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FOR DISCUSSION PURPOSES ONLY

CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE
Minutes – Regular Meeting
Tuesday – April 17, 2012

A regular meeting of the Connecticut Stem Cell Research Advisory Committee “Advisory Committee” was held on Tuesday, April 17, 2012, at the offices of Connecticut Innovations, 865 Brook Street, Rocky Hill, Connecticut.

Call to Order: Noting the presence of a quorum, Marianne Horn, representing Jewel Mullen, Chairperson of the Advisory Committee and Commissioner of the Department of Public Health, called the meeting to order at 1:05 p.m. Members present: Richard H. Dees (by phone); Gerald Fishbone, M.D; Myron Genel, M.D; David Goldhamer, Ph.D (by phone); Ronald Hart, Ph.D. (by phone); Marianne Horn, J.D.; Ann Kiessling, Ph.D.; Diane Krause, M.D., Ph.D.; Paul Pescatello, J.D., Ph.D.; and Milton B. Wallack, D.D.S.

Advisory Committee Members Absent: Treena Livingston Arinzeh, Ph.D., Ph.D.; and Anne Hiskes, Ph.D.

Other Attendees: Isolde Bates (UCONN); Terri Clark (CASE); Sara Donofrio (CI); Marianne Horn (DPH); Emily Smith (CI); Rick Strauss (CASE); and Paula Wilson (Yale) by phone.

Opening Remarks

Attorney Horn noted that she is the designee for Dr. Mullen for today’s meeting. She welcomed everyone and introduced Dr. Krause who was recently appointed as a member of the Advisory Committee. Dr. Krause is Professor of Laboratory Medicine and Cell Biology at Yale University.

Attorney Horn mentioned that the Stem Cell Research retreat recently held at Wesleyan University was successful. She noted that the growth and success of the stem cell research program in Connecticut was recognized at the retreat. The next retreat will be held at Yale University on November 5, 2012.

Approval of Minutes – Advisory Committee Meeting of 3/20/12

Attorney Horn asked the Advisory Committee members to consider the minutes from the March 20, 2012 meeting.

The spelling of Attorney Horn’s name will be corrected in the March 20, 2012 minutes.

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MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of adopting the minutes of the March 20, 2012 meeting as amended VOTE: 7-0-0 (Dr. Genel, Dr. Kiessling and Dr. Pescatello were not present for the vote).

Six-Month Fiscal Reports:

Ms. Smith mentioned that the following six-month reports were provided for informational purposes:

- 08-SCB-UCHC,022, Dr. Li, principal investigator
- 08-SCB-UCHC-012, Dr. Mayer, principal investigator
- 08-SCB-UCHC-021, Dr. Rosenberg and Dr. Giardina, principal investigators
- 08-SCB-UCHC-016, Dr. Morest, principal investigator
- 08-SCB-YSME-025, Dr. Niklason, principal investigator
- 08-SCC-YSME-005, Dr. Redmond, principal investigator
- 08-SCD-Yale-004, Dr. Lin, principal investigator

Ms. Smith indicated that the grants should be ending in August, and final reports are expected. No action is required at this time. Dr. Krause noted that about 65 to 70 percent of the direct costs of the grants are for personnel related costs and suggested that this information be emphasized when talking about job creation.

Interim Progress Report:

As requested at the November 2, 2011 Advisory Committee meeting, Ms. Smith mentioned that the interim progress report for grant 10SCA047, Dr. Drazinic was provided. A concern was raised that the completion date for the grant is September 2012, and it is unlikely that the projected will be completed before the expiration of the grant. Dr. Wallack asked the Advisory Committee members to consider whether the funding for the grant should be terminated and transferred to a seed project on the reserve list. There was some discussion about how returned or unspent funding from a grant could be utilized. Some concern was expressed with utilizing unspent funding on a reserve list that was compiled several years ago.

A discussion ensued on some of reasons Dr. Drazinic's project was delayed, and it was noted that much of the delay was out of her control. Ms. Bates indicated that Dr. Drazinic is intending to request an extension for her project. She explained that Dr. Drazinic will need a release of at least a portion of the second year of funding to continue the progress of the project and pay for personnel costs. In response to a question, Ms. Bates explained the salaries and benefits

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associated with the post doctorate position and the funds remaining in the first year budget.

There was some discussion about requesting more frequent updates on the progress of the project. It was noted that Dr. Drazinic's project is very unique because it deals with Huntington's disease, and it has been difficult for the principal investigator to obtain the materials for the project. After further discussion, there was general consensus that the project should be reevaluated when the next report is submitted and that a letter should be sent to Dr. Drazinic indicating that the interim report is approved but that additional reporting may be required if significant progress is not made before the next report.

MOTION: Upon a motion made by Dr. Dees, seconded by Dr. Hart, the Advisory Committee members voted in favor of accepting the interim progress report and releasing the second year of funding for project 10SCA047, Dr. Drazinic, principal investigator VOTE: 9-0-1 (Dr. Goldhamer abstained from the vote).

Request to Change PI:

Ms. Smith explained that Dr. Drane, principal investigator of grant 11SCA34, will be leaving his position at Yale University and has requested a change of principal investigator to Dr. Wu Tao, a postdoctoral associate at Yale University. She stated that the letter from Dr. Drane explains that the change will have no effect on the project, and the curriculum vitae for Dr. Wu Tao was provided. There was some discussion as to whether there is anything that can be done to require principal investigators to complete their work and not allow changes in principal investigators. It was noted that there is some precedence with National Institutes of Health grants. Some principal investigators take the grants with them to continue the work when they change positions and some transfer the grants to someone that has been working on the grant at the same institution.

MOTION: Upon a motion made by Dr. Pescatello, seconded by Dr. Wallack, the Advisory Committee members voted unanimously in favor of approving the change of principal investigator for grant 11SCA34 to Dr. Wu Tao. VOTE: 8-0-2 (Dr. Genel and Dr. Krause abstained from the vote).

Final Reports:

As requested at the March Advisory Committee meeting, the revised lay summaries were obtained for grants 06-SCB-UHC-14, Dr. Xu, principal investigator; 09-SCA-UHC-34, Dr. Schumacher, principal investigator; and 09-SCA-UHC-13, Dr. Antic, principal investigator. The Committee members were

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satisfied with the revised lay summaries. No formal action is required on this item. Ms. Smith indicated that she will provide guidance to the principal investigators on acceptable lay summaries.

Rebudgeting Request:

Ms. Smith stated that the agenda item for grant 08-SCB-UCHC-022, Dr. Li, principal investigator, was put on the agenda in error since this action was considered by the Advisory Committee in March. She asked the Advisory Committee members to consider removing it from the agenda.

MOTION: Upon a motion made by Dr. Wallack, seconded by Attorney Horn, the Advisory Committee members voted unanimously in favor of removing from the agenda the rebudgeting request for grant 08-SCB-UCHC-022, Dr. Li, principal investigator. (VOTE: 10-0-0).

Carry-Over Requests:

Ms. Smith stated that CI reviewed the carryover request for grant 09-SCB-Yale-14, Dr. Huang, principal investigator, and recommends approval. In response to a question, Ms. Wilson explained the request to rebudget funds and carry over the remaining unspent funds.

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Pescatello, the Advisory Committee members voted in favor of approving the rebudget of funds and carryover of funding for grant 09-SCB-Yale-14, Dr. Huang, principal investigator VOTE: 8-0-2 (Dr. Genel and Dr. Krause abstained from the vote).

No-Cost Extension Request:

Ms. Smith explained the no cost extension and reallocation of funds for grant 09-SCB-UCHC-01, Dr. Bavarsaihan, principal investigator.

MOTION: Upon a motion made by Dr. Krause, seconded by Dr. Wallack, the Advisory Committee members voted in favor of approving the no-extension and reallocation of funds for grant 09-SCB-UCHC-01, Dr. Bavarsaihan, principal investigator VOTE: 9-0-1 (Dr. Goldhamer abstained from the vote).

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Discussion of RFP Modifications:

As requested at the March Advisory Committee meeting, Dr. Goldhamer, Dr. Wallack and Attorney Horn discussed potential modifications to the Request for Proposals (“RFP”) for the 2013 funding round to determine whether all kinds of stem cell research could be encompassed within the existing Stem Cell Research Program based on existing statutes.

The Advisory Committee members reviewed the two versions of amendments, one of which contains minor changes and the other major changes. Attorney Horn noted that the major amendments would require legislative changes. She noted, however, that accepting the minor changes in the RFP does not preclude the Advisory Committee from proceeding with legislation for major changes in the future. Dr. Goldhamer was recognized and thanked for his efforts with drafting the proposed amendments. He explained the rationale for the amended language. Attorney Horn explained the original focus of the legislation. In response to a question, Attorney Horn opined that including animal models directly related to human disease is an acceptable extension of the language in the statutes, but extending the language further with more specificity is not advisable without amending the legislation.

After discussion, there was consensus to proceed with making the following minor changes to the overview section of the RFP for the 2013 funding round:

“It is the intent of the Connecticut Stem Cell Research Advisory Committee to consider funding any form of stem cell research. Priority will be given to human stem cell research and to other studies with clear potential relevance to human health, including animal models of human disease, regeneration/repair and aging.”

Attorney Horn noted that additional changes may be made to other sections after a full review of the RFP for the 2013 funding round. She asked the Advisory Committee members to provide any comments and/or potential changes before the fall.

Process for Stem Cell Grant Review Meeting:

Attorney Horn stated that arrangements have been made at the Farmington Marriott for the Stem Cell Grant Review meeting to be held on Monday, June 11, 8:30 a.m. to 5:00 p.m., and if needed, the morning of Tuesday, June 12. The Connecticut Academy of Science and Engineering is assisting CI with processing the applications. For informational purposes and to assist the Advisory Committee members with the evaluations of the grants, Attorney Horn will send a

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list of criteria from the RFP and a framework of items that may come up during the review meeting. The Advisory Committee members discussed the process for conducting the review meeting. Last year, the Advisory Committee reviewed the grants in the following order: 1) Established Investigator, 2) Group, 3) Seed and 4) Core. The Advisory Committee members generally agreed with the order of the reviews but indicated that the process may have to change not knowing the outcome of the Peer Review process. A suggestion was made to review the core grants first because there is a limit on the funding available for core proposals. A suggestion was made to consider placing less emphasis on the seed grants. Attorney Horn noted that the RFP for the 2012 round of funding does not allocate a percentage of funding for seed grants. There was consensus that the review and allocation of grants should be done in a manner that is consistent with the intent of the RFP for the funding round. The Advisory Committee members asked if the successes from the grants over the last several years can be tracked (i.e. any additional grant funding or publications as a result of the Stem Cell Research Advisory Committee funding). This information will be obtained from the institutions. CI will provide guidelines to the institutions with a questionnaire for the principal investigators. A suggestion was made to issue a press release on the information obtained.

Any recommendations on how to improve the grant review process meeting or any other suggestions should be directed to either Attorney Horn or Ms. Smith. Attorney Horn noted that the assignments for reviews of the grants will be provided in the near future.

Update on Peer Review Process:

Mr. Strauss provided an update on the peer review process. He noted that 54 seed proposals were reviewed, and 26 of the 54 (48 percent) required reconciliation by the primary and second reviewers. Reconciliation is required when the scores have more than a 1 point difference. Mr. Strauss stated that 4 of the seed grants were not reconciled and needed to be reviewed by the co-chairs for further reconciliation. Mr. Strauss indicated that 29 established investigator proposals were reviewed and 14 (48 percent) required reconciliation by the primary and secondary reviewers. One of the 14 is still outstanding. Two core proposals were reviewed and 1 proposal needed reconciliation by the primary and secondary reviewers and the reconciliation process is still ongoing. Mr. Strauss stated that 1 group project was reviewed and did not require reconciliation. Two disease related proposals were reviewed, one of which required reconciliation by the primary and secondary reviewers. Mr. Strauss indicated that the co-chairs will be reviewing all of the proposals for discussion at the study section that will be held on Friday, April 27. Ms. Clark noted that a reconciliation statement will be prepared and provided by the Peer Review Committee describing how the scores were reconciled and final scores

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determined. She stated that there were not a lot of proposals that had large discrepancies. Mr. Strauss reviewed the form that will be provided to each of the Advisory Committee members showing the final score, peer review score, initial scoring, etc. so the members have a the history of the final scoring. The document will be revised or a separate document provided to show the two Advisory Committee members reviewing the proposal and those proposals that have proprietary information.

In response to a question about the membership of the Advisory Committee, Attorney Horn stated that Ms. Smith will be helping to try to get the vacancies on the Advisory Committee filled. It is not expected that the vacancies will be filled before the grant review meeting.

A suggestion was made to consider a certain score as the cutoff for reviewing proposals in more detail. After discussing various options, there was consensus that the top 40 percent scored proposals rounded up to the highest half point should receive more attention. Attorney Horn clarified that all of the proposals will be reviewed. However, the top 40 percent scored proposals rounded up to the highest half point would be reviewed and discussed in more detail at the grant review meeting. Attorney Horn stated that any Advisory Committee member can bring up and discuss any of the other proposals if so desired.

There was consensus not to impose any time limits for review or discussion of the proposals.

Public Comments

Attorney Horn reminded the Advisory Committee members that Statement of Financial Interests filings must be filed no later than May 1, 2012 with the Office of State Ethics. A link to the Website was provided by DPH, and paper copies are also available.

Other Business

Dr. Wallack suggested that Connecticut further explore entering into a collaborative partnership with Maryland. A suggestion was made to have representatives from Maryland attend Connecticut's next stem cell retreat.

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Adjournment:

MOTION: Upon a motion made by Dr. Genel, seconded by Dr. Wallack, the Advisory Committee members voted unanimously in favor of adjourning the meeting at 2:55 p.m.

Respectfully submitted:

Dr. Jewel Mullen, Chair