

HEALTH RESEARCH SCIENCE BOARD

Business Meeting & Public Hearing May 6, 2019 MINUTES

Locations

NYS DOH Metropolitan Area Regional Office, Conference Room 4B, 90 Church Street, 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 M. Suzanne Hicks Diana E. Lake, M.D. Randa Maher Catherine Putkowski-O'Brien Regina Resta, M.D. James L. Speyer, M.D.

Ex-Officio Members Present

Victoria Derbyshire, Ph.D. Richard Dickinson

NYS Staff Present

Teresa Ascienzo
Charles Burns
Andrea Garavelli
Jonathan B. Karmel
Kerri Kluetzman, Ph.D.
Farrah O'Brien
Ryan MacFee
Jeannine Tusch
Carlene Van Patten

HRSB Members Absent

Donald W. Distasio Annette T. Lee, Ph.D. Marc Wilkenfeld, M.D.

Call to Order and Opening Remarks of the Chair

The meeting was called to order at 10:35 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.

Board Membership Update

Dr. Conklin noted that Dr. Maria Carney, appointed in 2014, concluded her time as a member. The HRSB members thanked her for her service during this essential time. Dr. Conklin 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:
 - o One (1) regional seat in the Hudson Valley region and
 - o One (1) regional seat in Western, NY

Dr. Conklin announced that Joan K. Harris, Esq. who has worked closely with the HRSB since 2016 will no longer be the DOH Counsel. Dr. Conklin welcomed Jonathan B. Karmel on his recent appointment to represent the DOH at HRSB meetings.

Exhibit 1. Consideration of June 18, 2018 Meeting Minutes

Dr. Conklin asked the HRSB to consider Exhibit 1, the minutes from the June 18, 2018 meeting.

During discussion, Beverly Canin asked to amend the minutes as presented to include the bulleted details below.

- The funding amounts of \$270,000 would be available for the Patricia S. Brown Breast Cancer Risk Reduction Education Research Projects (Brown Round 6) Request for Applications (RFA) and \$540,000 would be available for the Healthcare Practitioner Breast Cancer Education Research Projects (Healthcare Practitioner Round 2) and the funding available for these two (2) RFAs would alternate every subsequent year thereafter.
- In the summary of recommended awards for the Brown Round 5 RFA, the applicant, Huntington Breast Cancer Action Coalition was not recommended for funding (\$0).

ACTION

James L. Speyer, M.D. made a motion to approve the minutes as amended and Ms. Canin 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 the three (3) breast cancer scientific/education research RFAs; the procurement timelines are bulleted below.

Exhibit 2. Order of Review, Peter T. Rowley Breast Cancer Scientific Research Projects (Rowley Round 5)

- There is \$2.16 million available to fund approximately five-seven (5-7) awards
- This RFA was issued on October 2, 2018
- Thirty-seven (37) applications were received by the due date
- Independent peer review of the applications was held on February 26, 2019 through March 1, 2019, applications were scored on a scale of 1.0-9.0 and no applications were triaged
- The Research Plan score is the tie-breaker and the Impact score is the second tiebreaker

Exhibit 3. Order of Review, Brown Round 6

- There is \$270,000 available to fund approximately one (1) award
- This RFA was issued on October 2, 2018
- Two (2) applications were received by the due date
- Independent peer review of the applications was held on February 14, 2019, applications were scored on a scale of 1.0-9.0 and there were no ties

Exhibit 4. Order of Review, Healthcare Practitioner Round 2

- There is \$540,000 available to fund approximately two (2) awards
- This RFA was issued on November 13, 2018
- Two (2) applications were received by the due date
- Independent peer review of the applications was held on February 14, 2019, applications were scored on a scale of 1.0-9.0 and there were no ties

Ms. Garavelli noted that contracts from these three (3) procurements were scheduled to begin on September 1, 2019; however, the contract start dates will be postponed. Ms. Garavelli said the three-year Brown Round 6 and Healthcare Practitioner Round 2 contracts will start in October 2019 and the two-year Rowley Round 5 contracts will start in November 2019.

ACTION

Jeanette Dippo moved to adjourn into Executive Session for the purpose of discussing the applications received in response to the three (3) RFAs. M. Suzanne Hicks seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

Members of the public and non-essential staff were asked to leave the 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 three (3) RFAs:

Dr. Conklin began the process of considering Exhibit 2, Rowley Round 5 peer review results (including the order of review, critiques and scores). In summary, the HRSB recommended \$1.76 million for five (5) awards. Details are provided on page 5.

Dr. Conklin began the process of considering Exhibit 3, Brown Round 6 peer review results. In summary, the HRSB recommended \$270,000 for one (1) award. Details are provided on page 6.

Dr. Conklin proceeded with the process of considering Exhibit 4, Healthcare Practitioner Round 2 peer review results.

ACTION

Ms. M. Suzanne Hicks made a motion to recommend to the Commissioner of Health that the top two (2) applications be funded using the peer review results in score order as the basis for this decision. Randa Maher seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

In summary, the HRSB recommended \$528,828 for two (2) awards. Details are provided on page 7.

Exhibit 5. Program Update

Jeannine Tusch provided a review of Exhibit 5, 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 the newest contracts will be included in the 2019-2020 HRSB Biennial Report. A summary of these contracts is bulleted below.

- Rowley Round 3: Eight (8) of the ten (10) contracts received no cost extensions. These two-year contracts totaled \$3.5 million and began on January 1, 2017.
- Rowley Round 4: Seven (7) contracts began on January 1, 2019. These two-year contracts totaled \$2.46 million.
- Brown Round 5: Two (2) contracts began on January 1, 2019. These three-year contracts totaled \$513,000.

Future RFAs

Ms. Garavelli asked the Board to reaffirm the available funding and release of three (3) recurring breast cancer scientific/education research RFAs in 2019. For the next rounds of the breast cancer education research RFAs (Brown and Healthcare Practitioner), the HRSB discussed expanding the eligibility requirements so that community-based organizations can partner with academic institutions <u>and</u> other organizations such as hospitals and community/medical health centers.

ACTION

Ms. Canin made a motion to approve the recurring breast cancer scientific/education research RFAs. Suggestions were discussed and agreed upon. The DOH would incorporate those suggestions distribute the revised drafts to Dr. Conklin, Chair. Dr. Conklin would have two (2) weeks after the day the revised drafts are sent via email to provide comments to the DOH staff. No further meetings would be held to modify the following draft RFAs:

- Rowley Round 6 with \$2.16 million available (for five-seven (5-7) awards)
- Brown Round 7 with \$540,000 available (for up to two (2) awards)
- Healthcare Practitioner Round 3 with \$270,000 available (for up to one (1) award) Ms. Dippo seconded. A roll call vote was taken and the motion was unanimously approved (9-0).

HRSB Vacant Seats

HRSB members are concerned regarding the number of HRSB's vacant positions that Dr. Conklin previously mentioned (see page 1) because it's been difficult to achieve quorum, inhibits the Board to function properly as written in statute and ultimately discourages current members. Dr. Speyer would like the Department of Health's (Commissioner of Health) assistance in sending a letter to the appropriate parties with the HRSB's concerns so that the legislative leaders are notified to fill vacant seats.

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 8-10 and will be included in the 2019-2020 HRSB Biennial Report.

Public Comment

There were no public comments.

Future Meetings

At its next meeting in 2020, the HRSB will recommend applications for funding the three (3) breast cancer research and education RFAs (Rowley Round 6, Brown Round 7, and Healthcare Practitioner Round 3) 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 2:40 p.m.

Peter T. Rowley Breast Cancer Scientific Research Projects (Round 5): A total of \$1.76 million for five (5) awards were recommended. These projects are two-year awards.

| Organization | Project Title | Investigator(s) | Recommended Funding | Votes (Y-N) |
|---|---|--|------------------------|----------------|
| Albert Einstein College of Medicine, Inc. | Racial Disparity in Pro-Metastatic Breast Cancer Microenvironment and Response to Chemotherapy | Maja Oktay, M.D., Ph.D. | \$360,000 | 9-0 |
| The Trustees of Columbia University in the City of New York | A Novel Biomarker to Improve Risk-Prediction in Familial Breast Cancer Patients | Piero D. Dalerba, M.D. Mary Beth Terry, Ph.D. | \$359,899 | 9-0 |
| Research Foundation for SUNY, University at Buffalo | The Association Between Follicle Stimulating Hormone, Obesity, and Breast Cancer in Postmenopausal Women | Heather Ochs-Balcom, Ph.D. | \$343,354 | 9-0 |
| Albert Einstein College of Medicine, Inc. | Extracellular S100A4 in Breast Cancer Metastasis | Anne Bresnick, Ph.D. Jonathan M. Backer, M.D. | \$0 | 7-2 |
| Albert Einstein College of Medicine, Inc. | Direct Visualization of Physiologically Relevant Metastasis Using Surgical and Optical Engineering | David Entenberg, Ph.D. | \$360,000 | 9-0 |
| University of Rochester | Elimination of Breast Cancer Metastasis by Killing Cancer Cells and Interfering in the Host Environment | Zhenqiang Yao, M.D., Ph.D. | \$338,741 | 9-0 |

Patricia S. Brown Breast Cancer Risk Reduction Education Research Projects (Round 6): A total of \$270,000 for one (1) award was recommended. This project is a three-year award.

| Organization | Partnering Organization | Project Title | Investigator(s) | Recommended Funding | Votes (Y-N) |
|---|----------------------------|--|---|---------------------|----------------|
| Research Foundation for SUNY at Buffalo | Our Curls, Inc. | You cannot change your family history, but you can change what you do with it: A peer-based education program to reduce breast cancer risk in African American women | Laurene M. Tumiel-Berhalter, Ph.D. Charise Walker-Betts, B.S.W. | \$270,000 | 9-0 |

Healthcare Practitioner Breast Cancer Education Research Projects (Round 2): A total of \$528,828 for two (2) awards were recommended. These projects are three-year awards.

| Organization | Partnering Organization | Project Title | Investigator(s) | Recommended Funding | Votes (Y-N) |
|-----------------------------------|---|---|---|---------------------|----------------|
| New York University | SHARE: Self Help for Women with Breast or Ovarian Cancer & NYU School of Medicine | Developing a Patient- Centered Curriculum for Primary Care Practitioners to Enhance Breast Cancer Survivorship Care that Informs and Engages Diverse Breast Cancer Survivors | Victoria H. Raveis, Ph.D. Jacqueline Reinhard, M.Ed. Simona Kwon, Dr.P.H. | \$260,493 | 9-0* |
| Rochester Institute of Technology | Breast Cancer Coalition of Rochester | PAMI: Physician Assistant Motivational Inverviewing and Health Literacy to Enhance Health in Breast Cancer Survivors | Elizabeth H. Ruder, Ph.D., M.P.H. Holly Anderson, B.S., R.N. | \$268,334 | |

^{*}These (two) applications were recommended to be funded using the peer review results in score order as the basis for this decision.

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

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Annual DEC update to the Health Research Science Board (May 6, 2019) Provided by Richard Dickinson, Chief of the Pesticide Reporting & Certification Section, NYSDEC

2018 Annual Report

DEC staff are currently processing the 2018 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 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.

2017 Annual Report Data

Letters were mailed December 29, 2017 to the regulated community reminding them to file an annual report of pesticide applications and/or sales made in 2017. A total of 16,977 applicators, technicians, aquatic antifouling paint applicators, and 292 commercial permittees were required to submit an annual report. The reports were due February 1, 2018.

Overdue notices were mailed in April 16, 2018 to 1,845 applicators and technicians and 26 commercial permittees notifying them we had not received their 2017 report. Many of the individuals receiving this notice responded. Notices of Violation and Consent Orders were mailed May 14, 2018 to 851 applicators, technicians and aquatic antifouling paint applicators and 14 commercial permittees that still had not submitted a report as required.

Seventy-two applicators, technicians, and commercial permittees paid the fine to resolve their violation. Violations were resolved or removed for 121 applicators, technicians and aquatic antifouling paint applicators and commercial permittees for various reasons (lost mail, typographical errors, extenuating circumstances). A total of 8,936,301 records (which includes sales and applications) were reported for 2017. Of those, 8,160,721 (91%) were submitted electronically and 775,580 (9%) were submitted on paper reports. This continues a trend of increasing numbers of data being reported electronically. And this is a milepost for us in that this is the first 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 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, 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 more detailed instructions than in the past, 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 2017 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.

A project continues to develop a comprehensive, in-house pesticide program database, which is replacing multiple, separate databases maintained by Cornell. A proposal has been submitted to begin work on the phase that 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 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.

PRL Audit

The PRL program underwent an audit conducted by the Office of the New York State Comptroller (OSC) commencing in the summer of 2017. The OSC released the final report in November 2018. The report was largely favorable on the DEC's oversight of the Pesticide Reporting Law and made several recommendations for changes to the DEC's program, including moving the database to the DEC, which the department is pursuing as discussed above.