

## Meeting Logistics

Item	Description
Date	Monday, July 12, 2021
Time	10:00 AM to 11:30 PM
Location	Call-in Only
Purpose/Focus	Health Research Advisory Committee meeting – public
Notetaker	Health Research Office Staff Sargents stenographer
Call-in and Skype	Microsoft Teams meeting <b>Join on your computer or mobile app</b> <a href="#">Click here to join the meeting</a> <b>Or call in (audio only)</b> <a href="tel:+12673328737">+1 267-332-8737</a> Phone Conference ID: 689 378 043#

## Attendees

### HRAC Members:

#### In Attendance

- Alison V. Beam, JD, Acting Secretary of the Department of Health
- Dwight Davis, MD, Professor of Medicine and Medical Director, Cardiac Rehabilitation Program, Pennsylvania State University School of Medicine
- Karen Wolk Feinstein, PhD, President and Chief Executive Officer of the Jewish Healthcare Foundation and Pittsburgh Regional Health Initiative
- Anantha Shekhar, MD PhD, Senior Vice Chancellor for Health Sciences and Dean of the School of Medicine, University of Pittsburgh
- Michael Parmacek, MD, Frank Wister Thomas Professor of Medicine; Chair, Department of Medicine and Director of the Penn Cardiovascular Institute, University of Pennsylvania School of Medicine
- Michele Masucci, PhD, Vice President for Research; Professor, Department of Geography and Urban Studies; Director, Information Technology and Society Research Group, Temple University

#### Not in Attendance

- Donna Gentile O'Donnell, PhD, Special Assistant to the President and Senior Vice President of Innovation Programs and Partnerships, Thomas Jefferson University
- Peter Tombros, MBA, Professor and Distinguished Executive in Residence, Eberly College of Science BS/MBA Program, Penn State University
- Pat Vance, retired PA state Senator, having represented the 31st State Senatorial District

#### Department of Health Staff Present:

- Keara Klinepeter, Executive Deputy Secretary
- Jared Shinabery, MHA, Deputy Secretary for Health Innovation, Acting Chair, Pennsylvania Department of Health
- Penny E. Harris, M.Ed., CAC, LPC, Director, Health Research Office
- Christopher Albright, Administrative Officer, Health Research Office
- Pamela Brown, Management Technician, Health Research Office
- Keith Fickel, Senior Counsel, Chief Counsel's Office
- Tirzah McClinton, Program Health Program Administrator, Health Research Office

#### Public in Attendance:

- Margaret McDonald, Associate Vice Chancellor for Academic and Global Affairs, Health Sciences, University of Pittsburgh
- Stephanie Sherwood, Section Manager, ORAU
- Madison Stromswold
- Kara Beem

## Agenda

ID	Description	Owner	Time
1	Welcome and Introductions	<i>Deputy Secretary Jared Shinabery</i>	10:00 am – 10:10 am
2	Overview and COVID-19 Update	<i>Deputy Secretary Jared Shinabery</i>	10:10 am – 10:20 am
3	Review and Approval of Meeting Minutes	<i>Deputy Secretary Jared Shinabery</i>	10:20 am – 10:25 am
4	Review of the CURE Program and Updates a) Budget update b) 2019 Alzheimer’s RFA update c) 2020 COVID-19 RFA update	<i>Deputy Secretary Jared Shinabery</i>	10:25 am – 10:35 am
5	Non-formula Funds Priority 2021-2022 and planning for 2022-2023	<i>Acting Secretary Alison Beam</i>	10:35 am – 11:05 am
6	Open Discussion	<i>Deputy Secretary Jared Shinabery</i>	11:05 am – 11:20 am
7	Public Comments and Questions	<i>Deputy Secretary Jared Shinabery</i>	11:20 am – 11:25 am
8	Closing and Next Steps	<i>Deputy Secretary Jared Shinabery</i>	11:25 am – 11:30 pm

## Discussion

ID	Discussion
1	<p><i>Jared Shinabery, Deputy Secretary for Health Resources and Services</i>, greeted Committee members, introduced himself. Committee members, DOH staff and Public attendees introduced themselves. Attendees were made aware a stenographer was present for record keeping, and to ensure minutes accurately reflect the actions and recommendations made by the Committee.</p>
2	<p><i>Jared Shinabery</i> stated the purpose of today's meeting is to:</p> <ul style="list-style-type: none"> <li>• Review and approve the minutes of the meeting held on April 19, 2021,</li> <li>• Provide an update on CURE funds and RFAs pending,</li> <li>• Confirm the SFY 2021-2022 non-formula priority topic, and</li> <li>• Planning for state fiscal year 2022-2023.</li> </ul>
3	<p><i>Dr. Shekhar</i> moved to accept the meeting minutes of April 19, 2021. <i>Dr. Parmacek</i> second. No discussion. No opposition or abstentions. The motion passed unanimously.</p>
4	<p><i>Jared Shinabery</i> provided a review of the CURE program and other updates.</p> <p><u>BUDGET UPDATE</u></p> <ul style="list-style-type: none"> <li>• The Tobacco Settlement Funds have been received for the 2020-2021 SFY as \$45,664,000 and \$3,624,000 for cancer funds, for a total of \$49,288,000.</li> <li>• The amount for the 2020-2021 COVID-19 priority is \$11,562,114, the remaining balance is designated for Formula funds.</li> </ul> <p><u>ALZHEIMER'S APPLICATIONS STATUS UPDATE</u></p> <ul style="list-style-type: none"> <li>• The final amount available for the 2019 non-formula Alzheimer priority was \$11,288,807.</li> <li>• The recipients of the funds:            University of Pittsburgh's Dr. Karl Herrup <i>Functional Interpretation of Alzheimer's Loci Across Cell Types, Age and DNA Damage</i> received \$3,965,632;            Temple University's Dr. Silvia Fossati <i>Vascular Contributions to Mechanisms and Biomarkers of Alzheimer's Disease</i> received \$3,822,700; and            University of Pennsylvania's Dr. David Wolk <i>Aging Brain Cohort Dedicated to Diversity Study</i> received \$3,500,475.</li> </ul> <p><u>COVID-19 RFA UPDATE</u></p> <ul style="list-style-type: none"> <li>• The COVID-19 RFA recommendation for awardees are finalizing their documents for submission to Procurement for final review and approval.</li> <li>• The final amount available for the COVID-19 priority was <b>\$11,562,114</b>. Each awardee received less than \$4M. 1<sup>st</sup> ranked received \$3,963,531; 2<sup>nd</sup> ranked received \$3,963,531; and 3<sup>rd</sup> ranked received \$3,635,052.</li> <li>• The applicants' requested and utilized all the funds.</li> </ul>

5 *Jared Shinabery* provided the Committee with a brief overview of Formula and Non-Formula funds, reaffirming that identifying nonformula research priorities is the main task of the HRAC.

*Jared Shinabery* shared:

- Non-formula is 30% of tobacco settlement funds with part of the funding used to pay for the vendor who assists the program with peer review of non-formula applications, an interim for non-formula as well as a final performance review of completed grants. \$1M is set aside for the Spinal Cord Injury Research Program.
- Formula fund priorities have been set as clinical, health services and/or biomedical research as defined by the Act. *Jared* opened the discussion of the committee's desire to continue with the recommendation regarding the research priority.
- *Dr. Masucci* moved to continue the priorities for SFY2022-23 for the formula fund. *Dr. Shekhar* second. No discussion. No opposition or abstentions. The motion passed unanimously.

6 *Acting Secretary Beam* updated the members on the recently passed Fiscal Code for the 2021-2022 state fiscal year. Act 24, amending the Fiscal Code, was submitted to the House, and amended by the Senate and signed by the Governor on June 30, 2021. She highlighted the changes that were made affecting the non-formula funding.

- \$1M remains for Spinal Cord Injury Research with the remaining
- 75% for Pediatric Cancer Research for institutions equipped and actively conducting pediatric cancer research. No more than \$2.5M in a fiscal year can be provided to a given pediatric cancer research institution. These institutions have been identified by the PA Cancer Control, Prevention and Research Advisory Board as Lehigh Valley Health Network, Weis Children's Hospital/Geisinger, CHOP, CHOP-Pitt, PSU, and St. Christopher's/Drexel and approved by DOH memo.
- 25% for capital and equipment grants to be allocated "to entities engaging in biotechnology research, including entities engaging in regenerative medicine research, regenerative medicine medical technology research, hepatitis and viral research, drug research and clinical trials related to cancer, research relating to pulmonary embolism and deep vein thrombosis, genetic and molecular research for disease identification and eradication, vaccine immune response diagnostics, nanotechnology research and the commercialization of applied research."

Discussion:

- Request for the clarification on the list of institutions for pediatric cancer research and the impact to the members' work. Response by SOH to inquire of the legislature. Encouraged all of members to use their institutions and universities great government affairs staff to work with the legislature routinely, get them briefed on this issue and prepared to ask questions of the legislature as was not advanced by the DOH.
- Members have stated a request to be apprised of such issues as the role of committee is to assist in providing advice on the research areas. Question was raised if reviewed in terms of the original intent of Act 77 and CURE. Legal counsel addressed identifying the Fiscal Code as an annual process that takes pieces of various legislation and changes them for a particular year. The passage of the Fiscal Code is a passage of a law that would supersede other general legislation like an amendment to a law. SOH recommended understanding of timing.
- Officially adopted Biology of Aging and are on that cycle as well as the public comment for 2022-2023 was the next planned discussion as the statutory role of the committee. SOH understood the Fiscal Code limitation is of one year's project and research priorities. Request for legal clarity if Fiscal Code negates the already existing decisions that were made under the work of the committee. Deputy Secretary of Health Resources and Services identified the removal of the funding by the Fiscal Code.
- Criteria of underfunded and impact Pennsylvania residents is not met by topics identified in the Fiscal Code.
- Concern expressed of the potential for precedence of a drive of personal interest in making a decision that goes against the process per CURE. Emphasized the requests for legality of the Fiscal Code and if this is standard operating procedure for next year.
- Peer review process concern with the 25% biotechnology broadly defined research. SOH identified potential for the committee to identify the priority within the two areas, following the review of the legal analysis, to narrow extremely broad categories.
- Return to a concern with the list of institutions presented. Deputy Secretary identified no institutions were identified in the Fiscal Code. The history is from the PA Cancer Control, Prevention and Research Advisory Board that had identified certain pediatric cancer research institutions which can be reviewed for adding others. Recommendation of the committee was to be careful having a defined list due to the potential discrimination with a system that was to have input for diverse populations. SOH responded to inclusion of any school with a

	<p>medical institution affiliated. Committee recommendation to not list institutions to keep it open to anyone who can do the research in that area.</p> <ul style="list-style-type: none"> <li>Final member concerns for that do not end up with same conversation next year that a process unfolds delegitimizing the intent of how decisions are made on research priorities and funding by a vested interest or clientele that permits a change without consultation. The 75-percent allocation for pediatric cancer and 25-percent to biotech broadly defined was confirmed as one year by the SOH.</li> </ul> <p>Outcomes:</p> <ul style="list-style-type: none"> <li>Request by members to have a formal review of the Fiscal Code for legality</li> <li>Biology of Aging is in process, how does the decision of the HRAC stand as publicly announced</li> <li>Understanding this is a one-year exception</li> <li>Fiscal Code has redirected funding</li> <li>Recommendation to include an institution with a School of Medicine for pediatric cancer research eligibility</li> <li>Committee to work further on this when receive the response to concerns – legality/conflict of Fiscal Code with statute and identification of pediatric cancer research institutions.</li> </ul>
7	<p><i>Jared Shinabery</i> noted the date of the next meeting as Monday, October 4<sup>th</sup> from 10 to 11:30 AM. <i>Dr. Masucci</i> recommended meeting before to receive the update on the Fiscal Code. A date would be explored after consult with the legal team for a timeline.</p>
8	<p><i>Jared Shinabery</i> expressed appreciation for the Committee’s guidance, ideas, and discussion with Secretary Beam. He requested a motion to adjourn. <i>Dr. Parmacek</i> moved to accept the motion. <i>Dr. Davis</i> second. No discussion. No opposition or abstentions. The motion passed unanimously. Meeting was adjourned at 10:54 am.</p>