

**CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE**  
**Minutes – Regular Meeting**  
**Tuesday – August 21, 2012**

A regular meeting of the Connecticut Stem Cell Research Advisory Committee “Advisory Committee” was held on Tuesday, August 21, 2012, at the offices of Connecticut Innovations, 865 Brook Street, Rocky Hill, Connecticut.

**Call to Order:** Noting the presence of a quorum, Marianne Horn, temporarily representing Jewel Mullen, Chairperson of the Advisory Committee and Commissioner of the Department of Public Health, called the meeting to order at 1:15 p.m. Members present: Treena Livingston Arinzeh, Ph.D. (by phone) (arrived at 1:22 p.m.), Richard H. Dees (by phone); Gerald Fishbone, M.D; Myron Genel, M.D; James Hughes, Ph.D.; Jewel Mullen, M.D., M.P.H., M.P.A. (arrived at 1:45 p.m.); Paul Pescatello, J.D., Ph.D. (by phone); and Milton B. Wallack, D.D.S.

Advisory Committee Members Absent: David Goldhamer, Ph.D; Ronald Hart, Ph.D.; Ann Kiessling, Ph.D.; and Diane Krause, M.D., Ph.D.

**Other Attendees:** Terri Clark (CASE); Sara Donofrio (CI); Marianne Horn (DPH); Joseph Landry (CI); Leslie Larson (CI); Claire Leonardi (CI); Rick Strauss (CASE); and Paula Wilson (Yale).

**Opening Remarks**

Attorney Horn noted that she will open the meeting and represent Dr. Mullen for today’s meeting until Dr. Mullen arrives. She welcomed everyone and introduced Dr. Hughes who was recently appointed as a member of the Advisory Committee. Dr. Hughes is a bioethicist and sociologist at Trinity College and previously worked for the Center of Clinical Ethics in Chicago.

**Approval of Minutes – Advisory Committee Meeting of 4/17/12 and 6/11/12**

Attorney Horn asked the Advisory Committee members to consider the minutes from the April 17, 2012 and June 11, 2012 meetings.

**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 April 17, 2012 and June 11, 2012 meetings as presented. VOTE: 7-0-0 (In favor: Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.** (Dr. Arinzeh was not present for the vote).

### **Six-Month Fiscal Reports:**

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

- 08-SCB-UCHC-011, Dr. Zecevic, principal investigator
- 08-SCB-UCON-006, Dr. LoTurco, principal investigator

CI has reviewed the reports and Ms. Donofrio stated that there is nothing unusual to report.

**MOTION:** Upon a motion made by Dr. Dees, seconded by Dr. Wallack, the Advisory Committee members voted in favor of accepting the six-month fiscal reports for grants 08-SCB-UCHC-011, Dr. Zecevic, principal investigator, and 08-SCB-UCON-006, Dr. LoTurco, principal investigator. VOTE: 7-0-0 (In favor: Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.** (Dr. Arinzeh was not present for the vote).

### **Annual Reports:**

Ms. Donofrio stated that annual reports were received for the following grants:

- 09SCBYALE06, Dr. Kocis, principal investigator
- 09SCBYALE13, Dr. Sutton, principal investigator
- 09SCBYALE14, Dr. Huang, principal investigator
- 09SCBYALE21, Dr. Xu, principal investigator
- 09SCBYALE27, Dr. Lu, principal investigator
- 09SCDUCHC01, Dr. Xu and Dr. Grabel, principal investigators
- 09SCBUCHC09, Dr. Shapiro, principal investigator
- 09SCBWESL26, Dr. Naegele, principal investigator
- 09SCBUCHC01, Dr. Bayarsaihan, principal investigator
- 09SCBUCHC20, Dr. Lichtler, principal investigator

The Advisory Committee members asked for better lay summaries for grants 09SCBYALE 13, Dr. Sutton, principal investigator, and 09SCBYALE14, Dr. Huang, principal investigator. It was noted that the lay summary for grant 09SCBUCHC09, Dr. Shapiro, principal investigator, is an excellent example of an acceptable lay summary.

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the Advisory Committee members voted in favor of accepting the annual reports for the following, some of which are conditional and indicated below: VOTE: 7-0-1 (In favor: Arinzeh, Dees, Fishbone, Horn, Hughes, Pescatello and Wallack; Abstention: Genel) **MOTION PASSED.**

- 09SCBYALE06, Dr. Kocis, principal investigator
- \*09SCBYALE13, Dr. Sutton, principal investigator, conditioned upon the receipt and acceptance of a revised lay summary
- \*09SCBYALE14, Dr. Huang, principal investigator, conditioned upon the receipt and acceptance of a revised lay summary
- 09SCBYALE21, Dr. Xu, principal investigator
- 09SCBYALE27, Dr. Lu, principal investigator

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the Advisory Committee members voted unanimously in favor of accepting the annual reports for the following grants: VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.**

- 09SCDUCHC01, Dr. Xu and Dr. Grabel, principal investigators
- 09SCBUCHC09, Dr. Shapiro, principal investigator
- 09SCBWESL26, Dr. Naegele, principal investigator
- 09SCBUCHC01, Dr. Bayarsaihan, principal investigator
- 09SCBUCHC20, Dr. Lichtler, principal investigator

### **Final Reports**

Ms. Donofrio mentioned that final reports have been received for grants 06SCB11, Dr. LoTurco, principal investigator, and 09SCBWESL26, Dr. Naegele, principal investigator. It was noted that the final fiscal report was received for grant 09SCBWESL26, Dr. Naegele, principal investigator. The final technical report was not received and will be provided at the next meeting. CI keeps track of the receipt of financial and technical reports.

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the Advisory Committee members voted unanimously in favor of accepting the final reports for grant 06SCB11, Dr. LoTurco, principal investigator, and grant 09SCBWES26, Dr. Naegele, principal investigator. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.**

### **Rebudget Requests**

The Advisory Committee members discussed the request to transfer funds from supplies to salary and wages for grant 11SDIS02, Dr. Boelsterli, principal investigator (UCONN). Ms. Donofrio explained that the amount requested to be transferred in year 3 exceeds 20 percent and must therefore be approved by the Advisory Committee. The Advisory Committee members also reviewed the rebudget request for grant 11SCA33, Dr. Amos, principal investigator (Yale), to reflect a decrease in the salary paid to the principal investigator.

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Genel, the Advisory Committee members voted unanimously in favor of approving the rebudget request for grant 11SDIS02, Dr. Boelsterli, principal investigator. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.**

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the Advisory Committee members voted in favor of approving the rebudget request for grant 11SCA33, Dr. Amos, principal investigator. VOTE: 7-0-1 (In favor: Arinzeh, Dees, Fishbone, Horn, Hughes, Pescatello and Wallack; Abstention: Genel) **MOTION PASSED.**

### **Rebudget Requests for 2012 Proposals**

The Advisory Committee members discussed the following rebudget requests which resulted from changes to the amount and/or term of the grant proposal as discussed at the grant review meeting of June 11, 2012:

- 12SCBUCHC09, Dr. Chamberlain, principal investigator
- 12SCDISYALE01, Dr. Redmond, principal investigator
- 12SCBUCON01, Dr. Goldhamer, principal investigator

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the Advisory Committee members voted in favor of

approving the rebudget request for grant 12SCBUCHC09, Dr. Chamberlain, principal investigator, and grant 112SCBUCON01, Dr. Goldhamer, principal investigator. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.**

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the eligible Advisory Committee members voted unanimously in favor of approving the rebudget requests for grant 12SCDISYALE01, Dr. Redmond, principal investigator, and grant 11SCA33, Dr. Amos, principal investigator. VOTE: 7-0-1 (In favor: Arinzeh, Dees, Fishbone, Horn, Hughes, Pescatello and Wallack; Abstention: Genel) **MOTION PASSED.**

### **Carryover Requests**

The Advisory Committee discussed the request for a carryover of funding for grant 09SCDUCHC01, Dr. Xu and Dr. Grabel, co-principal investigators. There was some discussion about the large amount of unspent funding, and the Advisory Committee members asked for further clarification.

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Genel, the Advisory Committee members voted unanimously in favor of requesting more specific written information about the unspent funds for grant 09SCDUCHC01, Dr. Xu and Dr. Grabel, co-principal investigators. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.**

### **No Cost Extensions**

The Advisory Committee members discussed the requests for no-cost extensions for the following grants:

- 10SCA23, Dr. Chhabra, principal investigator, (UCHC)
- 10SCD01, Dr. Antic, principal investigator, (UCHC)
- 10SCA47, Dr. Drazinic, principal investigator, (UCHC)
  
- 09SCBUCON18, Dr. Rasmussen, principal investigator
- 10SCA22, Dr. Rodenheffer, principal investigator, (Yale)
- 10SCA05, Dr. Ge, principal investigator, (Yale)
- 10SCA13, Dr. Cheng, principal investigator, (Yale)

It was noted that the Advisory Committee members in the past had requested more frequent updates on grant 10SCA47, Dr. Drazinic. CI was asked to clarify whether the principal investigator has left the country or intends to leave the country, and if so whether or how the grant will be affected.

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of requesting an update on the progress of grant 10SCA47, Dr. Drazinic, principal investigator, and confirmation on whether the principal investigator has left or will be leaving the country and how the project will be impacted. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.**

Mr. Landry reported that he was not able to locate any technical or fiscal reports received for grant 10SCA23, Dr. Chhabra, principal investigator.

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of requesting acceptable progress reports for grant 10SCA23, Dr. Chhabra, principal investigator, before considering a no-cost extension. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Horn, Hughes, Pescatello and Wallack) **MOTION PASSED.**

Commissioner Mullen arrived during this discussion and took over as chair of the meeting.

The Advisory Committee members asked for more clarity on the status of the research for grant 10SCD01, Dr. Antic, principal investigator.

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of requesting more information on the status of the research for grant 10SCD01, Dr. Antic, principal investigator, before considering a no-cost extension. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Hughes, Mullen, Pescatello and Wallack) **MOTION PASSED.**

There were no issues with the requests for no cost extensions for grants 09SCBUCON18, Dr. Rasmussen, principal investigator; 10SCA22, Dr. Rodenheffer, principal investigator; 10SCA05, Dr. Ge, principal investigator; and 10SCA13, Dr. Cheng, principal investigator.

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of authorizing a no-cost extension for grants 09SCBUCON18, Dr. Rasmussen, principal investigator. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Hughes, Mullen, Pescatello and Wallack) **MOTION PASSED.**

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of authorizing no-cost extensions for grants 10SCA22, Dr. Rodenheffer, principal investigator; 10SCA05, Dr. Ge, principal investigator; and 10SCA13, Dr. Cheng, principal investigator. VOTE: 7-0-1 (In favor: Arinzeh, Dees, Fishbone, Hughes, Mullen, Pescatello and Wallack; Abstention: Genel) **MOTION PASSED.**

### **Change in Personnel Request**

The Advisory Committee members reviewed the request for change in personnel for grant 10SCA06, Dr. Aneskievich, principal investigator, (UCON).

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Wallack, the Advisory Committee members voted unanimously in favor of approving the change in personnel for grant 10SCA06, Dr. Aneskievich, principal investigator. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Hughes, Mullen, Pescatello and Wallack) **MOTION PASSED.**

### **Extension of Time Served as PI**

Mr. Landry reviewed the request to extend the time served as principal investigator for grant 10SCA29, Dr. Filipovic. The Advisory Committee members asked for additional information and the budget related to the request.

**MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Mullen, the Advisory Committee members voted unanimously in favor of requesting additional information and budget related to the extension of time to serve as principal investigator for grant 10SCA29, Dr. Filipovic. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Hughes, Mullen, Pescatello and Wallack) **MOTION PASSED.**

### **Addition of Co-PI Request**

As a result of suggestions made by the Peer Reviewers with respect to the UCONN core facility, a request has been made to add co-principal investigator, Dr. Lalande, for grant 09SCDUCHC01, along with Dr. Xu.

**MOTION:** Upon a motion made by Dr. Genel, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of approving the addition of Dr. Lalande as co-principal investigator along with Dr. Xu for grant 09SCDUCHC01. VOTE: 8-0-0 (In favor: Arinzeh, Dees, Fishbone, Genel, Hughes, Mullen, Pescatello and Wallack) **MOTION PASSED.**

### **Update on Funding of 2012 Assistance Agreement**

Paula Wilson asked about the start date for the 2012 assistance agreements. Mr. Landry explained the steps that must occur before the Assistance Agreements become effective and funds can be released for the 2012 grants. He noted that CI has to receive verifications and certification reports from the universities before the Assistance Agreements are sent to the universities. After further discussion on the issue, there was consensus that since the start date is somewhat dependent upon the universities providing information to CI and because of the new team members involved, the goal for the effective date should be October 15 but no later than November 1, 2012. There was also general consensus to try to work on shortening the time frame between the grant awards and receipt of the grant funds for the next round of funding. The time frame should be communicated to all of the universities.

### **Grant Review Process Evaluation**

Mr. Strauss discussed the results of the evaluation of the grant review process. He indicated that input was provided by CASE, from the Peer Reviewers and from the Advisory Committee members. Mr. Strauss reviewed some of the recommendations made for next year's process. One of the recommendations is to strengthen the orientation for the peer reviewers. Another recommendation is to focus the peer review assignments to specific grant categories depending on each peer reviewer's expertise. Mr. Strauss discussed the need to include in the screening process for new peer reviewers a preference for researchers with experience in conducting reviews using the National Institutes of Health ("NIH") criteria. He indicated that it is recommended that the two peer reviewers assigned to each proposed each conduct a "primary" review rather than the current process of having a "primary" and "secondary" review for each proposal. Mr. Strauss described other recommended changes to the peer review process, including the reconciliation process. He noted that the recommended reconciliation process, among other things, would include more written

information about the differences in the scoring by the two peer reviewers. Mr. Strauss described recommended improvements to the Study Section review of the proposals for final scoring. He suggested that the peer review scores be extended to a 10 to 90 point scale rather than the 1 to 9 point scale to help further discriminate scores. Some concern was expressed that changing the point scale may not solve some of the problems with large discrepancies in the scoring between the two peer reviewers. It was noted that a written explanation or statement about the scoring from the peer reviewers will be helpful in understanding the scoring and reconciling the scores, and having two primary reviewers may also provide more consistency with the scoring.

There was general consensus that the grant review process was better than in past years as a result of CASE being involved; however, the Advisory Committee wants to strive to make the process even better for future years.

A suggestion was made to consider increasing the number of peer reviewers and using three reviewers for each proposal. Attorney Horn noted that the maximum number of peer reviewers is determined by statute. Another suggestion was made to consider using experts on ad hoc basis as needed.

Attorney Horn reviewed some additional comments received from the Advisory Committee members which are not provided to CASE before the evaluation report was prepared. She mentioned that a recommendation was made for the Advisory Committee not to spend much time reviewing the proposals that were scored the worst.

In response to a question, Mr. Strauss indicated that the Peer Review Committee was provided with a copy of the evaluation prepared by CASE for informational purposes.

Mr. Strauss explained some of the suggested changes for the next Request for Proposal ("RFP"). He suggested that the RFP request that applicants indicate if they have already received a Connecticut stem cell research grant. If so, the applicant should include specific information about the grant award. Mr. Strauss stated that the applicant should also indicate whether he/she has submitted any other proposals for the current proposal cycle. Additionally, applicants should clearly highlight any proprietary information that should not be publicly disclosed.

Mr. Strauss discussed recommendations related to the Advisory Committee. He talked about some of the benefits of having Advisory Committee members with conflicts remove themselves from the room when discussing his/her proposal. Mr. Strauss suggested that Advisory Committee members have access to all proposals as soon as they become available online to identify conflicts of interest early in the process. He also suggested that Advisory Committee members test computer systems for access to the documents so that any technical issues can

be resolved in timely manner. CASE was complimented for the excellent review and recommendations.

A suggestion was made to provide the peer reviewers with a copy of the RFP so that they are aware of the Advisory Committee's focus. Some concerns were expressed with providing the RFP to the peer reviewers since the focus of the peer reviewers should be to evaluate the science of the proposals.

Attorney Horn reported that three comments have been received appealing the decisions made at the June grant review meeting. She suggested forming a small ad hoc committee to determine whether an appeal process is necessary and to discuss how to deal with these types of issues. Attorney Horn summarized that two of the complaints were related to awards for proposals that received worse scores than others that did not get funded. The Advisory Committee members discussed the fact that award decisions are not based solely on the scientific merits of proposals and that there are other factors that are considered when making decisions on the grant awards.

Attorney Horn explained that another complaint was about the discrepancy in scoring by the two peer reviewers and one peer reviewer not agreeing with one of the institutions about a research integrity issue. She mentioned that the complainant requested that this issue be brought to the Advisory Committee for an independent review. It was noted that NIH has a formal appeals process. After further discussion on the issue, there was consensus to form an ad hoc committee to discuss whether an appeals process is needed. The ad hoc committee will consist of Attorney Horn, Dr. Hughes, Dr. Wallack and Mr. Strauss. The ad hoc committee will report back to the Advisory Committee with some recommendations/guidelines to potentially include in the next RFP.

Attorney Horn and Dr. Mullen noted the importance of the Advisory Committee members being as objective as possible and cautious with discussions on matters that could get misconstrued by others during these open and public meetings.

### **Next Steps**

Ms. Leonardi discussed the importance of documenting the successes, the scientific merits and results of the program over the last six years. She spoke about the collaborative efforts of the universities as a result of the program. Ms. Leonardi asked for support and input from the Advisory Committee members and CASE with respect to the future of the program. There was general consensus that the scientific merits, successes and full explanation of the program should be conveyed in lay terms to the general public. The explanation should also include information on how the program started and has evolved and helped to leverage other funding. There was also consensus that the information/report should come from an independent source such as CASE. Ms. Leonardi will provide questions to the Advisory Committee members before the next meeting. A report/evaluation of the program to date should be completed before the end of the year and in time for the next legislative session. It was noted that strategic decisions will have to be made about legislation for the future of the program.

Attorney Horn reported that California is interested in working with Connecticut if possible (i.e. by sending people virtually to retreats and other workshops). It is anticipated that legislation will be presented at the next session to allow Connecticut to formally collaborate with other countries and states on stem cell research.

### **Public Comments**

Paula Wilson invited the Advisory Committee members to attend the Yale Stem Cell Center annual retreat which will be held on October 19.

### **Adjournment:**

**MOTION:** Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of adjourning the meeting at 3:43 p.m.

Respectfully submitted:

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Dr. Jewel Mullen, Chair