DRAFT

FOR DISCUSSION PURPOSES ONLY

CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE
Minutes – Regular Meeting
Tuesday – September 21, 2010

A regular meeting of the Connecticut Stem Cell Research Advisory Committee "Advisory Committee" was held on Tuesday, September 21, 2010, at the Connecticut Economic Resource Center, Brook Street, Building #4, Rocky Hill, Connecticut.

Call to Order: Dr. Galvin, Chairman of the Advisory Committee, called the meeting to order at 1:05 p.m. Members present: Treena Livingston Arinzeh, Ph.D. (by phone); Richard H. Dees, Ph.D. (by phone); Gerald Fishbone, M.D.; Robert Galvin, M.D., M.P.H., M.B.A. (Chair); Myron Genel, M.D.; David Goldhamer, Ph.D; Ronald Hart, Ph.D. (by phone); Ann Kiessling, Ph.D. (by phone); Robert Mandelkern (by phone); and Paul Pescatello, J.D., Ph.D.

Advisory Committee Members Absent: Anne Hiskes, Ph.D.; and Milton B. Wallack, D.D.S.

Other Attendees: Marianne Horn (DPH); Chelsey Sarnecky (CI); Paula Wilson (Yale); and Warren Wollschlager (DPH).

Opening Remarks

Dr. Galvin emphasized the need for the citizen's of Connecticut to recognize the importance of Connecticut's Stem Cell Research program. He acknowledged the foresight of the Governor and President of the Senate several years ago for putting Connecticut on the map with respect to stem cell research. Dr. Galvin mentioned that footage will be put on the Department of Public Health Website and referred to the gubernatorial candidates.

Approval of Minutes – 7/20/10 Meeting

Dr. Galvin asked the Advisory Committee members to consider the minutes from the July 20, 2010 meeting.

A suggestion was made on page 2, to change the word "property" to "properly," and on page 5 and/or 6 to change the reference to "Advisory Committee" funding, to funding from the "State of Connecticut."

> **MOTION:** Upon a motion made by Dr. Fishbone, seconded by Mr. Mandelkern, the Advisory Committee members voted in favor of adopting the minutes of the July 20, 2010 meeting as amended (Dr. Arinzeh, Dr. Genel and Dr. Pescatello were not present for the vote).

Disease Team Discussion:

Attorney Horn explained the proposed language in the Request for Proposals ("RFP") about the disease team award. She indicated that language was tailored after California. Attorney Horn explained that the original recommendation was to make an award under a Disease Team category of up to $2,000,000 over four years. However, Dr. Wallack has requested that the amount be changed to $1,000,000 over three years. Dr. Fishbone indicated that he also spoke with Dr. Wallack, and Dr. Wallack thought that $1,500,000 over three years may be more appropriate since $2,000,000 would more severely impact the number of other grants that could be awarded. Discussion ensued on the proposed amount for the Disease Team, and a suggestion was made to appropriate at least $2,000,000 over four years because it is more costly getting a project ready for FDA review.

It was noted that the Advisory Committee would not have to appropriate any funds for any of the projects if the projects are not meritorious. There was some discussion about having four-year disease team grants rather than three year grants because it is more difficult putting a team together and moving towards FDA review. Questions arose as to whether this type of grant is a Group Grant and should be merged in with the group grants in the RFP. Several members indicated a desire to have the amount and funding term the same as the group grants.

A discussion ensued as to whether there should be a separate category for the Disease Team projects. A suggestion was made to include Disease Team awards under the Group Grants and to add language encouraging related research. It was noted that having a separate category emphasizes the desire to have disease related research that leads to clinical trials. Some concern was expressed that if a separate category is created, it will force researchers to move into certain directions even if the science is not sound. Concern was also expressed that having a separate category creates ambiguity.

Dr. Fishbone indicated that the purpose of the original law for stem cell research in Connecticut was to try to find areas for disease. He noted that there have been five years of basic research, and it is now time to focus on trying to address disease problems.

Dr. Kiessling explained the rationale in California for establishing a Disease Team category. She explained that the under the Disease Team category, the focus is on bringing together a clinical and research team for the FDA review process. She suggested that in the Connecticut RFP, priority be given to clinical teams and academic institutions that begin FDA review within four years. Dr. Kiessling noted that the goal of the category should be to put together a clinical team to do translational work with a goal of developing therapies that could be put before FDA review within four years. A suggestion was made to set up a parallel review process by venture capitals for those

seeking venture capital funds. It was noted that the Connecticut funding should be used to fill funding gaps that cannot be obtained otherwise.

The Advisory Committee members discussed how to proceed. There was consensus that it is appropriate to focus on and encourage translational projections either by establishing a separate category or to including language in the Group Grant category in the RFP. The Advisory Committee discussed some of the advantages and disadvantages of having a separate category.

The Advisory Committee members discussed the proposed timing for the RFP for the 2011 round of funding. Ms. Sarnecky reviewed the timing for the 2010 RFP and funding round. A majority of the members concurred with proceeding based on the timing from previous years if possible. There was consensus to approve the RFP document in concept and to take an electronic vote on the specific language regarding the Disease Team before the RFP is mailed.

> Upon a motion made by Dr. Kiessling, seconded by Dr. Dees, the Advisory Committee members voted in favor of giving priority in the Request for Proposals to projects that lead to U.S. Federal Drug Administration review within four years of the award (Dr. Pescatello and Dr. Goldhamer were opposed).
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> Upon a motion made by Dr. Genel, seconded by Dr. Fishbone, the Advisory Committee members voted in favor including Disease Team language in the Group Grant category of the Request for Proposals for the 2011 round of funding. (Dr. Kiessling and Dr. Dees were opposed).

Attorney Horn indicated that the draft language will be sent to the Advisory Committee members for review and approval through an electronic vote.

Substitution of Grant from the Reserve List:

Ms. Sarnecky reported that one of the seed grant projects from the 2010 funding round has dropped out and the next proposal from the reserve list that was agreed upon at the June 8, 2010 Advisory Committee meeting is grant proposal 10SCA18, Yale University, "Control of mRNA Translation in Neuronal Differentiation from hESC" Dr. Wells, principal investigator, in the amount of $200,000. She stated that no further action is necessary by the Advisory Committee because a vote was taken on the reserve list at the June 8, 2010 meeting.

09SCBYALE14-Huang Effort Reallocation:

Ms. Sarnecky reviewed the request from Dr. Huang, grant 09SCBYALE14, to increase the principal investigator's effort from 5 percent to 50 percent from years 2 through 4 and remove the 100 percent effort for a postdoctoral associate starting in year 2. She noted that effective July 1, 2010, Yale will cover the costs for 50 percent effort to the research assistant. Ms. Sarnecky explained that Dr. Huang has requested permission to reduce the materials and supplies category for year 2. She reviewed the variance percentages in the proposed budgets. Attorney Horn reminded those members that are ineligible to vote, not to vote on this proposal.

> **MOTION:** Upon a motion made by Dr. Pescatello, seconded by Mr. Mandelkern, the eligible Advisory Committee members voted unanimously in favor of approving the reallocation of effort and revised budgets for grant 09SCBYALE14, Dr. Huang, principal investigator.

06SCD01 and 08-SCD-YALE-004, Dr. Lin, Leave of Absence

Ms. Sarnecky discussed the request by Dr. Lin to take a four-month triennial leave from grants 06SCD01 and 08-SCD-YALE-004, effective September 1. Dr. Lin will remain at Yale during the period and continue to devote 25 percent effort to the awards, but the grants will not be charged for his salary.

> **MOTION:** Upon a motion made by Mr. Mandelkern, seconded by Dr. Fishbone, the eligible Advisory Committee members voted unanimously in favor of authorizing the four-month triennial leave from grant 06-SCD01 and 08-SCD-YALE-004, Dr. Lin, principal investigator.

06SCD01, and 10SCB-03 Dr. Krause, Leave of Absence

Ms. Sarnecky reviewed the request by Dr. Krause to take a 16-week triennial leave from grants 06SCD01 and 10SCB-03, effective September 6, 2010 to December 10, 2010. Dr. Krause will remain at Yale during the period and continue to devote 10 percent effort and 15 percent effort respectively to the awards, but the grants will not be charged for her salary.

> **MOTION:** Upon a motion made by Mr. Mandelkern, seconded by Dr. Pescatello, the eligible Advisory Committee members voted unanimously in favor of authorizing the 16-week triennial leave from grant 06SCD01 and 10SCB-03, Yale University, Dr. Krause, principal investigator.

08SCAYALE036, Wang, Resignation

Ms. Sarnecky explained that Dr. Wang, principal investigator for grant 08SCAYALE036, retired June 11, 2010, two months early than the grant ended on August 31, 2010. Dr. Wang informed CI that the aims and milestones of the grant would be completed by June 11, 2010. No action is required on this item. It was noted that there is a balance of approximately $900 in the budget for this grant, and the funds will be returned.

08SCBYALE13, Vaccarino, Budget Reallocation and Carryover of Funds

Ms. Sarnecky reviewed the request by Dr. Vaccarino for a reallocation of carryover funds from year 2 into year 3 for grant 08SCBYALE13. She explained that Dr. Vaccarino would like to reallocate a portion of the remaining salary and benefit funds to repeat a micro array study in order to obtain a greater number of samples. The carryover amount would be used to support 15 percent of Dean Palejev's salary, a research scientist in the Vaccarino lab. Ms. Sarnecky stated that Dr. Palejev's curriculum vitae is attached.

> **MOTION:** Upon a motion made by Dr. Fishbone, seconded by Dr. Pescatello, the eligible Advisory Committee members voted unanimously in favor of authorizing the reallocation of carryover funds from year 2 into year 3 for grant 08SCBYALE13, Yale University, Dr. Vaccarino, principal investigator.

09SCAYALE30, Horsley, Budget Reallocation

Ms. Sarnecky reviewed the request by Dr. Horsley for a budget reallocation for grant 09SCAYALE30. Dr. Horsely is requesting that the funds originally slated for a postdoctoral fellow be reallocated to cover another microscope to use in the hESC culture room for basic cell maintenance and materials and supplies.

> **MOTION:** Upon a motion made by Mr. Mandelkern, seconded by Dr. Fishbone, the eligible Advisory Committee members voted unanimously in favor of authorizing the budget reallocation for grant 09SCAYALE30, Dr. Horsley, principal investigator.

2010 Contract Update

Ms. Sarnecky indicated that the universities have requested minor changes to the contract for the 2010 grant recipients. The changes will be made and it is hopeful that the contracts will be fully executed within the next week or so. All ESCRO approvals and certification letters have been received. CI is working on getting verification forms. The start date for the grants is October 1, 2010.

Other Business

Attorney Horn reviewed the recommendation by the Ethics and Law Subcommittee that was discussed at the July 20, 2010 Advisory Committee meeting with respect to the human embryonic stem cells (hESCs) developed by Harvard University coded as HUES 1-28 that were approved by the National Institutes of Health (NIH) with restrictions.

Attorney Horn explained that at the July 20, 2010 meeting, a question arose as to how Connecticut's law is different from NIH with respect to informed consent. She stated that Connecticut's law indicates that written consent must be obtained for the donation of embryos, consistent with the National Academy of Science ("NAS"), and the embryos must be voluntarily donated. Attorney Horn stated that NAS guidelines do not specifically say that you must identify the scope of the research. Questions arose about the interpretation of the HUES 1-28 lines. It was noted that the NIH has opined that assumptions cannot be made about the donors' consent and the embryos should be used for diabetic and pancreatic research only.

Attorney Horn reiterated that the subcommittee felt that research using HUES 1-28 hESC lines should not be funded for research that is not within the scope of the research described in the informed consent forms. However, the subcommittee concurred that the harm caused by interrupting ongoing research should be balanced against the consent-related harm of continuing to use the lines in such research; and in cases where it is impossible to use different stem-cell lines without seriously disrupting research, such research could be permitted to continue. It was noted that the consent form is a very old form and that future forms should be less restrictive.

After further discussion, there was consensus to adopt the recommendation of the Ethics and Law Subcommittee.

> **MOTION:** Upon a motion made by Dr. Galvin, seconded by Dr. Dees, the Advisory Committee members voted in favor of adopting the following recommendation of the Ethics and Law Subcommittee regarding the hESC research (Dr. Genel abstained from the vote):
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> 1. *Any funding from the CT Stem Cell Research Fund for future hESC research should be limited to research that is consistent with the NIH consent-related restrictions for NIH-funded research using these lines; and*
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> 2. *Principal Investigators on Connecticut-funded research projects already using stem cell lines for research in a manner inconsistent with NIH consent-related restrictions should work with their institutional ESCROs to ensure that different lines are substituted in*

their research whenever, and as soon as practicable. Only in cases where the ESCRO agrees that such substitution is impossible without serious disruption of the ongoing research should that research be permitted to continue without substitution of property-consented stem-cell lines.

Grant Modification Subcommittee Report

Ms. Sarnecky explained that the Grant Modification Subcommittee (GMS) was formed to take action on routine and time sensitive items between regular Advisory Committee meetings. She mentioned that the GMS met on September 9 and approved a reduction in effort for grant 08SCCYSME005, Dr. Redmond and Dr. Elsworth, principal investigators.

Public Comments

There were no public comments.

Next Meeting

The next meeting will be held on Tuesday, October 19.

Adjournment

MOTION: Upon a motion made by Mr. Mandelkern, seconded by Dr. Fishbone, the Advisory Committee members voted unanimously in favor of adjourning the meeting at 2:50 p.m.

Respectfully submitted:

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Dr. Robert Galvin, Chair