

## Minutes of the Maryland Stem Cell Research Commission

Wednesday, September 9, 2009  
UMB BioPark, Baltimore, MD

### Action Items from September 9, 2009

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1. The Commission has requested that Management attach the two public testimonial speeches to the June 4, 2009 meeting minutes (Dan Gincel).
  2. The Commission has requested that TEDCO management modify and re-send the RFA drafts to all Commission members via email for a final vote of approval (Dan Gincel).
  3. The Commission approved a recommendation to the TEDCO Board to execute the CIRM-TEDCO MOU conditioned on the resolution of the outstanding legal, programmatic and budgetary issues. There will be further consideration of the extensive practical and logistical barriers if adequate resources become available (Dan Gincel).
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#### Members in attendance:

Brenda Crabbs, Vice Chair  
Margaret Conn Himelfarb  
Suzanne Ostrand-Rosenberg  
Linda Powers  
Karen Rothenberg, Chair  
Steven Salzberg  
Ira Schwartz  
Jeremy Sugarman  
Bowen Weisheit  
Joel Zaiman

#### Others in attendance:

Dan Gincel (TEDCO)  
John Wasilisin (TEDCO)  
Sabrina Manning (TEDCO)  
Mike Ulrich (Commission Intern on Ethics)

The Commission meeting was called to order at 2:11 p.m.

#### ~Introduction of John Wasilisin as the new acting President and CEO of TEDCO~

##### I. Approval of Minutes

The Commission considered the minutes of June 4, 2009. As requested, the initial draft of the meeting minutes was revised to include the closed meeting notations. The Commission has requested Management to attach the two testimonial speeches to the meeting minutes. A motion was moved and seconded to approve the minutes as amended. The motion passed unanimously.

##### II. Administrative Report

Dr. Gincel provided an update on administrative activities since the June 4, 2009 Commission meeting.

A. 2009 World Stem Cell Summit Logistics

- To date, there are over 800 confirmed registrants.
- There will be 50-60 exhibit areas, in which TEDCO and the Commission will have designated exhibit areas with representation.
- The 55 hour conference will consist of keynote speakers, scientific, business, advocacy, and ethics lectures, sessions and workshops.
- Several members of the Commission have agreed to speak and moderate the Summit panels.
- The 2<sup>nd</sup> Annual 2009 Stem Cell Symposium poster session will be held the Baltimore Convention Center on Monday, September 21<sup>st</sup> from 8am – 12 noon. For this day only, the MSCRF poster session and other miscellaneous workshops will be open to the public with free admission. The MSCRF poster presenters and a few uniformed volunteers will be available onsite to assist with scientific inquires pertaining to stem cell research. The poster exhibition area will be open for viewing throughout the duration of the conference.

**\*NOTE\*:** Representatives from UMB are currently extending invitations for Maryland Legislators to attend the poster session.

- Governor Martin O'Malley is scheduled to attend the Summit on Monday, September 21<sup>st</sup>. During this time he will be presented with a Leadership award, which will be followed by his 20 minute speech. The Governor will also be present for the official signing ceremony announcing collaboration with Maryland TEDCO and the California Institute for Regenerative Medicine.

Additional information (including the agenda) for the World Stem Cell Summit is now available online at: [www.worldstemcellsummit.com](http://www.worldstemcellsummit.com).

B. Future Commission Meeting Cancellation

- November 18, 2009 UMB BioPark 2:00 – 5:00

C. SRO Proposals

Over the past 3 years, TEDCO has contracted services from SROs (Scientific Review Officers) to assist with the scientific review process. In effort to reduce expenses for future services, an RFP was released, which solicited 5 SRO proposals that are currently under evaluation.

D. Events and meetings :

Dan Gincel reported updates and self-participation for the following:

- The next Interstate Alliance of Stem Cell Research (IASCR) meeting will be on October 7-8, 2009 in Washington, D.C.
- The National Institute of Standards & Technology (NIST) has volunteered to host the 3<sup>rd</sup> Annual MSCRF Symposium.
- New York Stem Cell Symposium was held on June 11-12, 2009
- The Kennedy Krieger Institute Cell Based Therapy Symposium was held on June 20, 2009

- The 2009 Adult Stem Cell conference was held in Cleveland, OH, at which Commission member Linda Powers presented a keynote address.
- Continuous meetings with potential stem cell research applicants; encouraging interest and fostering stem cell research from various sectors within the scientific community.
- Currently in correspondence with the FDA in effort to foster participation in organizing a FDA compliance workshop.

### **III. NIH Guideline Discussion**

Dan Gincel reported that the NIH developed new guidelines for stem cell research in July 2009, which became mandatory for all Federal Agencies to implement. A State and Federal Guideline Comparison table was presented to the Commission in which a comparative analysis was performed. Through a brief discussion, there was a consensus amongst the Commission to keep a close observation of the Federal Guidelines but make no changes to the current mechanism implemented by MSCRF

### **IV. RFA Discussion**

An RFA Subcommittee was formed during the June 4, 2009 Commission meeting, with an objective to thoroughly review and modify the existing RFAs for future implementation. The Subcommittee consisted of several members of the MSCR Commission, and Brenda Crabs (Commission -Vice Chair) and Dan Gincel both reported and presented the following RFA modifications for Commission approval.

#### **A. Exploratory RFA**

- Key date change
- Ethical language modifications

#### **B. Investigator Initiated RFA**

- Key date change
- Up to \$1 million in funds with a flexible project duration period of 2-5 yrs.
- Preference given to collaborative research between for-profits and non-profit organizations.

#### **C. Post Doctoral Fellowship RFA**

- Key date change
- Preference given to collaborative research between for-profits and non-profit organizations.

Through further discussion, there was a consensus amongst the Commission to apply additional language modifications to the RFAs prior to approval. The Commission has requested TEDCO management to revise and submit the final drafts to all Commission members via email for a final vote of approval. Pursuant to the Commission approval, the new RFAs will be posted and accessible online through the MSCRF website.

### **V. CIRM & TEDCO Memorandum of Understanding (MOU)**

Dan Gincel reported that the California Institute for Regenerative Medicine (CIRM) expressed an interest in exploring a collaborative funding program with TEDCO for stem cell research. Dan Gincel and Commission members Ira Schwartz and Brenda Crabs (Vice Chair) met with representatives from CIRM to discuss their proposition and for clarification of the respective missions for both organizations.

The Commission was presented with an MOU draft which is pending Commission and TEDCO Board approval. Conditioned on the approvals, the MOU would be executed in a signing ceremony during the World Stem Cell Summit on September 21, 2009.

The Commission discussed the MOU and various concerns such as:

- Appropriate stewardship of state resources
- Policy issues
- Budgetary issues
- Limited resources
- Potential disadvantages
- Leveraging
- Beneficial gains
- Clarification on the implication

There was a consensus that the Commission welcomes collaboration to move science forward and supports the notion of collaboration; however, there are a number of practical issues that warrant extensive clarity prior to the approval of a future binding agreement.

A motion was moved and seconded to recommend that the TEDCO Board approve the execution of the MOU. There will be further consideration of the extensive, practical and logistical barriers if adequate resources become available. The motion passed unanimously.

## **VI. Statement for Closing the Meeting**

A motion was made and approved unanimously for the Commission go into a closed session. The motion stated the following:

### **Statutory Authority to Close Session**

#### **State Government Article Sec.10-503(a)(1)(i):**

This subtitle does not apply to ... a public body when it is carrying out ... an administrative function.

#### **State Government Article Sec.10-508(a)(5):**

A public body may meet in closed session ... to consider the investment of public funds.

#### **State Government Article Sec.10-508(a)(13):**

A public body may meet in closed session ... to comply with a specific constitutional, statutory, or judicially imposed requirement that prevents public disclosures about a particular proceeding or matter.

#### **REASON FOR CLOSING:**

To discuss the application for and potential modifications to an awarded KKI grant.

## **V. ~Closed Meeting Notes~**

Dan Gincel informed the Commission that KKI recently identified an institutional error with an FY2008 awarded Investigator Initiated grant from which KKI omitted the 15% indirect cost during the FY2008 online application submission. Although the Commission approved the submitted

budget, KKI has issued a request to amend the award amount to include the 15% indirect costs for the research.

Dan informed the Commission that in 2008 a few awarded institutes made similar administrative errors which were identified and resolved prior to executing the grant agreements. However, KKI did not realize the administrative error until the second year of research and believes there will be a hindrance of the conducted research if the Commission should decline their request.

TEDCO management presented a recommendation to approve the KKI request to include the 15% indirect costs only for the 2<sup>nd</sup> and 3<sup>rd</sup> year of research. In addition, TEDCO management will modify all RFAs to specify no revisions will be allowed once the application is submitted through TEDCO Funds.

Through further discussion some Commission members questioned the idea of honoring a request for funds due to administrative negligence by the institution.

A motion was made and seconded to approve the KKI request to amend the grant award to include the 15% (\$76,187.55) total indirect costs for the 2<sup>nd</sup> and 3<sup>rd</sup> year of research contingent on available funds. The motion passed 6 approved, 1 abstain, 1 decline, 2 recusals.

The meeting adjourned at 5:05 p.m.