

HEALTH RESEARCH SCIENCE BOARD

Business Meeting & Public Hearing May 8, 2020 DRAFT AND UNADOPTED MINUTES

Locations

Video conferencing technology was utilized since in-person meetings were suspended for this due to "NY State on Pause" in response to the COVID-19 pandemic. Staff who participated from the NYS DOH Wadsworth Center, Biggs Laboratory, Sturman Conference Room, Empire State Plaza, Albany, NY were physically distanced.

HRSB Members Present

Douglas S. Conklin, Ph.D., Chair Beverly Canin Jeanette Dippo Donald W. Distasio M. Suzanne Hicks Diana E. Lake, M.D. Annette T. Lee, Ph.D. Randa Maher James L. Speyer, M.D.

NYS Staff Present

Teresa Ascienzo Andrea Garavelli Jonathan B. Karmel Farrah M. O'Brien Brian Rourke Jeannine Tusch Carlene Van Patten

Members of the Public

Nila Charles

HRSB Members Absent

Catherine Putkowski-O'Brien Regina Resta, M.D. Marc Wilkenfeld, M.D.

Ex-Officio Members Absent

Victoria Derbyshire, Ph.D.

Ex-Officio Members Present

Richard Dickinson

Call to Order and Opening Remarks of the Chair

The meeting was called to order at 10:10 a.m. with a welcome by Chair, Douglas S. Conklin, Ph.D. followed by introductions of Health Research Science Board (HRSB) members, the New York State Department of Health (DOH) staff, and members of the public.

Exhibit 1. Consideration of May 6, 2019 Meeting Minutes

Dr. Conklin asked the HRSB to consider Exhibit 1, the minutes from the May 6, 2019 meeting.

ACTION

James L. Speyer, M.D. made a motion to approve the minutes as presented and Diana E. Lake, M.D. seconded.

A roll call vote was taken and the minutes were unanimously approved (9-0).

Consideration of Applications for Funding

Andrea Garavelli provided an overview of the applications received in response to two (2) recurring breast cancer scientific/education research request for applications (RFAs); the procurement timelines are bulleted below.

Exhibit 2. Order of Review, Peter T. Rowley Breast Cancer Scientific Research Projects (Rowley Round 6)

- There is \$2.16 million available to fund approximately five-seven (5-7) awards
- This RFA was issued on August 14, 2019
- Thirty-three (33) applications were received by the due date

- Independent peer review of the applications was held in January 2020, twenty-nine (29) applications were scored on a scale of 1.0-9.0 and four (4) applications were triaged
- The Research Plan score is the tie-breaker and the Impact score is the second tiebreaker

Exhibit 3. Order of Review, Patricia S. Brown Breast Cancer Risk Reduction Education Research Projects (Brown Round 7)

- There is \$540,000 available to fund approximately two (2) awards
- This RFA was issued on September 3, 2019
- One (1) application was received by the due date
- Independent peer review of the application was held on December 16, 2019 and the application was scored on a scale of 1.0-9.0.

Ms. Garavelli stated the three-year Brown Round 7 and the two-year Rowley Round 6 contracts will start in January 2021. She said the HRSB may decide to program available funds towards more Rowley Round 6 awards.

Ms. Garavelli provided a summary of the HRSB's third recurring RFA, although no applications were received from its latest issuance, the procurement timeline is bulleted below.

Healthcare Practitioner Breast Cancer Education Research Projects (Healthcare Practitioner Round 3)

- There was \$270,000 available to fund approximately one (1) award
- This RFA was issued on August 21, 2019
- No applications were received by the October 10, 2019 due date
- A non-applicant poll was sent, and a few respondents said they may apply if the opportunity is offered again.

ACTION

Dr. Conklin moved to adjourn into Executive Session for the purpose of discussing the applications received in response to the RFAs. Dr. Speyer seconded.

A roll call vote was taken and the motion was unanimously approved (9-0).

Members of the public and non-essential staff were placed in a virtual waiting room. After discussion, the HRSB reconvened in Public Session.

HRSB Award Recommendations

Dr. Conklin proceeded with the next order of business to vote on the recommended awards for the RFAs:

Dr. Conklin began the process of considering the Brown Round 7 peer review results (including the critique and score) of Drs. Scarfo and Garland's application (DOH01-PBWRN7-2021-0003, Icahn School of Medicine at Mount Sinai and Vision Urbana, Inc).

ACTION

Donald W. Distasio made a motion to not fund (not approve) the Brown Round 7 application for funding. Dr. Speyer seconded.

A roll call vote was taken and the motion was unanimously approved (9-0).

In summary, the HRSB did not recommend the Brown Round 7 application for funding.

Dr. Conklin began the process of considering Exhibit 2, Rowley Round 6 peer review results (including the order of review, critiques and scores).

ACTION

Jeanette Dippo made a motion to recommend the top eight (8) applications to the Commissioner of Health using the peer review results in order of best to worst scores up to the funding that is available in this program. Application details are provided on page 5. Dr. Speyer seconded.

A roll call vote was taken and the motion was unanimously approved (9-0).

ACTION

Dr. Lake made a motion to approve, but not fund, other meritorious applications to the Commissioner of Health in order of peer review ranking in case an awarded organization declines an award. These applications are:

- DOH01-ROWLEY6-2021-00042, Dr. Thompson-Carino, Stony Brook University, and then
- DOH01-ROWLEY6-2021-00049, Dr. Lin, Stony Brook University Ms. M. Suzanne Hicks seconded.

A roll call vote was taken and the motion was unanimously approved (9-0).

In summary, the HRSB recommended \$2.83 million for eight (8) Rowley Round 6 awards, and designated two (2) awards as "approved, but not funded." Ms. Garavelli stated that the HRSB's recommendations will be sent to the Commissioner of Health for approval.

Future RFAs

Dr. Conklin said applicants who were not recommended for funding are encouraged to address the (summary statements) comments and to resubmit their applications, noting they should contact the DOH staff for assistance if needed when applying for future RFAs. He said the DOH will use statewide and county wide listings to ensure various community-based organizations (CBOs) receive notice of future RFAs via email alerts.

Dr. Conklin asked the Board to reaffirm the available funding and release of three (3) recurring breast cancer scientific/education research RFAs in 2020.

ACTION

Ms. Maher made a motion to approve the recurring Healthcare Practitioner Round 4 RFA with \$540,000 available for two (2) awards for release in 2020. Beverly Canin seconded.

A roll call vote was taken and the motion was unanimously approved (9-0).

ACTION

Ms Dippo made a motion to approve the recurring Brown Round 8 RFA with \$270,000 available for one (1) award for release in 2020. Ms. Hicks seconded.

A roll call vote was taken and the motion was unanimously approved (9-0).

ACTION

Ms Maher made a motion to approve the recurring Rowley Round 7 RFA with \$2.16 million available for six (6) awards for release in 2020. Ms. Dippo seconded.

A roll call vote was taken and the motion was unanimously approved (9-0).

Exhibit 4. Program Update

Jeannine Tusch provided a review of Exhibit 4, current programming of the breast cancer research and education funding. She stated that the DOH will continue to carefully monitor the expenditures and scientific progress of the contractors and the scientific progress of any closed and current contracts will be included in the 2019-2020 HRSB Biennial Report. A summary of the seventeen (17) current contracts is bulleted below.

- Brown Round 5: Two (2) contracts began on January 1, 2019. These three-year contracts totaled \$513,000.
- Rowley Round 4: Seven (7) contracts began on January 1, 2019. These two-year contracts totaled \$2.46 million.
- Rowley Round 5: Five (5) contracts began on November 1, 2019. These two-year contracts totaled \$1.76 million.
- Brown Round 6: One (1) contract began on October 1, 2019. This three-year contract totaled \$270,000.
- Healthcare Practitioner Round 2: Two (2) contracts began on October 1, 2019. These three-year contracts totaled \$530,000.

Board Membership Update

Ms. Tusch provided an update on the HRSB's eight (8) vacant seats, details are provided below.

- Two (2) gubernatorial candidates are in the vetting process to fill scientist vacancies;
- Four (4) other vacant scientist seats are to be filled by legislative leadership; and
- Two (2) regional breast cancer survivor advocate seats are to be filled by legislative leadership; this breakdown includes:
 - One (1) regional seat in the Hudson Valley region and
 - One (1) regional seat in Western, NY

She thanked the HRSB members for their dedication to this important program.

Dr. Speyer thanked the Governor's office for moving forward with seat recommendations and urges the legislative leaders to fill vacant seats.

Future Meetings

At its next meeting in 2021, the HRSB will recommend applications for funding the three (3) breast cancer research and education RFAs (Rowley Round 7, Brown Round 8, and Healthcare Practitioner Round 4) to the Commissioner of Health.

Public Hearing

The public hearing convened, and Dr. Conklin introduced Richard Dickinson from the NYS Department of Environmental Conservation. Mr. Dickinson provided a summary of the report on the Efficiency and Utility of Pesticide Reporting. The full report is provided on pages 6-8 and will be included in the 2019-2020 HRSB Biennial Report.

Public Comment

Nila Charles, Chairty Director at Kwakwaduam, a non-profit organization that specializes in assistance and health (maternal health and breast cancer) to the Bronx, NY and Ghana communities, said she is interested in applying for the Brown Round 8 RFA.

Adjournment

Ms. Dippo thanked the DOH staff for making this meeting possible and Ms Hicks wished everyone good health. The HRSB unanimously voted to adjourn and the meeting ended at 2:20 p.m.

Peter T. Rowley Breast Cancer Scientific Research Projects (Round 6): A total of \$2.83 million for eight (8) awards were recommended. These projects are two-year awards.

Organization	Project Title	Investigator(s)	Recommended Funding
Icahn School of Medicine at Mount Sinai	Identifying Regulators of Breast Cancer Immunity Through Pro- Code/CRISPR Genomics	Brian Brown, Ph.D.	\$360,000
Icahn School of Medicine at Mount Sinai	A Novel Approach to Overcoming Endocrine Therapy Resistance of ER+ Breast Cancer Cells	Hanna Y. Irie, M.D., Ph.D.	\$359,846
Icahn School of Medicine at Mount Sinai	Dissecting the Role of miR-424(322)/503 in Stem Cell Control and Pregnancy Associated Tumors	Jose Silva, Ph.D.	\$360,000
Icahn School of Medicine at Mount Sinai	Developing a Culturally Adapted Education Program to Increase African Immigrants' Breast Cancer Screening	Jamilia R. Sly, Ph.D.	\$360,000
New York University School of Medicine	Targeting the Senescence-Associated Secretory Phenotype as an Adjuvant Therapy to Prevent Breast Cancer Progression	Gregory David, Ph.D.	\$360,000
Research Foundation for SUNY Stony Brook	Centrosome Clustering as a Survival Mechanism Driven by Mutant p53 in Breast Cancer	Amr Ghaleb, Ph.D. Natalia Marchenko, Ph.D.	\$312,112
Sloan Kettering Institute for Cancer Research Sub-applicant: Icahn School of Medicine at Mount Sinai	Trastuzumab-Induced Cardiotoxicity: Genomic and Cellular Signatures in Patient Specific Induced Pluripotent Stem Cell-derived Cardiomyocytes from Breast Cancer Survivors	Angel T. Chan, M.D., Ph.D. Srinivas (Ravi) Iyengar, Ph.D.	\$360,000
The Trustees of Columbia University in the City of New York	Discovery of Ferroptosis Inducers Targeting CoQ10-Dependent Breast Cancers	Brent R. Stockwell, Ph.D.	\$359,453

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

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Annual DEC update to the Health Research Science Board (May 8, 2020) Provided by Richard Dickinson, Chief of the Pesticide Reporting & Certification Section, NYSDEC

2020 Annual Report

DEC staff are currently processing the 2019 annual reports. Staff are working as best as they can with submitters to help them correct their reports as needed and following up with applicators and technicians who are delinquent in submitting their reports. Due to the COVID-19 emergency our staff are working remotely currently and will be preparing to impose violations on those applicators and technicians who have failed to report. It is too early in the process to make any accurate assessments of the quality of data that has been submitted.

2018 Annual Report Data

Letters were mailed the first week of January 2019 to the regulated community reminding them to file an annual report of pesticide applications and/or sales made in 2018. A total of 16,788 applicators, technicians, aquatic antifouling paint applicators, and 287 commercial permittees were required to submit an annual report. The reports were due February 1, 2019.

Overdue notices were mailed to 1,900 applicators and technicians and 30 commercial permittees notifying them we had not received their 2018 report. Many of the individuals receiving this notice responded. Notices of Violation and Consent Orders were mailed to 840 applicators, technicians and aquatic antifouling paint applicators and 10 commercial permittees that still had not submitted a report as required.

A total of 9,248,600 records (which includes sales and applications) were reported for 2018. Of those, 8,503,985 (92%) were submitted electronically and 744,615 (8%) were submitted on paper reports. This continues a trend of increasing numbers of data being reported electronically. And this is the second year that we have received greater than 90% of the reporting data in electronic form.

Available Annual Reports

Pesticide Reporting Law (PRL) sales and application annual reports are available on DEC's website from 1997 through 2013. Although the data has not been finalized, summarized data from 2014, 2015, 2016 and 2017 is now available on the Cornell website: http://psur.cce.cornell.edu/

Uses of the Data

Over the life of the PRL, a significant amount of staff time and resources have been invested in managing the data reported. DEC and Cornell receive, review and aggregate the data by zip code and County for public use. Only health researchers who have been approved by the Health Research Science Board (HRSB) can access and use the site-specific application and



Department of Environmental Conservation sales data. Only two entities have ever requested the confidential, site specific-data, and none have requested it since 2006. However, data about pesticide applications, or data that can approximate it, is necessary for DEC to investigate potential environmental impacts from such use. This is important in terms of fulfilling the mandate under Title 7 of Article 33 of the Environmental Conservation Law (ECL) for DEC to utilize water quality information in making pesticide product registration decisions as well as implementing other initiatives. Municipalities, public interest groups and others also can and do use the annual aggregated data for education, outreach and other purposes.

Efforts to Improve Data Quality

The large volume of data submitted in the annual reports has proven cumbersome to manage. Also, errors in many individual reports raises questions about the quality of the data. Based on the suspect quality of the data and other factors, the HRSB recommended in 2013 that the pesticide reporting database be abolished. Following the Board's recommendation, but in light of the need for aggregated data for education, outreach, monitoring and investigation purposes mentioned above, the Governor proposed sweeping changes to the PRL in his SFY 2014/15 Budget which were intended to improve data quality, utility and timeliness. Those changes were not enacted.

Since then DEC has attempted to improve data quality in several ways. DEC continues to meet with representatives of associations representing commercial and private applicators to discuss their concerns and questions about recordkeeping and reporting and provides extensive outreach on recordkeeping and reporting to the regulated community. Beginning in 2014 annual report reminder letters sent to applicators in January included detailed instructions for completing the annual reports along with examples of common reporting errors to avoid. DEC also drafted guidance on recordkeeping and reporting and posted it on DEC's website in 2016. Finally, although not a new procedure, Cornell developed a program several years ago that reviews the annual report data and identifies errors. Cornell then provides a report of those errors to DEC. DEC staff then work with the submitters of the reports to make corrections.

For the 2018 Annual Reports, DEC has continued the process of reviewing paper reports as they are received. When errors are identified, the submitter is contacted to correct the report. Similarly, staff at Cornell also review the electronic reports for errors as they are received. When an error is identified, the report is rejected, and the submitter is contacted to make any necessary corrections. This has proven to result in a demonstrable and dramatic improvement in the quality of the data imported into the database.

DEC continues to pursue completion of its comprehensive, in-house pesticide program database, which has replaced multiple, separate databases maintained by Cornell. That project will result in moving the pesticide reporting database from Cornell to DEC. It includes plans to develop a web-based portal for submission of pesticide annual reports, which will be designed to make reporting easier and improve data quality by preventing some, but not all, common data input errors. Other methods that might streamline and simplify electronic reporting for applicators will also be evaluated and pursued.

As noted above, concerns about the efficiency and utility of the data for health research purposes led the Board to recognize in 2013 "that the pesticide database no longer meets its primary purpose, to provide scientifically useful information regarding a relationship between pesticide use and human health, and recommends that the database should be abolished." The Board therefore recommended that §§33-1205 and 33-1207 of the ECL be modified so that reporting of pesticide use and sales data would no longer be required and related provisions of the Public Health Law be modified as appropriate.

Despite DEC and Cornell's efforts to improve the submitted data, significant concerns remain about its quality and the resources expended to collect and manage this voluminous data, which is not being utilized as originally envisioned in the PRL. While the current site-specific PRL data may not be used or useful for health research purposes, it is important and necessary to collect some form of pesticide use and sales data for monitoring, investigation, trend analysis, outreach and education, and other evaluations. DEC continues to recommend that the PRL be modified to accomplish these purposes.