

MINUTES OF THE MARYLAND STEM CELL COMMISSION

Thursday, September 14, 2006
University of Maryland Law School
Baltimore, MD

Members in attendance:

Joseph Capizzi
Jack Chow
Brenda Crabbs
John Kellermann
Gloria Marrow
Suzanne Ostrand-Rosenberg
Linda Powers, Chair
Karen Rothenberg
Murray Sachs (via teleconference)
Steven Salzberg
Jack Schwartz
Bowen Weisheit
Joel Zaiman

Members absent:

Jeremy Sugarman
Diane Griffin

Others in attendance:

Steven Fritz, TEDCO
Renee Winsky, TEDCO

Ms. Powers called the Commission meeting to order at 2:10 p.m.

I. Summary of Commission Progress and Game Plan

Ms. Powers thanked and complimented the Commission members for being active on the ad hoc working groups that were designed to organize issues and drafts for the full Commission's attention. She explained that the major focus of the meeting would be the contents of the Request For Applications (RFA) under which grant applications will be solicited for the stem cell funding. A consensus was being sought on all material RFA issues so that the RFA ad hoc working group could produce a draft RFA document for review at the October 10 Commission meeting. Draft regulations and bylaws would be voted upon, time permitting.

II. Approval of the Minutes of the July Commission Meeting

Amendments to the July 27, 2006 minutes included:

- Under II, Swearing In, Ms. Suzanne Mensh was incorrectly identified as the Clerk of the Circuit Court of Baltimore *City*, and it should be Baltimore *County*.
- Under III, Election of Chairman, Ms. Marrow should be listed as nominating Ms. Powers, and Mr. Schwartz as seconding the nomination.
- Under V, Subcommittees, the activity "Scientific Review Committee Selection" should read "Scientific Review Committee."

Ms. Rothenberg felt that consensus was reached on other issues relating to the RFP that were not reflected in the minutes, specifically the letter of intent. Ms. Powers suggested that any such issues could be identified during the meeting, and that the minutes be approved provisionally. The minutes were approved provisionally by consensus. The *RFA Content and Procedures: Issues for Decision* document identified areas where consensus was reached, however the full Commission did not identify and approve them as such.

III. Development of RFA

A. Background

Ms. Powers prepared a consolidated list of issues for the ad hoc working group. The working group spent three hours reaching a consensus on all of the issues as a starting point for the full Commission. An issues list was distributed to the Commission and thoroughly discussed.

B. Ad Hoc Working Group Substantive Issue Recommendations and Commission Consensus

The recommendations of the ad hoc working group are noted below. Preliminary consensus to guide the final development of the RFA was reached by the full Commission unless otherwise noted.

1. **Eligible awardees** are specified in legislation: academic, for-profit and non-profit entities.
2. **Form of awards:** grants.
3. **Single vs. multiple projects or program grants:** single projects that address a single problem (single principal investigator, co-principal investigators allowed).

4. **One category of grant vs. multiple categories:** The ad hoc committee recommended two categories of grants:
 - A. Innovative grants with little or no preliminary data (pilot grants), up to \$100K per year for up to two years.
 - B. Investigator-initiated grants requiring preliminary data (regular grants), up to \$500K per year for up to three years, may include multiple centers and co-PIs.

The Commission felt that personnel from outside of Maryland should be allowed, as well as supplies and equipment purchased outside of Maryland, as long as no Maryland funds are used for such activity.

5. **Eligible types of research and uses of funds** are specified in legislation: both basic and translational research; use of human cells only, not animal; the ad hoc committee recommended for “facilities” that equipment is acceptable insofar as it is necessary for the research and directly related/involved in the research; but building expenses (construction/renovation) will not be eligible.
6. **Duration of awards:** single year vs. multi-year. Commit all multi-year funding out of the \$15M. Either (a) put whole multi-year amount into earmarked escrow account and fund in pieces as grant work is completed or (b) fund all up-front, depending upon whether doing (a) will cause budget process difficulties for legislators. Legislators to provide guidance to working group.

The Commission discussed the mechanics of funding (whether the money is disbursed all at once or over multiple years), as well as the level of certainty of the funding for the applicant (whether all three years are given or just one year at a time). A vote was taken whether between Scenario A (three years at \$500,000 each, for a total of \$1.5M all counted against the \$15M) and Scenario B (applicant is told that the second and third years of funding may be at risk). Scenario A received eight votes, Scenario B received three votes, and there was one abstention.

7. **Award size** was covered in #4.
8. **Allowable cost items beyond direct costs:** except for equipment costs, NIH rules apply.
9. **Translation potential and/or plan:** the application should describe the importance/potential/relevance/pathway to translation of the proposed research into medical treatments.

10. **Intellectual property rights and rewards:** follow existing Federal practice. The IP belongs to the awardee; government rights the same under Bayh-Dole.
11. **Scope of out-of-state collaboration allowed:** allow out-of-state collaboration/involvement, as long as no Maryland money is used by or for out-of-state parties, unless such person comes to Maryland and does the work in Maryland.

C. Ad Hoc Working Group Substantive Issue Recommendations and Commission Consensus

1. **Single solicitation/submission for all \$15 million or multiple submissions?** Conduct additional solicitation/submission if not enough high quality applications received in first cycle.
2. **Notice of solicitation - publication/distribution process.** Notice will be posted on TEDCO website, will be sent to universities, and be provided to newspaper and other outlets.
3. **Solicitation and award schedule.** Steps to include: initial announcement, submission of letters of intent, submission of applications, scientific peer review, delivery of scores and reports from Scientific Peer Review Committee to Commission, Commission review and evaluation under additional criteria, Commission discussion and decision, announcement and then funding. Key recommended dates: Written RFA circulated before October meeting, written comments solicited from Commission before October meeting, agree on and produce final RFA at October meeting, applications submitted before year end, the Peer Review Committee meeting in January and the Commission decision in February.

The remainder of the procedural issues provided to the Commission were not discussed in the interest of time.

IV. Draft Regulations

A draft set of regulations was distributed to the Commission. Mr. Schwartz focused the Commission on those areas not already discussed in the RFA discussion.

1. .05 A was discussed and accepted: The scientific merit of the stem cell research described in the application, taking into account the evaluation, rankings, and recommendations of an independent scientific review committee pursuant to §5-2B-06 of the Act.

2. .07 D was omitted, as a letter of intent will not be required in the regulations.
3. .08 A 1. Discussion was held whether to amend to read, “make disbursement of financial assistance contingent on evidence of IRB approval or evidence of formal notice of exemption from IRB review.” The Commission decided to uphold the draft regulation as written.
4. .07 C was changed to omit “which may not exceed three years.”
5. .05 D was discussed and changed to: “The potential impact of the stem cell research described in the application on technological innovation and the development of the biotechnology industrial, academic or non-profit sectors in Maryland.”

Motion was made by Steven Salzberg to accept the draft regulations as modified by the Commission, allowing for some minor language modification in the final version. The motion was seconded by Karen Rothenberg and passed unanimously.

Next meeting will occur Tuesday, October 10. A vote was taken regarding morning or afternoon meetings. Twelve votes were received for afternoon hours, and six votes were received for morning hours.

The meeting adjourned at 5:02 p.m.