

CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE
Minutes – Special Meeting
Tuesday – October 2, 2012

A special meeting of the Connecticut Stem Cell Research Advisory Committee “Advisory Committee” was held on Tuesday, October 2, 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 1:04 p.m. Members present: Gerald Fishbone, M.D (by phone); Myron Genel, M.D (arrived at 1:07 p.m.); David Goldhamer, Ph.D; Ronald Hart, Ph.D.; Marianne Horn, J.D.; James Hughes, Ph.D.; Ann Kiessling, Ph.D. (joined by phone at 1:43 p.m.); Diane Krause, M.D., Ph.D. (by phone); and Milton B. Wallack, D.D.S.

Advisory Committee Members Absent: Treena Livingston Arinzeh, Ph.D.; Richard H. Dees; and Paul Pescatello, J.D., Ph.D.

Other Attendees: Isolde Bates (UCONN); Terri Clark (CASE); Sara Donofrio (CI); Marianne Horn (DPH); Joseph Landry (CI); Claire Leonardi (CI); and Rick Strauss (CASE).

Opening Remarks

Attorney Horn thanked the members for making themselves available to convene a special meeting and work around the holidays.

Approval of Minutes – Advisory Committee Meeting of August 21, 2012

Attorney Horn asked the Advisory Committee members to consider the minutes from the August 21, 2012 meeting.

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Hughes, the Advisory Committee members voted in favor of adopting the minutes from the August 21, 2012 meeting as presented. VOTE: 8-0-0 (In favor: Fishbone, Genel, Goldhamer, Hart, Horn, Hughes, Krause and Wallack) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

Annual Reports:

Attorney Horn reminded those members that have a conflict to refrain from discussion and vote on those proposals.

Mr. Landry discussed the final report received for grant 08-SCA-UCON-040, Dr. Carter, principal investigator. He mentioned that the final fiscal report was received, but the technical report was not received. In reviewing the financial records, Mr. Landry stated that the principal investigator, who is no longer at the university, did not receive the second year of funding for the two year grant. In response to a question, it was noted that after receipt of the required first year reports, the second year of funding should have been released. Mr. Landry stated that the funds did not get released, and there is no record of the principal investigator requesting the funding. He indicated that the fiscal report shows expenditures of approximately \$200,000. There was general consensus to table the acceptance of the annual report and release of the second year of funding until the next meeting and have Matt Cahill at the Office for Sponsored Programs at UCONN explain to the Advisory Committee how the work was performed without the second year of funding.

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Hughes, the Advisory Committee members voted in favor of tabling the acceptance of the annual report and second year of funding for grant 08-SCA-UCON-040, Dr. Carter, principal investigator, until further information is obtained from UCONN on the request. VOTE: 7-0-1 (In favor: Fishbone, Genel, Hart, Horn, Hughes, Krause and Wallack; Abstention: Goldhamer) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

Ms. Donofrio mentioned that annual reports for grants 09SCBYALE 13, Dr. Sutton, principal investigator, and 09SCBYALE14, Dr. Huang, principal investigator, were submitted in August, but the Advisory Committee members requested better lay summaries. The revised lay summaries were provided, and there were objections with the revised summaries.

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 grant 09SCBYALE13, Dr. Sutton, principal investigator, and grant 09SCBYALE14, Dr. Huang, principal investigator. VOTE: 6-0-2 (In favor: Fishbone, Goldhamer, Hart, Horn, Hughes, and Wallack; Abstention: Genel and Krause) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

Ms. Donofrio indicated that that annual reports were also received for the following Yale grants:

- 10SCB03, Dr. Krause, principal investigator
- 10SCA22, Dr. Rodeheffer, principal investigator
- 10SCA38, Dr. Qiu, principal investigator
- 10SCA13, Dr. Cheng, principal investigator
- 10SCB05, Dr. Bordey, principal investigator
- 10SCB02, Dr. Rizzolo, principal investigator
- 10SCA05, Dr. Ge, principal investigator
- 10SCB36, Dr. Flavell, principal investigator
- 10SCB19, Dr. Qiu, principal investigator

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 nine grants listed below. VOTE: 6-0-2 (In favor: Fishbone, Goldhamer, Hart, Horn, Hughes, and Wallack; Abstention: Genel and Krause) **MOTION PASSED.** (Dr. Kiessling was not present for the vote):

- 10SCB03, Dr. Krause, principal investigator
- 10SCA22, Dr. Rodeheffer, principal investigator
- 10SCA38, Dr. Qiu, principal investigator
- 10SCA13, Dr. Cheng, principal investigator
- 10SCB05, Dr. Bordey, principal investigator
- 10SCB02, Dr. Rizzolo, principal investigator
- 10SCA05, Dr. Ge, principal investigator
- 10SCB36, Dr. Flavell, principal investigator
- 10SCB19, Dr. Qiu, principal investigator

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

- 10SCB30, Dr. Li, principal investigator
- 10SCB12, Dr. Lai, principal investigator

MOTION: Upon a motion made by Dr. Wallack, seconded by Fishbone, the Advisory Committee members voted in favor of accepting the annual reports for grant 10SCB30, Dr. Li, principal investigator, and grant 10SCB12, Dr. Lai, principal investigator. VOTE: 7-0-1 (In favor: Fishbone, Genel Hart, Horn, Hughes, Krause and Wallack; Abstention: Goldhamer) **MOTION PASSED.** (Dr. Kiessling was not present for the vote):

Final Reports Received:

Attorney Horn noted that final reports were received for the following grants four grants and asked if there were any comments:

- 09SCBUCHC17, Dr. Srivastava, principal investigators
- 09SCAYALE35, Dr. Herold, principal investigator
- 09SCAUCON02, Dr. Wang, principal investigator
- 09SCBWESL26, Dr. Naegele, principal investigator

Attorney Horn stated that no formal action is required by the Advisory Committee.

Carryover Request:

Ms. Donofrio mentioned that the carryover funding request for grant 09SCDUCHC01, Dr. Xu and Dr. Gabel, co-principal investigators, was presented to the Advisory Committee in August, and the Advisory Committee members requested additional information about the large amount of unspent funding. The information was provided by the co-principal investigators, and there were no further questions.

MOTION: Upon a motion made by Dr. Krause, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of approving the carryover request for grant 09SCDUCHC01, Dr. Xu and Dr. Gabel, co-principal investigators. VOTE: 7-0-1 (In favor: Fishbone, Genel, Hart, Horn, Hughes, Krause and Wallack; Abstention: Goldhamer) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

Grant Modification Subcommittee Report:

Ms. Donofrio explained that the Grant Modification Subcommittee was formed to take action on routine matters and/or time sensitive items that come up in between regular Advisory Committee meetings. She noted that a Grant Modification Subcommittee meeting was held on September 21, and the subcommittee members approved no-cost extensions for grant 10SCA47, Dr. Drazinic, principal investigator; grant 10SCA23, Dr. Chhabra, principal investigator; and grant

10SCD01, Dr. Antic, principal investigator. Attorney Horn mentioned that the regular September Advisory Committee meeting was postponed, and the three requests brought to the subcommittee needed approval before the end of September in order to move forward with the research. She indicated that if there had been an issue with any of the actions for consideration by the subcommittee, the items would have been brought to the Advisory Committee.

No-Cost Extension Requests:

Ms. Donofrio reviewed the no-cost extension requests for grant 10SCA06UCON, Dr. Aneskievich, principal investigator, and grant 11SCD02YALE, Dr. Lin, principal investigator.

MOTION: Upon a motion made by Dr. Fishbone, seconded by Dr. Genel, the Advisory Committee members voted in favor of approving the no-cost extension for grant 10SCA06UCON, Dr. Aneskievich, principal investigator. VOTE: 7-0-1 (In favor: Fishbone, Genel, Hart, Horn, Hughes, Krause and Wallack; Abstention: Goldhamer) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

MOTION: Upon a motion made by Dr. Fishbone, seconded by Dr. Wallack, the Advisory Committee members voted in favor of approving the no-cost extension for grant 11SCD02YALE, Dr. Lin, principal investigator. VOTE: 6-0-2 (In favor: Fishbone, Goldhamer, Hart, Horn, Hughes, and Wallack; Abstention: Genel and Krause) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

Extension of Time Served as PI

Ms. Donofrio mentioned that the request to extend the time served as principal investigator for grant 10SCA29, Dr. Filipovic, principal investigator, was discussed at the August meeting, and the Advisory Committee members asked for additional information for the request. The requested information was provided, and there were no further questions.

MOTION: Upon a motion made by Dr. Krause, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of accepting the extension of time served as principal investigator for grant 10SCA29, Dr. Filipovic, principal investigator. VOTE: 7-0-1 (In favor: Fishbone, Genel, Hart, Horn, Hughes, Krause and Wallack; Abstention: Goldhamer) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

Change of Key Personnel

Ms. Donofrio discussed the requests for changes of key personnel for grant 09SCDUCHC01, Dr. Xu, principal investigator; grant 09SCBUCON18, Dr. Rasmussen, principal investigator; and grant 11SCB08, Dr. Drissi, principal investigator.

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Fishbone, the Advisory Committee members voted in favor of accepting the requests for changes of key personnel for grant 09SCDUCHC01, Dr. Xu, principal investigator, grant 09SCBUCON18, Dr. Rasmussen, principal investigator, and grant 11SCB08, Dr. Drissi, principal investigator. VOTE: 7-0-1 (In favor: Fishbone, Genel, Hart, Horn, Hughes, Krause and Wallack; Abstention: Goldhamer) **MOTION PASSED.** (Dr. Kiessling was not present for the vote).

Amendment to Title

Ms. Donofrio noted that this issue has been resolved, and no discussion is necessary.

Annual Report Discussion

Mr. Strauss stated that CASE starting working on a project to review the accomplishments of the Connecticut Stem Cell Research Program. One of the first steps is a survey that will be sent to the principal investigators of the grant recipients, followed by an interview/survey process with the universities and other stakeholders. A Study Committee has been formed and will consist of Dr. Jane Auben, Dr. Troyen Brennan, Dr. Charles Jennings, Dr. Matthew Kohn, and Dr. Jeanne Loring. The Study Committee will oversee the work of the Research Team which will consist of study manager, Maria Borowski, and Academy Project Staff of Richard Strauss, Terri Clark and Ann Bertini. The Research Team will assist with reviewing the report before it gets presented to the Advisory Committee, DPH and CI.

Mr. Strauss explained the survey process for the principal investigators that have received more than one grant. He mentioned that there are opportunities within the document for principal investigators to provide additional comments.

Ms. Kiessling joined the meeting during this discussion.

Dr. Wallack provided some input on the review process being performed by CASE. He stated that he hopes the process will help validate the program so that the legislature will continue funding the program for another 10 years. Dr. Wallack indicated that he has provided comments to Mr. Strauss, and some of the input has been included in the draft survey. Dr. Wallack questioned the definition of “clinical significance.” He indicated the need to include different questions to obtain more

specific information about the number of jobs created, economic development to the State and the amount of other funding being leveraged as a result of the grant funding. Dr. Wallack suggested expanding the questionnaire to ensure the receipt of information that is more validating for the program. He stated that the program has been instrumental in creating different opportunities for bioscience in Connecticut and has spurred collaboration between the universities. Dr. Wallack suggested that at least two members from the Advisory Committee who have been associated with the program since its inception be included on the Study Committee and/or Research Team.

Mr. Strauss noted that the review is an independent analysis of the program and the accomplishments, and it would not be appropriate to have members of the Advisory Committee on the Research Team or Study Committee. He mentioned that the Research Team will be interviewing members of the Advisory Committee and others involved in the program. Mr. Strauss described the process taken to develop the survey and noted the survey is in line with surveys developed for the stem cell research programs in New York and Canada. He explained that the survey being reviewed today is specific to the principal investigators and the next step is to design the interviews and/or surveys for the institutions. It is anticipated that the survey process for the principal investigators will be underway by the next meeting which is scheduled for October 16. In response to a question, Mr. Strauss stated that CASE is not doing an economic impact analysis.

Mr. Strauss noted that there are several questions in the survey about the impact of collaborations, research and accomplishments. He reiterated the importance of having a credible, independent review of the program's accomplishments.

It was noted that there is a question in the survey about translational research, and a question arose about the definition. Attorney Horn read the language in the Request for Proposals ("RFP") under Group Grant Proposals relating to disease specific applicants. Following a discussion about the vagueness and different interpretations of translational research, there was general consensus to create a more clear definition of translational research, and Dr. Goldhamer, Dr. Genel and Dr. Krause offered to help with the definition for purposes of the study.

A suggestion was made to have two documents—1) for the scientific accomplishments, and 2) for the economic impact of the grant funds to help make a determination of whether funding should continue for the program. The Advisory Committee members noted the importance of having clear and specific economic results from the scientific survey.

A concern was raised that the survey may be too long and that question number 13 about the staffing levels may take too much time and not provide valuable information. Ms. Leonardi responded that this type of information can show the percentage by which the grant funds have increased diversity in this kind of science. Mr. Strauss and CASE were commended for their efforts developing the

survey. Any additional comments or suggestions on the survey should be directed to Mr. Strauss as soon as possible.

Mr. Strauss provided an update on the Peer Review Committee and noted that the terms for three of the members are due for reappointment. The three Peer Reviewers with expiring terms have been extended the opportunity to continue, and the remaining Peer Reviewers have been asked if they want to continue to serve the remainder of their terms. Mr. Strauss mentioned that an orientation session is being put together for the Peer Reviewers and will be held after the release of the RFP for the 2013 funding round.

Mr. Strauss talked about the management of the required reports for the grant recipients. He mentioned that CASE will be putting together a spread sheet to ensure that grant recipients have provided all of the required reports. If there are any missing reports, the universities will be contacted. CI will be asked about the actual contract value of the grant and a comparison will be done of the actual grant expenditures to determine actual versus contracted value.

RFP Discussion

Attorney Horn reviewed the draft RFP for the 2013 funding round, pointing out the language that has changed from the 2012 RFP. She noted that the letter of intent to submit applications is due November 16, 2012, and the deadline for submissions of responses to the RFP is January 4, 2012.

A discussion ensued on the language on page 2 under special considerations about “priority of the program to support research on human embryonic stem cells that is not currently eligible for federal funding.” There was general consensus that applicants should be “welcomed” to apply and that the word “priority” should no longer apply and be taken out of the language.

The Advisory Committee members reviewed the four types of grants and the proposed funding levels for each of the categories. There was general consensus to leave the funding limits the same. A discussion ensued on the limit for the core proposals, and there was general consensus to keep the funding level at \$1,000,000 total.

The Advisory Committee members discussed the “Selection Criteria” which include:

- scientific merit of the proposal research,
- conformance to high ethical standards,
- ability to perform the proposed research,
- commitment to host institutional, hospital or company and (where applicable) collaborators to the proposed project, including cost sharing
- potential for collaboration across disciplines and institutions, hospitals or companies

- benefits (including financial benefits) to the State of Connecticut, and
- alignment with funding priorities as determined by the Connecticut Stem Cell Research Advisory Committee

In addition to the scientific merits and Peer Review Committee score, Attorney Horn noted that the selection criteria published in the RFP can be considered when making a funding determination. Ms. Horn mentioned that other issues (i.e. funding from other sources or receipt of prior funding, unique needs, etc.) have been occasionally discussed, and she asked the Advisory Committee members for input on whether any changes should be made to the list of criteria. In response to a question, it was noted that approximately 22 principal investigators have received more than one grant. A question arose as to whether an applicant should be required to disclose if he/she has applied for another grant in the funding cycle. After further discussion on the matter, there was no clear consensus on whether priority should be given to applicants who only apply for one grant rather than multiple grants in one funding cycle or to applicants who have not received a grant in the past. Several Advisory Committee members noted the advantages of utilizing the grant funds to leverage other funding. A discussion ensued on how to ensure there is no scientific overlap with a proposed project and a project that has already received funding. A suggestion was made to include in the applicant's bio-sketch a description of the applicant's grants funded and any other grants currently submitted. In response to a suggestion to include in the selection criteria a demonstration of the unique needs to complete a project, it was noted that this issue is already considered under the last existing criteria. There was general consensus not to make any changes to the existing selection criteria.

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Genel, the Advisory Committee members voted unanimously in favor of approving the Request for Proposal with the amendments discussed for the 2013 funding round. VOTE: 9-0-0 (In favor: Fishbone, Genel, Goldhamer, Hart, Horn, Hughes, Kiessling, Krause and Wallack.

Update on 2012 Agreements

Ms. Donofrio reported that to date, CI has received all Yale Stem Cell Research Oversight Committee (“SCRO”) approvals and verification forms. The UCONN SCRO and verification forms are expected to be completed by mid-October. Ms. Donofrio stated that there should not be a problem with getting the Assistance Agreements out by November 1. In response to a question, there was no objection with CI starting to send out the Assistance Agreements for the grants that CI has received all necessary documentation and approvals.

Appeals Process Recommendation

Attorney Horn mentioned that at the August 21, Advisory Committee meeting, a decision was made to form an ad hoc subcommittee to discuss whether an appeal process and/or policy for the grants-in-aid is necessary. The subcommittee consisted of Attorney Horn, Dr. Hughes, Dr. Wallack, and Mr. Strauss. Attorney Horn stated that the subcommittee met on September 7 and discussed the issue. She noted that e-mails received from Dr. Krause, Dr. Goldhamer and Dr. Hart regarding an appeal/grievance process were taken into consideration. She mentioned that the Subcommittee discussed the Maryland Stem Cell Research Fund process, the National Institute of Health (“NIH”) appeal process and the California Institute of Regenerative Medicine (“CIRM”) appeal process. After thorough discussion, Attorney Horn stated that the subcommittee concluded not to recommend the implementation of a formal appeal process at this time. Any issues that arise would be brought to the Advisory Committee Chair, and it would be the Chair’s discretion to decide the proper course of action (i.e. to send back to the Peer Review Committee if there is a perceived error and/or handled as a research misconduct matter). The subcommittee also concluded that once grants have been awarded, it is very difficult to appeal because there are no funds remaining. It was noted that applicants can apply for funding in a subsequent round. Attorney Horn stated that the Advisory Committee meetings are open to the public and cautioned everyone participating in the meeting to discuss factual information.

Grant Review Meeting for 2013 Funding Round

Ms. Donofrio will contact the members for potential dates in June 2013 to review grant applications applying for the 2013 funding.

Public Comments

Mr. Strauss mentioned that CASE will hold its annual meeting on May 22, 2013 at Quinnipiac University, and Dr. Grabel, Dr. Lin and Dr. Xu will be the keynote speakers. He invited the Advisory Committee members to attend the annual meeting.

Adjournment:

MOTION: Upon a motion made by Dr. Wallack, seconded by Dr. Hughes, the Advisory Committee members voted unanimously in favor of adjourning the meeting at 3:12 p.m.

Respectfully submitted:

Dr. Jewel Mullen, Chair