



HEALTH RESEARCH SCIENCE BOARD

Business Meeting & Public Hearing

June 22, 2016

1:00 PM to 5:00 PM

MINUTES

Locations

NYS DOH Metropolitan Area Regional Office, Conference Room 4C, 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
Maria Torroella Carney, M.D.
Jeanette Dippo*
Donald W. Distasio
Susan K. Gibbons, M.D.
M. Suzanne Hicks
Diana E. Lake, M.D.
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.

HRSB Members Absent

- Charles L. Shapiro, M.D.
Wendy Watkins
Marc Wilkenfeld

NYS DOH Staff Present

- Teresa Ascienzo
Charles Burns
Andrea Garavelli
Carole Ju
Jeannine Tusch
Carlene Van Patten
Diana Yang, J.D.

NYS DEC Staff Present

- Scott Menrath
Grace Farrell

Guests

- Erin McGrath

*non-voting member

Call to Order and Opening Remarks of the Chair

The meeting was called to order at 1:08 p.m. with a welcome by Chair, Douglas S. Conklin, Ph.D. followed by introductions of Health Research Science Board (HRSB or Board) members and the New York State Department of Health (DOH) staff.

Consideration of March 14, 2014 Meeting Minutes

Dr. Conklin asked the HRSB to consider Exhibit 1, the minutes from the March 14, 2014 meeting.

ACTION

Dr. Conklin made a motion to approve the minutes as a record of all motions, proposals, resolutions and any other matter formally voted upon and voted thereon, in compliance with NYS Public Officers Law Section 106. As such, these will be the meeting minutes that will be available to the public in accordance with both NYS Public Officers Law and the NYS Freedom of Information Law. Maria Torroella Carney, M.D. seconded. A roll call vote was taken and the minutes were unanimously approved (11-0).

Consideration of Applications for Funding

Andrea Garavelli provided an overview of the Requests for Applications (RFAs) for Peter T. Rowley Breast Cancer Scientific Research Projects and the Patricia S. Brown Breast Cancer Risk Reduction Education Projects (details listed below). She stated that the DOH's peer review contractor, the American Institute of Biological Sciences (AIBS), coordinated the scientific peer review of the applications. DOH has successfully secured independent peer review services with AIBS through 2019. She also said that HRSB is not obligated to recommend funding for any application.

The Peter T. Rowley Breast Cancer Scientific Research Projects Funding Opportunity

RFA Issued: March 2015

Applications Due: June 2015

Peer Review: August 2015

Available Funds: \$3.6 million

Review Process: Applications were scored on a scale of 1-9. Applications scored in the range of 4.0-9 were triaged and not considered for award.

The Patricia S. Brown Breast Cancer Risk Reduction Education Projects Funding Opportunity

RFA Issued: August 2015

Applications Due: November 2015

Peer Review: January 2016

Available Funds: \$1.08 million

Review Process: Applications were scored on a scale of 1-9. Applications scored in the range of 4.0-9 were triaged and not considered for award.

Ms. Garavelli noted the HRSB could elect to continue making recommendations for possible funding of proposals beyond what is available by deeming applications "approved, not funded" should additional funds become available.

James L. Speyer, M.D. motioned for the HRSB to adjourn into Executive Session for the purpose of considering applications for research funding. Donald W. Distasio seconded. Members unanimously approved this motion. Members of the public and non-essential staff were asked to leave the room. After discussing applications, the HRSB reconvened in Public Session.

Application Votes: Peter T. Rowley Breast Cancer Scientific Research Projects

Dr. Conklin began the process of considering the eligible applications. Details are provided on pages 6-8.

ACTION

Dr. Conklin made a motion to approve the Peter T. Rowley Breast Cancer Scientific Research Projects, voting en bloc (all together) to approve the top 10 applications (in score order of peer review results) and approve, not fund other meritorious applications, should funding become available.

Diana Yang, J.D., explained the HRSB decided to vote en bloc, using the peer review results as an objective score. She noted they would not be able to vote on the applications individually due to the number of recusals.

Beverly Canin seconded. A roll call vote was taken and the motion was unanimously approved (11-0).

ACTION

Ms. Canin made a motion to approve, not fund the next five (5) Peter T. Rowley Breast Cancer Scientific Research Projects applications (in score order of peer review results), voting en bloc.

Susan K. Gibbons, M.D. seconded. A roll call vote was taken and the motion was unanimously approved (11-0).

The HRSB recommended 10 awards for a total of \$3,560,955. The HRSB recommended five (5) “approved, not funded” awards should additional funds become available.

Application Votes: Patricia S. Brown Breast Cancer Risk Reduction Education Projects

Dr. Conklin began the process of considering the eligible applications. Details are provided on page 9.

The HRSB recommended one (1) award for a total of \$262,731.

Ms. Garavelli said the HRSB’s comments regarding the application that was not recommended for funding would be sent to the Office of the NYS Comptroller for review. Ms. Yang explained that these final award recommendations would be forwarded to the Commissioner of Health and upon his acceptance, the contract process would be initiated.

Public Hearing

The annual public hearing convened and Dr. Conklin introduced Scott Menrath, from the NYS Department of Environmental Conservation. Mr. Menrath presented a brief summary of the report on the Efficiency and Utility of Pesticide Reporting. The full report is provided on pages 10-13 and will be included in the 2015-2016 HRSB Biennial Report.

Public Comment

There were no public comments.

Notification of Proposal to Change Bylaws

Carlene VanPatten reviewed the proposed amendments to the HRSB Bylaws. She noted the proposed amendments were made for clarity and conformity to current practices and to be consistent with amendments to NYS Public Health Law Sections 2411 and 2413. A more detailed discussion would occur at the next meeting.

Ms. Garavelli discussed the proposed release of an RFA that was approved at a prior HRSB meeting. The composition of the Board had changed significantly since that time and Ms. Garavelli proposed a review and approval by the current members.

Healthcare Practitioner Breast Cancer Education Research Projects RFA Discussion

Anticipated RFA Issue Date: December 2016.

Available Funds: \$810,000 for a period of three-years (approximately 3 awards).

Purpose: to facilitate the delivery of superior breast healthcare in New York State through an investment in the planning, development, implementation, rigorous evaluation and revision of innovative breast cancer education and communication training programs for healthcare practitioners and students of these professions.

Who May Apply: a NYS not-for-profit community-based organization must partner with a NYS accredited academic institution or vice versa. The institution must have the authority to confer graduate degrees in medicine, nursing, health education or public health.

Evaluation Criteria:

- Need, Significance and Impact (20%)
- Team Composition/Integration and Environment (20%)
- Approach (40%)
- Budget (20%)

Review Process: Applications will be scored on a scale of 1-9. The Approach criterion was identified as the tie-breaker criterion. Applications scoring in the range of 4.0-9 will be triaged and not considered for award.

ACTION

Dr. Gibbons motioned for the Healthcare Practitioner Breast Cancer Education Research Projects to be approved and moved forward with new dates. Ms. Suzanne Hicks seconded. After review, a roll call vote was taken and the motion was unanimously approved (11-0).

Program Update

Ms. Garavelli provided an update that DOH staff had been working to increase and maintain HRSB membership, utilize the NYS Grants Gateway for procurement processes, and update training materials, reporting tools and the program website.

Ms. Garavelli reviewed reporting requirements for the HRSB Biennial Report and Utilization of Funds Report. She said, once finalized all reports are posted on the program's website. She reminded interested parties to sign up for eAlerts on the program's website (<http://www.wadsworth.org/extramural/breastcancer/ealerts>) to receive news, RFA/RFP and meeting information. She also reviewed an HRSB Program Procurement Report, which included a snapshot of funding history and plans to date.

Dr. Speyer emphasized the importance of the Board member's responsibility to meet on a regular basis and for the authorities to appoint members in an expeditious fashion to fill vacancies. HRSB members agreed.

Future Meetings

At its next meeting in October/November 2016, the HRSB will consider future RFAs for funding and continue these types of discussions. They will also meet in 2017 to vote on applications received in response to the Healthcare Practitioner Breast Cancer Education Research Projects RFA.

Adjournment

The HRSB unanimously voted to adjourn and the meeting ended at 5:00 p.m.

2016 Peter T. Rowley Breast Cancer Scientific Research Projects

Order of Review	Application Number	Organization	Project Title	Principal Investigator	Recommended Award
1	DOH01-Rowley-2015-00013	Health Research Incorporated, Roswell Park Cancer Institute	Novel Mechanism of Immune Subversion by Myeloid-Derived Suppressor Cells in Aggressive Breast Cancer	Sharon S. Evans, Ph.D.	\$360,000
2	DOH01-Rowley-2015-00076	Cold Spring Harbor Laboratory Sub-Applicant, New York University School of Medicine	Modulating Innate-adaptive Immune Cell Interactions for the Immunotherapy of Breast Cancer	Mikala Egeblad, Ph.D.	\$345,800
3	DOH01-Rowley-2015-00039	The Research Foundation for SUNY Upstate Medical University	Myosin 1e as a Potential Therapeutic Target in Breast Cancer	Mira Krendel, Ph.D.	\$360,000
4	DOH01-Rowley-2015-00012	Albert Einstein College of Medicine of Yeshiva University	Targeting the Epigenetic Regulator MLL3 Mutation in Breast Cancer	Wenjun Gao, Ph.D.	\$360,000
5	DOH01-Rowley-2015-00035	New York University School of Medicine	Reversing Tamoxifen Resistance in Estrogen Receptor Positive Breast Cancer	Robert J. Schneider, Ph.D.	\$360,000

2016 Peter T. Rowley Breast Cancer Scientific Research Projects

Order of Review	Application Number	Organization	Project Title	Principal Investigator	Recommended Award
6	DOH01-Rowley-2015-00101	University of Rochester	Safer and More Effective Treatment of Luminal Breast Cancer and Overcoming Tamoxifen Resistance	Mark Noble, Ph.D.	\$359,907
7	DOH01-Rowley-2015-00067	State University of New York Upstate Medical University	Structure-based Nanocarrier Design for Targeted Cabazitaxel Delivery to the Advanced Breast Cancer Brain Metastases	Juntao Luo, Ph.D.	\$360,000
8	DOH01-Rowley-2015-00011	The Research Foundation for SUNY Stony Brook	A New Strategy and Tool to Tackle Cancer Stem Cells and Metastasis in Triple-negative Breast Cancer	Chia-Hsin Chan, Ph.D.	\$359,999
9	DOH01-Rowley-2015-00099	The Research Foundation for SUNY Stony Brook	Single-cell Barcoding to Study Breast Cancer Evolution and Drug Resistance	Scott Powers, Ph.D.	\$350,302
10	DOH01-Rowley-2015-00090	University of Rochester	Amplifying Immune Responses to Breast Cancer Using a Novel IL.2 Therapy to Limit Side Effects and Enhance Efficacy	John G. Frelinger, Ph.D.	\$357,747

2016 Peter T. Rowley Breast Cancer Scientific Research Projects

Order of Review	Application Number	Organization	Project Title	Principal Investigator	Recommended Award
11	DOH01-Rowley-2015-00111	The Research Foundation of CUNY obo City College of New York	Laying the Foundation for Combination Therapy Against Breast Cancer: Analysis of Human Shelterin-DNA Complex	David Jeruzalmi, Ph.D.	Approve, not funded
12	DOH01-Rowley-2015-00051	New York University School of Medicine	Mechanosensory Restraint in Breast Cancer	Pamela Cowin, Ph.D.	Approve, not funded
13	DOH01-Rowley-2015-00049	The Research Foundation for SUNY University at Buffalo	Lactate Transporter as a Therapeutic Target in Triple Negative Breast Cancer	Marilyn E. Morris, Ph.D.	Approve, not funded
14	DOH01-Rowley-2015-00096	The Research Foundation for SUNY Stony Brook	Development of Phospholipase D inhibitors for Breast Cancer	Michael A. Frohman, M.D., Ph.D.	Approve, not funded
15	DOH01-Rowley-2015-00052	Albert Einstein College of Medicine of Yeshiva University	The Role of Akt3 in Breast Cancer Regulation	Rachel B. Hazen, Ph.D.	Approve, not funded

2016 Patricia S. Brown Breast Cancer Risk Reduction Education Research Projects

Order of Review	Application Number	Organization	Project Title	Principal Investigator	Votes (Y-N)	Recommended Award
1	DOH01-PBROWN-2015-00012	Icahn School of Medicine at Mount Sinai	Breast Cancer and the Environment Education for Multicultural Communities: Adapting the Advocates Mentoring Advocates Model for Latina Populations	Sarah F. Evans, Ph.D., MPH	Randa Maher motioned. Dr. Speyer seconded. Votes: 5-6	\$0
2	DOH01-PBROWN-2015-00007	Health Research Inc. and Roswell Park Cancer Institute Sub-Applicant, University at Buffalo: For Our Daughters, Inc.	Increasing Breastfeeding by African American Women as a Breast Cancer Risk Reduction Intervention	Deborah O. Erwin, Ph.D.	Ms. Maher motioned. Dr. Carney seconded. Votes: 11-0	\$262,731

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

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Annual DEC update to the Health Research Science Board (June 2016)

Provided by Richard Dickinson,

Chief of the Pesticide Reporting & Certification Section, NYSDEC

2015 Annual Report

DEC staff are currently processing the 2015 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.

2014 Annual Report Data

Letters were mailed January 2, 2015 to the regulated community reminding them to file an annual report of pesticide applications and/or sales made in 2014. A total of 16,925 applicators, technicians, aquatic antifouling paint applicators, and 306 commercial permittees were required to submit an annual report. The reports were due February 1, 2015.

Overdue notices were mailed in March 2015 to 1,916 applicators and technicians and 32 commercial permittees notifying them we had not received their 2014 report. Many of the individuals receiving this notice responded. Notices of Violation and Consent Orders were mailed later that month to 855 applicators, technicians and aquatic antifouling paint applicators and 12 commercial permittees that still had not submitted a report as required.

Fifty technicians and aquatic antifouling paint applicators, and two commercial permittees paid the fine to resolve their violation. Violations were resolved or removed for 98 applicators, technicians and aquatic antifouling paint applicators and four commercial permittees for various reasons (lost mail, typographical errors, extenuating circumstances). In addition, close to 80 applicators, technicians and aquatic antifouling paint applicators surrendered their certification. A total of 7,499,145 records (which includes sales and applications) were reported for 2014. Of those, 6,454,981 (86%) were submitted electronically and 1,044,164 (14%) were submitted on paper reports.

Available Annual Reports

We identified gross errors that affected the data statewide for **2006, 2007, 2008, 2009 and 2010**. DEC and Cornell staff worked together to correct that data. The 2006, 2007, 2008, 2009 and 2010 data, aggregated and summarized by zip code and County, has been made available to the public on DEC's website. Staff continue to work on the 2011 and 2012 data and it is anticipated that this data will become available in the near future.

Uses of the Data

Over the life of the Pesticide Reporting Law, 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 determined in 2013 that the pesticide database did not meet its primary purpose, that is, to provide scientifically useful information regarding a relationship between pesticide use and human health. Upon reaching this determination the HRSB recommended 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 in 2014 and 2015 to discuss their concerns and questions about recordkeeping and reporting. Staff from DEC, Cornell and DEC's database contractor met with staff from NYC DOHMH for a demonstration of their on-line pesticide reporting program. The 2014 and 2015 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. 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 2014 and 2015 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. Staff sent out over 400 of these rejection letters for 2014 reports. It is hoped that this will serve two purposes. First, it will improve the data before it is entered into the database and therefore less data correction will be required after it is in the database. Second, it is hoped that once the submitter is aware of their error and how to correct it, they will submit better quality reports in subsequent years.

DEC is also in Phase 2 of a project to develop a comprehensive, in-house pesticide program database, which will replace 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. This portal will have built-in verification requirements and other features 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.