



HEALTH RESEARCH SCIENCE BOARD
Business Meeting & Public Hearing
June 18, 2018
MINUTES

Locations

NYS OSC, 59 Maiden Lane, 29th Floor, Conference Room B, New York, NY

NYS DOH Wadsworth Center, Biggs Laboratory, Sturman Conference Room, Empire State Plaza, Albany, NY

HRSB Members Present

- Douglas S. Conklin, Ph.D., Chair
Beverly Canin
Jeanette Dippo
Donald W. Distasio
M. Suzanne Hicks
Annette T. Lee, Ph.D.
Randa Maher
Catherine Putkowski-O'Brien
Regina Resta, M.D.
James L. Speyer, M.D.

Ex-Officio Members Present

- Victoria Derbyshire, Ph.D.

NYS Staff Present

- Teresa Ascienzo
Charles Burns
George Cotich, Jr.
Andrea Garavelli
Joan K. Harris, Esq.
Kerri Kluetzman, Ph.D.
Ryan MacFee
Brian Rourke
Mary Thatcher
Jeannine Tusch
Carlene Van Patten

HRSB Members Absent

- Maria Torroella Carney, M.D.
Diana E. Lake, M.D.
Marc Wilkenfeld, M.D.

Call to Order and Opening Remarks of the Chair

The meeting was called to order at 10:15 a.m. with a welcome by Chair, Douglas S. Conklin, Ph.D. followed by introductions of Health Research Science Board (HRSB) members and the New York State Department of Health (DOH) staff.

Consideration of Applications for Funding

Andrea Garavelli provided an overview of the applications received in response to the three (3) breast cancer scientific/education research RFAs; the procurement timelines are bulleted below:

1. Patricia S. Brown Breast Cancer Risk Reduction Education Research Projects (Brown Round 5) Request for Applications (RFA)

- This RFA was approved by the HRSB in November 2016 and issued on August 1, 2017
Three (3) applications were submitted by the January 11, 2018 due date
Independent peer review of the applications was held on March 5, 2018
This RFA made \$540,000 available to fund approximately two (2) awards
The contracts are expected to begin on January 1, 2019 for a term of two (2) years

2. Healthcare Practitioner Breast Cancer Education Research Projects (Healthcare Practitioner Round 1) RFA

- This RFA was approved by the HRSB in June 2016 and issued on November 18, 2016
Three (3) applications were submitted by the April 3, 2017 due date and one (1) application passed administrative eligibility review

- Independent peer review of the application was held on June 1, 2017
- This RFA made \$810,000 available to fund approximately three (3) awards
- This contract is expected to begin on January 1, 2019 for a term of three (3) years

3. Peter T. Rowley Breast Cancer Scientific Research Projects (Rowley Round 4) RFA

- This RFA was approved by the HRSB in November 2016 and issued on August 1, 2017
- Thirty-five (35) applications were submitted by the October 26, 2017 due date
- Independent peer review of thirty-one (31) applications was held on January 17-19, 2018; four (4) were triaged
- This RFA made \$1.8 million available to fund approximately five (5) awards
- The contracts are expected to begin on January 1, 2019 for a term of two (2) years

Ms. Garavelli noted that applications were scored on a scale of 1.0-9.0 and scoring ties were resolved using the score for “Research Plan” among those applications involved in the ties.

The HRSB unanimously voted to adjourn into Executive Session for the purpose of discussing the applications received in response to the three (3) RFAs. Members of the public and non-essential staff were asked to leave the room.

Randa Maher joined the meeting during the Executive Session.

After discussing the applications, 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 three (3) RFAs:

1. Brown Round 5

Dr. Conklin began the process of considering Exhibit 1, Brown Round 5 peer review results (including the order of review, critiques and scores). In summary, the HRSB recommended \$513,000 in the form of two (2) awards. Details are provided on page 5.

2. Healthcare Practitioner Round 1

Dr. Conklin proceeded with the process of considering Exhibit 2, Healthcare Practitioner Round 1 peer review results.

ACTION

Regina Resta, M.D. made a motion to recommend Dr. Ruder of the Rochester Institute of Technology application for funding. Annette T. Lee seconded. Beverly Canin recused herself. A roll call vote was taken and the motion was not approved (2-7).

3. Rowley Round 4

Dr. Conklin stated that a few Rowley Round 4 applications’ Overall and Research Plan scores were tied and the Board should identify additional criteria to be used in the case of a tie. Board members discussed utilizing the Budget, Impact and/or Innovation criteria to discern applications in the event the Overall and Research Plan scores are tied.

ACTION

James L. Speyer, M.D. made a motion to use the Impact as a second tie-breaker and then the Innovation score as a third tie-breaker. Catherine Putkowski-O’Brien seconded. A roll call vote was taken and the motion was approved (9-1).

Dr. Conklin began the process of considering Exhibit 3, Rowley Round 4 peer review results. In summary, the HRSB recommended \$2.46 million in the form of seven (7) awards. The HRSB recommended five (5) “approve, but not funded” meritorious applications in order of peer review ranking in case a funded organization should decline an award. Details are provided on pages 6-7.

Future RFAs

Ms. Garavelli asked the Board to confirm their decision to offer the three (3) breast cancer scientific/education research RFAs to ensure breast cancer research and education funding is expended every year. Dr. Speyer would like to issue the three (3) RFAs again and disseminate the announcement to a wider community and be explicit in the eligibility requirements.

Dr. Speyer exited the meeting.

Ms. Canin questioned if she could work with the DOH staff individually to draft proposals before a meeting or if the business would need to occur during an open meeting. Joan K. Harris, Esq. said the HRSB can make a formal vote at a HRSB business meeting to modify the language in the RFA(s) and they are also authorized to establish Ad Hoc Committees per their Bylaws.

ACTION

Ms. Maher made a motion to approve a Rowley Round 5 RFA, as written, for a release date in 2018. Ms. Putkowski-O'Brien seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

ACTION

Ms. Putkowski-O'Brien made a motion to approve a Healthcare Practitioner Round 2 RFA, as written, for a release date in 2018. Dr. Lee seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

ACTION

Ms. Maher made a motion to approve a Brown Round 6 RFA, as written, for a release date in 2019. Ms. Putkowski-O'Brien seconded.

During discussion, Ms. Canin stated that the Brown RFA should be released every year. Teresa Ascienzo confirmed all three (3) RFAs would be released every year; specifically, \$270,000 would be available for the Brown Round 6 RFA, and \$540,000 would be available for the Healthcare Practitioner Round 2 RFA and the funding for these two (2) RFAs would alternate every subsequent year thereafter.

Ms. Maher amended the motion to approve a Brown Round 6 RFA as written for a release date in 2018. A roll call vote was taken and the motion was unanimously approved (9-0).

Consideration of November 2, 2016 Meeting Minutes

Dr. Conklin asked the HRSB to consider Exhibit 4, the minutes from the November 2, 2016 meeting.

ACTION

Ms. Canin made a motion to approve the minutes as submitted and Ms. Maher seconded. A roll call vote was taken and the minutes were unanimously approved (9-0).

Dr. Lee exited the meeting.

Program Update

Ms. Garavelli provided a review of Exhibit 5, current and future 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. A summary of the newest contracts is listed below.

- Rowley Round 3: Ten (10) contracts which totaled \$3.5 million began on January 1, 2017. These contracts conclude December 31, 2018 and their progress will be reported in the 2017-2018 HRSB Biennial Report.

Board Membership

Jeannine Tusch provided an update on Board membership. She stated that Susan K. Gibbons, M.D. and Charles L. Shapiro, M.D. service has ended and DOH thanked them for their service. In result, potential members are in the vetting process to fill these gubernatorial vacancies. There are five (5) other seats to be filled by legislative leadership; three (3) are scientist seats and two (2) are breast cancer survivor seats in the Hudson Valley and Western, NY regions. She thanked the current members for their understanding and flexibility as it has been challenging to achieve quorum due to the number of vacancies.

Public Hearing

The public hearing convened and Dr. Conklin introduced Scott Menrath from the NYS Department of Environmental Conservation. Mr. Menrath provided a summary of the report on the Efficiency and Utility of Pesticide Reporting. The full report is provided on pages 8-11 and will be included in the 2017-2018 HRSB Biennial Report.

Public Comment

There were no public comments.

Future Meetings

At its next meeting in the spring of 2019, the HRSB will recommend applications for funding the three (3) breast cancer research and education RFAs (Rowley Round 5, Healthcare Practitioner Round 2 and Brown Round 6) to the Commissioner of Health.

Adjournment

Dr. Conklin thanked the members for their dedication to this important program. The HRSB unanimously voted to adjourn and the meeting ended at 2:15 p.m.

Patricia S. Brown Breast Cancer Risk Reduction Education Research Projects (Round 5): A total of \$513,000 in the form of two (2) awards were recommended. These projects are three (3) year awards.

Organization	Partnering Organization	Project Title	Investigator(s)	Recommended Funding	Votes (Y-N)
The Research Foundation of CUNY obo Hunter College	Korean Community Services of Metropolitan New York, Inc.	A Culturally Tailored Education Program to Reduce Breast Cancer Risk in Korean Immigrant Women	Jin Young Seo, Ph.D., So-hyun Park, Ph.D.	\$245,002	10-0
Icahn School of Medicine at Mount Sinai	Gilda's Club NYC	Development of an Intergenerational Breast Health Community Education Program for Black Women: Reducing the Risk for Triple Negative Breast Cancer in Black Women through Breastfeeding	Lina Jandorf, M.A., Sly R. Jamilia, Ph.D., Torres Migdalia, M.A.	\$268,599	9-1
Huntington Breast Cancer Action Coalition	Icahn School of Medicine at Mount Sinai	Building Capacity Among Families for Environmental Health and Prevention	Karen J. Miller, Sarah Evans, Ph.D.	\$0	0-9 Dr. Conklin recused

Peter T. Rowley Breast Cancer Scientific Research Projects (Round 4): A total of \$2.46 million in the form of seven (7) awards were recommended. These projects are two (2) year awards. Five (5) “approve, but not funded” applications were recommended in case a funded organization should decline an award.

Organization	Project Title	Investigator(s)	Recommended Funding	Votes (Y-N)
Albert Einstein College of Medicine	Somatic Mutation Rate in Mammary Epithelial Cells and Peripheral B-Lymphocytes as Risk Factor for Breast Cancer	Cristina Montagna, Ph.D., Jan Vijg, Ph.D.	\$360,000	10-0
Research Foundation for SUNY, Stony Brook University	Effects of Anesthetics on Lung Metastasis in Mouse Models of Breast Cancer	Jun Lin, M.D., Ph.D.	\$360,000	10-0
Research Foundation for SUNY, University at Buffalo	The Microbiome in the Etiology and Prevention of Breast Cancer	Jo L. Feudenheim, Ph.D.	\$359,024	10-0
Icahn School of Medicine at Mount Sinai	Sensing Cell Geometry: A Novel Checkpoint Critical for Breast Tumor Suppression	Jose Silva, Ph.D.	\$360,000	10-0
Albert Einstein College of Medicine Sub-applicant: Northwell Health	High Throughput Functional Genomics to Guide Precision Care	Harry Ostrer, M.D., Kenan Onel, M.D., Ph.D.	\$326,910	9-0 Dr. Lee recused
Cornell University	Histone Citrullination in Estrogen Receptor Signaling and Breast Cancer	Scott A. Coonrod, Ph.D.	\$358,832	10-0
Research Foundation for SUNY, University at Albany	A Simultaneous Phase and Scatter Imaging Towards a Clinical System for Early Stage Breast Cancer Diagnosis	Jonathan C. Pertruccelli, Ph.D., Carolyn A. MacDonald, Ph.D.	\$335,905	9-0 Dr. Conklin recused
The Trustees of Columbia University in the City of New York	Milk Associated Markers and Breast Optical Spectroscopy Study (MAMA BOSS)	Jasmine A. McDonald, Ph.D., Mary Beth Terry, Ph.D.	Approve, but not funded	10-0

Organization	Project Title	Investigator(s)	Recommended Funding	Votes (Y-N)
University of Rochester	A New Approach to Prevent Implant Scarring and Failure After Breast Cancer and Radiotherapy	Richard P. Phipps, Ph.D.	Approve, but not funded	10-0
Albert Einstein College of Medicine	Novel Use of Listeria to Combat Metastatic Breast Cancer	Claudia Gravekamp, Ph.D.	Approve, but not funded	9-1
Yeshiva University	Estrogen Signaling Downstream of mTORC1 in Breast Cancer	Marina K. Holz, Ph.D.	Approve, but not funded	10-0
Roswell Park Cancer Institute Sub-applicant: Research Foundation for SUNY, University at Buffalo	Novel Approach to Breast Cancer Immunotherapy: Targeting Products of Abnormal Splicing Events Induced by Chemotherapy	Yurij Ionov, Ph.D., Jun Qu, Ph.D.	Approve, but not funded	10-0

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

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Annual DEC update to the Health Research Science Board (June 2018) Provided by Scott Menrath on behalf of Richard Dickinson, Chief of the Pesticide Reporting & Certification Section, NYSDEC

2017 Annual Report

DEC staff are currently processing the 2017 annual reports. Staff are working with submitters to help them correct their reports as needed, following up with applicators and technicians who are delinquent in submitting their reports, and imposing 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.

2016 Annual Report Data

Letters were mailed December 30, 2016 to the regulated community reminding them to file an annual report of pesticide applications and/or sales made in 2016. A total of 16,928 applicators, technicians, aquatic antifouling paint applicators, and 291 commercial permittees were required to submit an annual report. The reports were due February 1, 2017.

Overdue notices were mailed in March 2017 to 1,675 applicators and technicians and 33 commercial permittees notifying them we had not received their 2016 report. Many of the individuals receiving this notice responded. Notices of Violation and Consent Orders were mailed May 10, 2017 to 835 applicators, technicians and aquatic antifouling paint applicators and 11 commercial permittees that still had not submitted a report as required.

Sixty-two applicators, technicians, and commercial permittees paid the fine to resolve their violation. Violations were resolved or removed for 66 applicators, technicians and aquatic antifouling paint applicators and commercial permittees for various reasons (lost mail, typographical errors, extenuating circumstances). A total of 8,683,069 records (which includes sales and applications) were reported for 2016. Of those, 7,747,947 (89%) were submitted electronically and 935,122 (11%) were submitted on paper reports.

2015 Annual Report Data

Letters were mailed January 2, 2016 to the regulated community reminding them to file an annual report of pesticide applications and/or sales made in 2015. A total of 16,610 applicators, technicians, aquatic antifouling paint applicators, and 300 commercial permittees were required to submit an annual report. The reports were due February 1, 2016.

Overdue notices were mailed in March 2016 to 1,686 applicators and technicians and 25 commercial permittees notifying them we had not received their 2015 report. Many of the individuals receiving this notice responded. Notices of Violation and Consent Orders were

mailed April 20, 2016 to 762 applicators, technicians and aquatic antifouling paint applicators and 2 commercial permittees that still had not submitted a report as required.

Fifty-eight applicators, technicians, and commercial permittees paid the fine to resolve their violation. Violations were resolved or removed for 135 applicators, technicians and aquatic antifouling paint applicators and commercial permittees for various reasons (lost mail, typographical errors, extenuating circumstances). A total of 7,855,160 records (which includes sales and applications) were reported for 2015. Of those, 6,976,070 (88%) were submitted electronically and 909,090 (12%) were submitted on paper reports.

Available Annual Reports

Annual Pesticide Reporting Law (PRL) sales and use summary reports are available on DEC's website from 1997 through 2013. We identified gross errors that affected the data statewide for **2006, 2007, 2008, 2009 and 2010**. DEC and Cornell staff worked together to correct and publish that data. Subsequent to that the 2011, 2012 and 2013 data, aggregated and summarized by zip code and County, was made available to the public on DEC's website. Although the data has not been finalized, summarized data from 2014, 2015 and 2016 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 sales data. Data about pesticide applications, or data that can approximate it, is necessary for investigating 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) to utilize water quality information in making pesticide product registration decisions as well as implementing other DEC initiatives. Municipalities, public interest groups and others also can and do use the annual aggregated data for education, outreach and other purposes.

Only two entities have ever requested the confidential, site specific-data, and none have requested it since 2006. The New York City Department of Health and Mental Hygiene (NYC DOHMH) requested the confidential data in 2006 for a health study on birth outcomes in New York City; and Cornell University's Water Resources Institute (one of DEC's contractors for groundwater monitoring) requested the confidential data in 2006 to inform their decisions about where to monitor groundwater outside of Long Island and New York City.

Efforts to Improve Data Quality

The large volume of data submitted in the annual reports has proven cumbersome to manage. Also, a large number of errors in many individual reports has caused the quality of the data to be suspect. 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 met with representatives of several associations representing commercial and private applicators to discuss their concerns and questions about recordkeeping and reporting. Beginning in 2014 annual report reminder letters sent to applicators in January included more detailed instructions than in the past, along with examples of common reporting errors to avoid. DEC also drafted guidance on recordkeeping and reporting, shared it with several applicator associations for review and comment, and posted it on DEC's website in 2016. Finally, although not a new procedure, Cornell developed a program a number of years ago that reviews the annual report data and identifies errors. Cornell then provides a report of those errors to DEC.

For the 2016 Annual Reports, DEC has continued the process of reviewing paper reports as they are received. This requires a significant amount of staff time and diverts staff from other duties. When errors are identified, the report is set aside, and the submitter is contacted to correct the report. Similarly, staff at Cornell also reviewed the electronic reports for errors as they were received. When an error was identified, the report was rejected and the submitter was 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. As stated before, Cornell runs a program that reviews the data and provides us with a spreadsheet of errors found. In the past that spreadsheet would contain roughly 3,000 errors. The report received on the most current year's data contained just over 900 errors, which represents a reduction of some two-thirds.

DEC is also in the midst of a project to develop a comprehensive, in-house pesticide program database, which is replacing multiple, separate databases maintained by Cornell. A planned future phase will move the pesticide reporting database to DEC. It is anticipated this will include the development of 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 be evaluated and pursued at that time.

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 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 and serious concerns remain about its quality and the tremendous 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.

PRL Audit

The PRL program has been undergoing an audit conducted by the Office of the New York State Comptroller (OSC) since the summer of 2017. OSC should make the final report available by the end of 2018.