll call vote was taken and the motion was approved (10-1).

5. Resolutions prepared by Ms. Lieberman were distributed and discussed.
 - 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).

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

That all scientific review panels considering applications for funding under the SCI Law shall be instructed verbally and in writing to emphasize in reviewing such applications that the mission and goal of the SCI Law is unequivocally to provide funding for research to find a cure for spinal cord injury and, in furtherance of such mission and goal, (1) it is acceptable to recommend research applications that seek major advances toward a cure and not simply incremental research gains or incremental improvements for SCI patients, and/or (2) it is acceptable to recommend high risk/high reward research applications that seek a new or untested approach to cure SCI, and/or (3) it is acceptable to recommend research applications that state novel hypotheses or innovative research approaches that could result in advancing the field of SCI research significantly toward discovering a cure for SCI, and/or (4) it is acceptable to recommend research applications in which the research could result in a major leap forward in SCI research;

ACTION

Ms. Lieberman motioned that the substance of the ideas in paragraphs (1), (2) and (3) of the draft resolution, Interrelationship of Mission and Goal of the SCI Law and Funding Process, be specifically addressed in the notice to the scientific review board and incorporated in all RFAs going forward. The staff of DOH is empowered to work on the language along with the Chairman of the SCIRB, Dr. Mendell, to fix and choose the exact language. Dr. Grafstein seconded. A roll call vote was taken and the motion was unanimously approved (10-0), Dr. Mendell abstained from voting.

2. MISCELLAENOUS

- a. That all RFAs prepared in connection with the SCI Law shall expressly state that if an applicant seeking funding under the SCI Law had a previous application for a similar research project turned down, such applicant may include a statement that shall not be longer than 2 pages (and such statement shall not be counted toward any page limit set forth in the RFA for a new application by such application), (1) correcting any errors such applicant believes were contained in the scientific review panel's review of such previous

application, or (2) addressing any answers or rebuttals which such applicant believes are helpful or necessary for the scientific review panel to consider in connection with its most current application.

The SCIRB determined that this draft resolution is not applicable to current practice, since there is a possibility of having different peer review panelists for all SCIRB procurements.

- b. That if upon initial review of an application by DOH staff there is an obvious but inadvertent error in an application which would disqualify an otherwise acceptable application (e.g. a scientist is incorrectly listed as a member of the applicant's research team and is also a member of the SCIRB), and such error can be promptly corrected by the applicant without delaying the timing of the overall review process of all applications, then DOH staff shall promptly, upon recognizing such inadvertent error notify the applicant of such error and provide the applicant by email, telephone (which shall include voicemail) and overnight express mail, with at least 3, but not more than 5 business days to correct such error so that such application can be considered for funding by a scientific review panel.
 - o The DOH staff will look into this further.

In addition to draft resolution 2.b., the SCIRB recommended:

- Adding stronger language regarding submitting applications prior to the deadline.
 - o The DOH staff will edit the RFA contact information language for technical glitches or problems so it's explicitly clear and will add language encouraging applicants to submit their application prior to the deadline.
 - Implementing an Administrative Review period for technical issues to be resolved. Dr. Mendell noted, applications would not be accepted if they're late.
 - o The DOH staff will look into this further.
- c. The staff of the New York State Department of Health (DOH) shall provide all members of the SCIRB at least 2 weeks prior to a SCIRB meeting with all or substantially all materials they prepare or receive in connection with topics to be discussed or acted upon at any SCIRB meeting, including, without limitation, scientific review panel reports, applications submitted by applicants seeking funding under the SCI Law, draft RFA forms, draft application forms, draft instructions to be provided to scientific review panels, provided that if such documentation is unavailable to DOH staff 2 weeks prior to such SCIRB members as soon as possible prior to the SCIRB meeting at which such materials are to be discussed or acted upon; and
- d. That when DOH staff is requested to make available contracts, reports, reviews, documentation and other materials within the possession of DOH, but not previously supplied to SCIRB members, such staff shall provide such materials to SCIRB members requesting such information via email as promptly as possible, and in no event later than 5 business days after such request is made.

Draft resolutions 2.c. and 2.d. are consistent with current DOH practices to the extent practicable.

- 6. The SCIRB discussed dates, venues, costs and logistics for a 2016 New York State Spinal Cord Injury Research Program Symposium.

Future Meetings

At its next meeting in June/July 2016, the SCIRB will consider PART/IDEA applications for funding and continue these types of discussions.

Public Comment

No members of the public wished to comment.

Adjournment

The Board unanimously voted to adjourn and the meeting ended at 4:22 p.m.