

CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE
Minutes –Special Meeting
Wednesday – March 22, 2006

A special meeting of the Connecticut Stem Cell Advisory Committee was held on Wednesday, March 22, 2006, at Connecticut Innovations, Inc., 200 Corporate Place, Rocky Hill, Connecticut.

Call to Order: The meeting was called to order at 1:00 p.m. by Commissioner Robert Galvin, Chair. Members present: Robert Galvin, M.D., M.P.H. (Chair), Ernesto Canalis, M.D., Myron Genel, M.D., Charles Jennings, Ph.D, Julius Landwirth, M.D., J.D, M. William Lensch, Ph.D., Kevin Rakin, Milton B.Wallack, D.D.S., and Xiangzhong (Jerry) Yang, Ph.D.

Other Attendees: Catherine Kennelly (DPH), Denise Leiper (DPH), Warren Wollschlager (DPH), John Bigos (DPH), Stacy Owens (DPH), Carolyn Slayman (Yale), Diane Krause (Yale), Mark Horowitz (Yale School of Medicine), Nancy Rion (CI), Russell Tweeddale (CI), Ted Rasmussen (UCONN/CRB), Anne Hiskes (UCONN/CRB), David Goldhamer (UCONN/CRB), Leonardo Aguila (UCONN Health Center), Bruce Carlson (UCONN), Bob Mandelkern (Parkinson Rep. to Stem Cell Coalition), June Mandelkern (Parkinson Rep. to Stem Cell Coalition), and Henry Salton, Assistant Attorney General.

Opening Remarks (Commissioner Galvin/Attorney Salton):

Attorney Salton mentioned that at the meeting held on Tuesday, March 7, 2006, the Committee members voted unanimously in favor of tabling a motion to adopt the document entitled “Connecticut Stem Cell Research Grants Program, Proposal Instructions.” He explained that meeting was recessed before concluding the review of the document and this special meeting scheduled to continue with the review of the mentioned document. Attorney Salton explained that the Advisory Committee members could either take the motion off the table and proceed with the existing motion and additional amendments or dispose of the motion in a negative way and review the new document and make a new motion to adopt the new amended document. In response to a question, Attorney Salton and Dr. Jennings confirmed that the changes discussed and agreed upon at the March 7, 2006 meeting have been incorporated into the new draft document. After discussion, there was consensus that at the end of the meeting the Advisory Committee would make a motion to dispose of the motion on the table in a negative way and continue reviewing the new draft document and make a new motion to adopt the document at the conclusion of the review.

Members of the Advisory Committee and public were reminded by Dr. Galvin that the meetings were held by statute, were open to the public and were being recorded and videotaped.

Dr. Galvin commented on the high ethical standards that are expected and asked the members to exercise good judgment. He encouraged the Advisory Committee members in the review of the application document to be open minded and not so formulaic with rules that the process is stalled.

Review of Minutes – Stem Cell Research Advisory Committee Meeting – 3/7/06:

Recommendations were made to amend the 3/7/06 proposed meeting minutes as follows:

- Page 1, the spelling of Bob Mandelkern should be corrected under “other attendees.”
- Page 3, first paragraph, last line, add the word “modified” before the word “indirect.”
- Page 3, third paragraph, last line, change the word “Internal Revenue” to “Institutional Review.”
- Page 3, last paragraph, lines 5 and 7, take out the words “per year.”
- Page 4, under the ninth bullet, take out the words “per year.”
- Page 5, change the word “adjourning” to “recessing.”

MOTION: Upon a motion made by Dr. Jennings, seconded by Dr. Lensch, the Advisory Committee members voted unanimously in favor of adopting the minutes of the March 7, 2006 meeting with the above-noted corrections. Dr. Rakin was not present for the vote.

Public Comments (Dr. Galvin):

There were no public comments at this time.

Update on Legal and Ethical Considerations:

Attorney Owens noted that Ms. Horn from DPH would primarily be handling all of the legal matters. She gave an update on opinions that the Advisory Committee members are awaiting to receive regarding legal and ethical issues. Attorney Owens mentioned that a draft opinion was formulated by the Assistant Counsel of the Connecticut Ethics Commission and was presented to the Citizen’s Ethics Advisory Board on February 23, 2006. She mentioned that the draft appeared to be favorable to the Advisory Committee members with respect to voting and being able to maintain a quorum in terms of positions and present employment. However, the Citizen’s Ethics Advisory Board members want to familiarize themselves more with the process and the laws. Attorney Owens stated that it is not likely that the draft opinion will be the end product. The next meeting of the Citizen’s Ethics Advisory Board is scheduled for March 30, 2006. It was noted that the issues before the Citizen’s Ethics Advisory Board are related to the Committee members’ voting and recusing themselves from certain issues.

Application Process (Dr. Lensch and Dr. Jennings):

Dr. Jennings reviewed the additional changes and changes not reviewed at the March 7, 2006 meeting with respect to the document entitled “Connecticut Stem Cell Research Grants Program, Proposal Instructions (the ‘Application Document’)”.

The Advisory Committee members discussed whether or not to include a separate category for Hybrid Applications and Linked Applications. Dr. Canalis expressed concern that the hybrid and linked applications may add an additional element of confusion and complication. Dr. Jennings explained how this category could help stimulate collaboration between institutions. Dr. Lensch stated that hybrid and linked applications allow flexibility for a more continued approach to building a program around a common goal. Dr. Genel provided support for the category stating that it helps to provide greater flexibility for

applicants and is within the legislative intent to create infrastructure that does not currently exist for stem cell research in the State of Connecticut. Dr. Yang opined that hybrid and linked applications create healthy competition and give the institutions choice. Dr. Rakin joined the meeting during this discussion.

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Jennings, the Advisory Committee members voted in favor of including language in the Application Document to permit hybrid and linked applications and to indicate that funding under this award should not exceed \$5 million.

VOTE: (6-2-1) Drs. Genel, Jennings, Landwirth, Lensch, Rakin, and Wallack in favor; Drs. Galvin and Canalis opposed; and Dr. Yang abstained.

Dr. Wallack asked why four years was chosen for the length of time for expending the funds for the grants. It was noted that the average length for an NIH grant is four years. Dr. Jennings stated that he believes that four years was agreed to be a sensible length of time since grant funding is not available for a 5 – 10 year time frame, and less time is too short to expend the funds. Dr. Wallack requested further explanation on how the four years was agreed upon.

A discussion ensued as to which agency (CI or DPH) should sign the contract with the institutions. Dr. Wallack suggested that the funding should be provided through DPH in coordination with the Advisory Committee. Attorney Kennelly responded that if desirable, it would be appropriate for DPH to accept and disburse the funding. Concern was expressed that if funding went through DPH, the process may be more cumbersome and not as expeditious as if it went through CI. Dr. Galvin expressed the need to expedite funding under the grant awards process. Attorney Salton explained that there are two separate functions— 1) for signing the contract for the grant, and 2) for administering the contract. He explained that CI has been charged by the legislature for administering the contract, including the monitoring, reporting and ensuring the funds are being distributed on time. CI has been named as the administrative staff of the Advisory Committee and must assist the Advisory Committee in developing and implementing the application process, including application review and the execution of agreements. Clarification on how and who will distribute the funding will be sought and reported to the Advisory Committee at the next meeting.

The Advisory Committee members discussed the receipt of the application electronically. In response to a question, Ms. Rion indicated that if CI does not already have a secure server, it will ensure that a secure server is provided for the receipt of the Application Document electronically.

Dr. Jennings noted that a document has been circulated from the Deputy General Counsel at Yale suggesting language to address intellectual properties and financial benefits to be shared by the state developing from any stem cell research made possible by the awarding of a grant. Dr. Genel and Mr. Wollschlager reviewed the policies on financial benefits for intellectual properties for both New Jersey and California. It was noted that it may be difficult to attribute success to one specific grant or funding source. In addition to the financial benefits, Mr. Wollschlager stated that consideration should also be given to economic and social benefits for the state. Mr. Carlson, the Director of Technology Commercialization at UCONN clarified that the draft document circulated was also discussed with and agreed to by UCONN. He explained that at UCONN if an inventor's invention is commercialized, 33 percent of cash flow goes to the inventor, 33 percent to the inventor's school department and laboratory and 33 percent to the university. In an effort to move the process along, there was consensus to include general language in the Application

Document about the sharing of benefits from an intellectual property that proves to the benefit of the State of Connecticut and its citizens. More defined language would be put into the contract and agreed upon before the execution of the contract and disbursement of funds. There was consensus to create a subcommittee consisting of Drs. Rakin, Galvin and Wallack to pursue this issue further.

The Advisory Committee members discussed the possibility of including funding of start-up funds for faculty members yet to be hired. Dr. Jennings explained that there may on occasion be a need to hire new faculty in order to carry out a mission. Dr. Canalis expressed concern with the language on page 8 related to startup funds for faculty members yet to be hired and noted that a separate category for startup costs would be needed. The Advisory Committee members discussed possible ways to modify the language in the referenced paragraph. After further discussion, there was consensus that on the occasion when it is necessary to hire additional faculty, the faculty should be “identified” and the person to be recruited should have a detailed description of their project which is part of a larger strategy. Dr. Canalis indicated that he could support the inclusion of the paragraph in the Application Document if the faculty to be hired and his/her specific project were identified.

Ms. Rion explained CI’s current practice with administering grants. She noted that CI must receive proof of certain milestones prior to distributing additional funds. Discussion ensued on the advancement of funds and the requisite reporting information. It was noted that with some institutions/universities, financial reports are not available until at least three months following the reporting period. Recommendation was made to provide a six-month advance and work from that advance. This issue will be addressed further in the funding agreement and not included as part of the Application Document.

An opinion will be provided on how to manage the question of the donation of unfertilized eggs.

Ms. Kennelly will work with Ms. Rion on redesigning the proposal budget which is an attachment to the Application Document.

The following is a summary of suggestions, recommendations and/or observations with respect to the Application Document:

- Page 2, the one page letter of intent should be submitted by “May 1, 2006.”
- Page 2, last paragraph, add the following sentence after the first sentence: “Each applicant’s institution shall submit a list of names of ESRO members as well as the policies and procedures.”
- Page 4, the following should be added following the first paragraph under Hybrid Application and Linked Applications “Requested funding for a Hybrid and Linked Applications Award may be up to \$5 million (including indirect costs) and may be expended over 4 years. Project Descriptions for Core Facilities applications are limited to 50 pages (inclusive of the main text, methodology, figures and legends). Other proposal requirements are described under ‘Guidelines for Preparation of Proposals.’”
- Remove the existing second paragraph under Hybrid Applications and Linked Applications.
- Page 5, add a new E. “Potential to encourage collaboration across institutions and disciplines.”
- Page 5, under existing E, add “including financial,” after the word “benefits.”
- Page 5, reletter the remaining paragraphs.
- Page 5, second paragraph under Funding, remove the words “with Connecticut Innovations.”
- Page 5, third paragraph under Funding, change “30 days” to “60 days.”

- Page 7, last paragraph on the page, last sentence, add the following words at the end of the sentence “in the event the applicant is not a faculty member.”
- Page 8, fourth paragraph, first line, insert the words “or hybrid” following the word “project.” Line two, following the word “justification,” add “including the identity of the person to be recruited and a detailed description of their project.” Move this paragraph to page 4 just before the paragraph entitled “Selection Criteria.”
- Page 8, under the paragraph entitled “travel,” change \$2,500 to “\$5,000.”
- Page 9, first paragraph, delete, “(except costs for prior or early publication).”
- Page 9, delete the paragraph entitled “Patent Costs.”
- Page 9, leave the green paragraph as written.
- Page 9, delete the second to last paragraph that starts “In keeping with the 2005 . . .”
- Page 10, under “Adherence to Original Budget Estimates,” change 5 percent to “10 percent,” and change 15 percent to “20 percent.”
- Page 11, remove the last paragraph.
- Page 14, Ms. Kennelly will work with Ms. Rion on redesigning this attachment.

MOTION: Upon a motion made by Dr. Canalis, seconded by Dr. Galvin, the Advisory Committee members voted unanimously in favor of disposing of the motion made on March 7, 2006 to accept the document entitled “Connecticut Stem Cell Research Grants Program, Proposal Instructions.”

MOTION: Upon a motion made by Dr. Lensch, seconded by Dr. Wallack, the Advisory Committee members voted unanimously in favor of accepting the document entitled “Connecticut Stem Cell Research Grant Program, Proposal Instructions,” as amended, conditioned upon an acceptable budget format and Intellectual Property supplement proposal.

It is expected that the document will be mailed out by March 31, 2006 and responses will be due back by May 1, 2006.

Mr. Wollschlager encouraged the formation of members to the various proposed working groups.

The next meeting is scheduled for Tuesday, April 18, 2006.

MOTION: Upon a motion made by Dr. Canalis, seconded by Dr. Jennings, the Advisory Committee voted unanimously in favor of adjourning the meeting at 4:03 p.m.

Respectfully submitted:
