

Empire State Stem Cell Board
Funding Committee Meeting Minutes
May 21, 2013

The Funding Committee of the Empire State Stem Cell Board held a meeting on Tuesday, May 21, 2013, at the offices of the Department of Health, 90 Church Street, New York, New York. Janet Cohn, J.D., presided as Chair Designee.

Funding Committee Members Present:

Ms. Janet Cohn, Chairperson Designee
Dr. Bradford Berk
Mr. Robin Elliott
Dr. Richard Gronostajski
Dr. David Hohn *
Dr. Mario Loomis*
Dr. Samuel Packer
Dr. Allen Spiegel, Vice Chair
Dr. Melissa Wasserstein
Dr. Madelyn Wils
*participated via video-conference

Ethics Committee Members present:

Ms. Jann Armantrout
Dr. Inmaculada de Melo-Martin
Ms. Nancy Dubler
Dr. Samuel Gorovitz
Dr. Robert Klitzman
Rev. H. Hugh Maynard-Reid
Dr. Camille Wicher

Department of Health Staff Present:

Ms. Bonnie Brautigam
Dr. Kathy Chou
Dr. Matthew Kohn

Dr. Jill Taylor
Ms. Mary Thatcher

Observers Present:

Mr. Harley Bowman
Mr. John Gee
Dr. Julia Gelman
Dr. Steven Goldman
Dr. Ann Willey

Welcome and Introductions

Ms. Cohn called the meeting to order and welcomed members, staff and the public. She introduced the new Funding Committee member, Dr. Melissa Wasserstein, Director of the Program for Inherited Metabolic Diseases at the Mount Sinai Medical Center, and welcomed her to the Board.

Approval of Minutes for the November 16, 2012, Funding Committee Meeting

Ms. Cohn directed members to the draft minutes of the November 16, 2012, meeting of the Funding Committee and asked for a motion to approve them. Dr. Packer so moved, Dr. Gronostajski seconded, and the motion passed.

Discussion and Possible Approval of Revisions to Appendix A-2 to NYSTEM Contracts

Dr. Kohn described proposals by staff, which the Ethics Committee had recommended for approval earlier in the day, for changes to Appendix A-2, based on the lessons of another year's experience with NYSTEM contracts. As Dr. Kohn pointed out, the changes did not entail a substantive change, but rather served to clarify the language and/or the Board's intent.

Recommended changes included removal of the acronym HSC, since it is not a standard abbreviation; removing redundant language contained in E(1)(e) and elsewhere; dividing Section E(1)(c) into two separate categories because each represents a different cell type; removing the "E" from ESCRO (Embryonic Stem Cell Research Oversight), as those bodies oversee more than embryonic stem cell research and for greater consistency with the guidelines of the International Society for Stem Cell Research (ISSCR); and expanding the exemption from SCRO review to include research involving Induced Pluripotent and other types of stem cells discovered after the ISSCR and the National Academy of Science drafted their guidelines, upon which NYSTEM's were modeled.

Dr. Gronostajski moved to approve the revisions and Dr. Packer seconded the motion. The motion passed unanimously.

Discussion and Possible Approval of Request for Applications for Investigator Initiated Research Projects (IIRP) and Innovative, Developmental or Exploratory Activities (IDEA), Round V

For reference, Ms. Brautigam directed the attention of Funding Committee members to an excerpt from the Round IV Request for Application (RFA) for IIRPs and IDEAs, noting that those applications were due at the end of July.

First, members indicated they wished Section IB, Purpose of Funds, to remain broad.

Ms. Brautigam then turned to Section IC, Available Funds. Mr. Elliott asked whether experience with the first three rounds of IIRPs and IDEAs provided guidance on desirable modifications. Dr. Spiegel followed up, asking whether there were indications that the balance between money spent on IIRPs and on IDEAs should be adjusted.

Both Dr. Kohn and Ms. Brautigam noted that there were only two past rounds to judge by. Third round contracts were currently being executed, and the fourth round was in the application stage. Dr. Berk suggested a cross-check of NIH awards to check subsequent grant funding and Dr. Spiegel mentioned number of publications as a possible indicator. Ms. Brautigam pointed out that in the last three rounds, the number of awards, based on score, had been fairly equally balanced between the IIRPs and IDEAs.

Board members agreed that some analysis to support allocation of funds for these funding mechanisms would be useful and welcome.

Ms. Brautigam moved on to the issue of including a minimum percentage of professional effort by the Principal Investigator in the RFA, suggesting that it be dropped and that instead the assessment of adequacy of effort be left to the peer reviewers. A discussion followed in which Board members reiterated the concern that led them to require a specific percentage of effort initially, namely, that appropriate effort be dedicated to NYSTEM awards and that they be taken seriously by the community. Mr. Elliott questioned whether there was another, perhaps better, measure of Principal Investigator (PI) involvement.

Ms. Brautigam and Dr. Gronostajski explained that applicants would still have to provide their intended level of effort in applications and institutions would still be required to monitor actual effort. Funded scientists would report effort via progress reports and time and effort reporting would still be tracked. The intent in leaving out this requirement would be to reduce some of the burden on the researchers and institutions without undermining the importance of scientific effort toward NYSTEM-funded work. Dr. Gronostajski and Dr. Spiegel agreed that reduction of burden would be a positive step.

Next, Ms. Brautigam turned to Section 2, "Who May Apply?". She reminded members that for the last round they decided to limit applications to one IDEA and one IIRP per PI. Dr. Berk suggested that an investigator be allowed to submit as many applications as he or she chooses. If more than one per mechanism (i.e., more than one IDEA) is recommended for funding, the investigator would make a selection.

Ms. Brautigam went on to remind Board members of certain other provisions to see if they might want to change them, including the weighting of review criteria. Some discussion ensued about the high percentage going to the budget criterion – 20% -- but Ms. Brautigam reminded committee members that 20% was already a departure from the 30% generally required. Dr. Wasserstein suggested refining the budget evaluation criteria by requiring that the budget be appropriate for execution, that allocation of resources be properly geared to achieve the intended results.

Finally, it was agreed to set the cut-off for board review at 4.0, pending further analysis of the previous round of applications for these awards, to be considered before the next Funding Committee meeting.

Ms. Cohn asked for a motion to approve the RFA subject to the changes discussed, namely, allowing investigators to submit more than one application while permitting only one of each mechanism to be funded, at the investigators choice; and clarifying the budget criterion as suggested by Dr. Wasserstein. Dr. Spiegel so moved, Dr. Gronostajski seconded, and all members voted to approve.

Request for Applications for Consortia to Accelerate Therapeutic Applications of Stem Cells, Round II, and Request for Proposals for Consortia Oversight, Round II

Ms. Brautigam asked members to look at the draft RFA for Consortia, Round II, that had been included in their materials. She reminded members that although contracts for Round I have not yet been executed, they had been anxious to move promptly on Round II. She proceeded to identify recommended changes from the first round RFA.

First, she directed member attention to Section IB, “Purpose of Funds,” and stated that reference to platform and technology-based applications had been omitted, as well as to basic translational and preclinical research, as the Committee’s discussions of Round I applications made it clear that members wanted to support new clinical applications of stem cells that were closer to clinical trials.

Second, with respect to Section IC, Available Funds, Ms. Brautigam stated that the total to be awarded was \$32 million with a cap of \$13.3 in direct costs per consortium.

Third, Ms. Brautigam addressed Section II, “Who May Apply?” She suggested that the three institutions who received funding in Round I be barred from applying in Round II. Members disagreed, so long as there were a different PI and subject. Members would not exclude another application targeting the same disease, so long as the PI and approach were different (i.e. no overlap in scientific approach or investigators between the application and a Round I funded project).

Dr. Berk suggested, and the rest of the Committee agreed, that only one application per PI should be accepted. Members also agreed to eliminate a minimum percentage of effort for the PI, as recommended for IDEA and IIRP applications, but retained the requirement for a full-time scientific project manager.

Dr. Gronostajski suggested that the language clearly state that the requirements for Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) are to be consistent with Food and Drug Administration (FDA) regulations.

Finally, Ms. Brautigam turned to review criteria. First, she noted that staff recommended that there be triage based on proof-of-principle. If any of the three assigned peer reviewers believed that proof-of-principle in a particular application was less than “excellent,” he or she could suggest it be triaged. That suggestion would then go to the whole panel. If a panel member wanted to put the application back in the running, proof-of-principle would then be weighted at 10%; otherwise, the application would not be considered further. Second, she noted that the draft merged the categories of significance, impact and approach into one category to be weighted at 40%. Investigators and management were merged to form one category at 30%.

Ms. Cohn then asked for a motion to approve the RFA subject to the agreed-upon changes: all institutions may apply; one application per institution; one application per PI; same general topic by different PI and different institution is allowed; and FDA standards for GLP and GMP apply. Dr. Spiegel moved; Dr. Packer seconded. Approval was unanimous.

Finally, Ms. Cohn asked for a motion to recommend the same RFP which was used for the first round of Consortia Oversight. Dr. Spiegel so moved and Dr. Packer seconded. The motion passed unanimously.

Motion to Adjourn

Ms. Cohn asked for a motion to adjourn the Funding Committee meeting and Dr. Spiegel so moved. All members were in favor.

*s/ Janet Cohn
Executive Secretary to the
Empire State Stem Cell Board
Approved: October 3, 2013*