

**Advisory Committee of the
Regenerative Medicine Research Fund
Regular Meeting
Monday, June 1, 2015**

A regular meeting of the **Regenerative Medicine Research Fund Advisory Committee** (the “Committee”) was held on Monday, June 1, 2015, at the office of Connecticut Innovations, 865 Brook Street, Rocky Hill, Connecticut.

Call to Order: Nothing the presence of a quorum, interim Chair, Dr. Cartiera, called the Advisory Committee meeting to order at 9:04 a.m.

Committee members present: Margaret Cartiera, Ph.D.; Sandra Engle, Ph.D.; Ronald Hart, Ph.D.; Rosalba Sacca, Ph.D.; David Goldhamer, Ph.D.; Christopher Heinen, Ph.D.; John Hambor, Ph.D.; James Hughes, Ph.D.; Daniel Devine; Commissioner Jewel Mullen; Diane Krause, M.D., Ph.D, Mark Tomishima, Ph.D., Paul Pescatello, J.D., Ph.D. (joined the meeting at 9:14 a.m.).

Other Attendees: Philip Siuta (CI); Carrie Collins White (CI); Ariel Drew (CI); Leslie Larson (CI); Paula Wilson (Yale); Isolde Bates (UCHC); Milton Wallack, D.D.S.; Ivo Kalajzic (UCHC).

Dr. Cartiera welcomed the Advisory Committee to the 2015 annual grant review meeting. She reviewed the day’s agenda and discussed the meeting’s objectives. Dr. Cartiera summarized Connecticut Innovations’ conflict of interest policy; stating that a conflicted Committee member will follow the formal recusal process, as discussed at the May 19th RMRF Committee meeting.

2015 Withdrawn Application

Dr. Cartiera noted that a 2015 application, titled 15-RMB-UCHC-07, had been withdrawn. A discussion ensued regarding the effect this would have on funding dollars this award cycle. According to the strategy discussed at the May 19th RMRF Committee meeting, the Committee agreed to fund all top-scoring applications receiving a rating of “highly recommended”, with a raw score of 51 and above (with the exception of the withdrawn application, 15-RMB-UCHC-07).

Motion for Funding Approval of Applications Scoring 51 and Above

Dr. Krause was recused.

Dr. Cartiera asked for a consent agenda vote for the following 2015 applications, submitted by Yale University, with a score of 51 and above:

- 15-RMB-YALE-18, Krause
- 15-RMB-YALE-07, Niklason
- 15-RMA-YALE-09, Flowers
- 15-RMB-YALE-01, Crews
- 15-RMA-YALE-31, Dell'Anno
- 15-RMB-YALE-04, Hirschi
- 15-RMB-YALE-06, Lu
- 15-RMD-YALE-01, Lin
- 15-RMB-YALE-03, Guo
- 15-RMB-YALE-08, Qyang
- 15-RMB-YALE-13, Zhou
- 15-RMA-YALE-02, Cafferty
- 15-RMA-YALE-06, Coppola
- 15-RMA-YALE-32, Gupta

Upon a motion made by Dr. Heinen, seconded by Dr. Hart, the Advisory Committee members voted in favor of funding the top-scoring applications with a score of 51 and above, submitted by Yale University, as listed above by consent vote. VOTE: 12-1-0 (In favor: Cartiera, Mullen, Sacca, Goldhamer, Heinen, Hambor, Hughes, Devine, Pescatello, Tomishima, Hart, Engle; Recused: Krause).

Dr. Krause joined the meeting; Dr. Goldhamer and Dr. Heinen were recused.

Dr. Cartiera asked for a consent agenda vote for the following 2015 applications, submitted by the University of Connecticut and the University of Connecticut Health Center, with a score of 51 and above (with the exception of application 15-RMB-UCHC-07):

- 15-RMB-UCHC-04, Covault
- 15-RMD-UCHC-01, Lalande
- 15-RMA-UCONN-02, Burke
- 15-RMB-UCHC-08, Kumbar

Upon a motion made by Dr. Krause, seconded by Dr. Hart, the Advisory Committee members voted in favor of funding the top-scoring applications with a score of 51 and above, submitted by the University of Connecticut and the University of Connecticut Health Center, as listed above by consent vote. VOTE: 11-2-0 (In favor: Cartiera, Mullen, Sacca, Krause, Hambor, Hughes, Devine, Pescatello, Tomishima, Hart, Engle; Recused: Goldhamer, Heinen).

Dr. Goldhamer and Dr. Heinen joined the meeting.

Dr. Cartiera asked for a consent agenda vote for the following 2015 application, submitted by MultiClonal Therapeutics, with a score of 51 and above:

- 15-RMB-MCT-01, Xian

Upon a motion made by Dr. Engle, seconded by Commissioner Mullen, the Advisory Committee members voted in favor of funding the top-scoring application with a score of 51 and above, submitted by MultiClonal Therapeutics, as listed above by consent vote. VOTE: 13-0-0 (In favor: Cartiera, Mullen, Sacca, Krause, Hambor, Hughes, Devine, Pescatello, Tomishima, Hart, Engle, Goldhamer, Heinen).

Discussion of Applications Scoring Between 49 and 50

Ms. White reviewed the total amount of dollars spent thus far, stating that \$10,446,931 has been awarded to the 19 approved applications. With the remaining funds available, the Committee decided to fund the three (3) additional seed proposals. Given that five (5) seed applications received a rating of “worthy of consideration”, with a raw score of 49 or 50, the remainder of the meeting reviewed the merit of these proposals and which should move forward for funding approval.

In an effort to streamline the remainder of the meeting and adhere to the conflict of interest recusal process, Dr. Cartiera stated that the five (5) remaining seed applications will be grouped and reviewed by institution.

Dr. Goldhamer disclosed that a post-doctoral student in his lab has a seed application under consideration and that he was recusing himself from all voting motions of seed grants in this portion of the meeting.

Before the specific discussion began, the Committee members commented on the quality of the AAAS scientific peer review; there was unanimous agreement that the reviews were “extraordinary” and included valuable content.

Dr. Goldhamer and Dr. Heinen were recused.

- Discussion: 15-RMA-UCHC-03, Hao

Dr. Krause reviewed the strengths of the above application; stating the project is a novel idea and that the proposal could be successful. She recommended the application for funding. Concerns were raised regarding the scope of research and whether the application was aligned with regenerative medicine. A discussion ensued. There was general agreement from the Committee that the application was novel and significant.

- Discussion: 15-RMA-UCHC-04, Li

Dr. Sacca discussed the above application and reviewed the proposed research. Questions were raised regarding the application's potential and novelty. Dr. Krause discussed the project in terms of its stage as a "seed" application. A discussion ensued regarding the team, proposed research, and the research models.

- Discussion: 15-RMA-UCONN-04, Lees-Shepard

Dr. Hughes discussed the proposed research of the above application, the investigator and team that has been assembled, and the applications' novel approach. Dr. Sacca stated that the application is within the Fund's translational scope by highlighting the application's commercialization strategy. She stated that the application was a resubmission from 2014 and scientific concerns have been sufficiently addressed.

Dr. Heinen and Dr. Goldhamer joined the meeting; Dr. Krause was recused.

- Discussion: 15-RMA-YALE-05, Chen

Dr. Engle reviewed the AAAS scientific peer review concerns and the application's significance. She discussed the clinical relevance and potential issues of research translation, per the Fund's objectives. Dr. Hughes discussed the current market and the existing crowded space of the proposed research approach. There was general agreement that the market space consists of strong competitors with promising research.

- Discussion: 15-RMA-YALE-22, van del Pol

The Committee discussed the above application, and raised concerns regarding the proposed research plan. A discussion ensued regarding scientific concerns within the application including the clinical application of the proposal, and the novelty of the proposed research. There was general agreement that the proposed research plan was not sufficient.

Motion for Funding Approval of Applications Scoring 49 and 50

Dr. Heinen, Dr. Goldhamer and Dr. Krause were recused

Upon a motion made by Dr. Hart, seconded by Dr. Hughes, the Advisory Committee members voted in favor of funding application 15-RMA-UCONN-04, Lees-Shepard. VOTE: 10-3-0 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Devine, Pescatello, Tomishima, Hart, Engle; Recused: Heinen, Goldhamer, Krause).

Upon a motion made by Dr. Hart, seconded by Dr. Hughes, the Advisory Committee members voted in favor of funding application 15-RMA-UCHC-03, Hao. VOTE: 9-3-1 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Pescatello, Tomishima, Hart, Engle; Recused: Heinen, Goldhamer, Krause; Opposed: Devine).

Upon a motion made by Dr. Hughes, seconded by Mr. Devine, the Advisory Committee members voted in favor of funding application 15-RMA-UCHC-04, Li. VOTE: 10-3-0 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Pescatello, Tomishima, Hart, Devine, Engle; Recused: Heinen, Goldhamer, Krause).

Upon a motion made by Dr. Hughes, seconded by Dr. Tomishima, the Advisory Committee members voted in favor of not funding application 15-RMA-YALE-22, van del Pol. VOTE: 10-3-0 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Pescatello, Tomishima, Hart, Devine, Engle; Recused: Heinen, Goldhamer, Krause).

Upon a motion made by Dr. Hughes, seconded by Dr. Hart, the Advisory Committee members voted in favor of not funding application 15-RMA-YALE-05, Chen. VOTE: 10-3-0 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Pescatello, Tomishima, Hart, Devine, Engle; Recused: Heinen, Goldhamer, Krause).

Dr. Heinen, Dr. Goldhamer and Dr. Krause joined the meeting.

Dr. Cartiera suggested to the Committee members that they consider approving “back-up” applications should an award be withdrawn or refused for any reason. Dr. Cartiera discussed the benefits of establishing back-ups and administrative setback’s that would be avoided in the future, in the case where an award is withdrawn or refused. It was suggested that a back-up be selected for each grant type awarded: (1) seed and (2) established investigator. A discussion ensued.

Dr. Heinen, Dr. Goldhamer and Dr. Krause were recused.

Upon a motion made by Dr. Engle, seconded by Dr. Sacca, the Advisory Committee members voted in favor of approving application 15-RMB-YALE-15, Bennett, as a back-up award in the case where an awarded “established investigator application” is withdrawn or refused. VOTE: 10-3-0 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Pescatello, Hart, Tomishima, Devine, Engle; Recused: Heinen, Goldhamer, Krause).

Upon a motion made by Dr. Sacca, seconded by Dr. Hughes, the Advisory Committee members voted in favor of approving application

15-RMA-YALE-22, van del Pol as a back-up award in the case where an awarded “seed application” is withdrawn or refused. VOTE: 9-3-1 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Pescatello, Tomishima, Devine, Engle; Recused: Heinen, Goldhamer, Krause; Opposed: Hart).

Dr. Cartiera provided a summary of total dollars invested; stating that the Committee awarded \$11,046,917 and approximately \$53,000 remain unspent. A discussion ensued regarding the outstanding \$53,000 and how those dollars could roll into the 2016 RFP funding cycle. The Committee commented that the residual funds demonstrate discretion of responsibility on behalf of the Advisory Committee, and that they will benefit 2016 RFP funding opportunities.

Public Comment

Ms. Wilson thanked the Advisory Committee for their work and dedication. She inquired about awardee notification timelines, and whether access to the AAAS scientific peer review reports will be made available to applicants. Dr. Cartiera stated that the BioInnovation team will be informing all 2015 RMRF applicants of funding outcomes, and that each applicant will be provided their respective AAAS report.

Dr. Cartiera informed the Committee that the August Committee meeting will be a strategic meeting focused on the 2016 RFP. She encouraged the Committee members to think about the RFP and its objectives. She also stated that staff was working on a revised annual report template and that a draft version—including updated reporting requirements and data/metrics tracking—will be provided to the Committee members in advance of the August meeting.

For the next RFP award cycle, Dr. Krause suggested the possibility of establishing a sub-committee to decide on award funding. She suggested that the full RMRF Advisory Committee participate solely in strategic objectives. A discussion began and it was decided that this topic would be picked up once again at a later meeting.

Adjournment

Upon a motion made by Dr. Sacca, seconded by Dr. Goldhamer, the Advisory Committee members voted in favor of adjourning the meeting at 12:04 p.m. VOTE: 13-0-0 (In favor: Cartiera, Mullen, Sacca, Hambor, Hughes, Pescatello, Tomishima, Devine, Engle, Hart, Heinen, Goldhamer, Krause).

Respectfully Submitted,

Margaret Cartiera Ph.D., Interim Chair