

Meeting Logistics

Item	Description
Date	November 15, 2021
Time	1:00 p.m. – 2:30 p.m.
Location	Call-in only Public call-in for listen only
Purpose/Focus	Health Research Advisory Committee Meeting – Public
Notetaker	Health Research Office Staff

Agenda

ID	Description	Owner	Time
1	Welcome, Introductions	Deputy Secretary Jared Shinabery	1:00 pm – 1:15 pm
2	Review and Approval of Meeting Minutes for 7/12/2021 and 8/23/2021	Deputy Secretary Jared Shinabery	1:15 pm – 1:25 pm
3	Review of the CURE Program and Updates 2020-2021 COVID-19 update	Deputy Secretary Jared Shinabery	1:25 pm – 1:30 pm
4	Non-formula Funds Priority Language discussion 2021-2022	Deputy Secretary Jared Shinabery	1:30 pm – 2:15 pm
5	Open Discussion	All attendees	2:15 pm – 2:20 pm
6	Public Comments and Questions	Deputy Secretary Jared Shinabery	2:20 pm – 2:25 pm
7	Closing and Next Steps	Deputy Secretary Jared Shinabery	2:25 pm – 2:30 pm

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1	<p><i>Deputy Secretary Jared Shinabery</i>, introduced himself, and members and DOH staff introduced themselves. Public attendees introduced themselves. <i>Deputy Secretary Jared Shinabery</i>, reviewed Agenda. Attendees were made aware that meeting would be recorded for record keeping, and to ensure minutes accurately reflect the actions and recommendations made by the Committee.</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>HRAC Members in Attendance Dwight Davis, MD - Karen Wolk Feinstein, PhD Anantha Shekhar, MD PhD Michael Parmacek, MD Michele Masucci, PhD Peter Tombros, MBA</p> <p>HRAC Members not in Attendance Donna Gentile O’Donnell, PhD Pat Vance, retired PA state Senator</p> </td> <td style="width: 50%; vertical-align: top;"> <p>DOH Members Jared Shinabery Will Cramer Sylvia Golas</p> <p>Guests Ben Greenalee Margaret McDonald, UPitt Michael Smith, UPenn Stephanie Sherwood – ORAU Janet Kile – ORAU Charlie McLaughlin, UPitt</p> </td> </tr> </table>	<p>HRAC Members in Attendance Dwight Davis, MD - Karen Wolk Feinstein, PhD Anantha Shekhar, MD PhD Michael Parmacek, MD Michele Masucci, PhD Peter Tombros, MBA</p> <p>HRAC Members not in Attendance Donna Gentile O’Donnell, PhD Pat Vance, retired PA state Senator</p>	<p>DOH Members Jared Shinabery Will Cramer Sylvia Golas</p> <p>Guests Ben Greenalee Margaret McDonald, UPitt Michael Smith, UPenn Stephanie Sherwood – ORAU Janet Kile – ORAU Charlie McLaughlin, UPitt</p>
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2	<p><i>Dr. Shekhar</i> moved to accept the meeting minutes of July 12, 2021. <i>Mr. Tombros</i> second. No discussion. No opposition or abstentions. The motion passed unanimously. <i>Dr. Parmacek</i> moved to accept the meeting minutes of August 23, 2021. <i>Dr. Davis</i> second. No discussion. No opposition or abstentions. The motion passed unanimously.</p>		
3	<p><i>Deputy Secretary Jared Shinabery</i> provided a review of the CURE program and other updates.</p> <ul style="list-style-type: none"> ▪ <u>COVID-19 RFA UPDATE</u> <ul style="list-style-type: none"> ○ The final amount available for the COVID-19 priority is \$11,562,114. ○ There will be three awards. ○ Each awardee will receive less than \$4M. ○ The grant applications are in the final signatory process. ○ In the next HRAC meeting we should be able to share the names of the awardees after the grants have been fully executed. ▪ <u>FORMULA RFA</u> <ul style="list-style-type: none"> ○ The Formula fund priorities are clinical, health services and/or biomedical research as defined by the Act. ○ The Formula SFY2021-22 RFA is being reviewed by the Office of Procurement. ○ HRO will provide a opportunity for Formula grantees to discuss via webinar and submit questions. ▪ <u>NON FORMULA RFA</u> <ul style="list-style-type: none"> ○ The funded priorities amended with the fiscal code are pediatric cancer and capital equipment for biotechnology. ○ 75% of funds to go to pediatric cancer research. ○ Each awardee to receive no greater than \$2.5M per institution conducting research. ○ RFA will require that institutions demonstrate that they are actively equipped to perform pediatric cancer research. ○ Maximum amount of grant is \$4M for 4 years. ○ 25% of funds to go to Capital Equipment for Biotechnology for entities that engage in Biotechnology research to meet fiscal code. ○ SOH will approve maximum of \$2M x 4 years. 		

4

Deputy Secretary Jared Shinabery opened the discussion regarding draft NF language since last meeting:

Discussion:

- *Dr. Masucci* provided the Committee with a brief overview of the status of the draft language to date: There are two versions of the language to meet the fiscal code amendment, and the Committee needs to determine which focus areas are acceptable: 1) the first version, which was written by *Dr. Masucci* for the last closed meeting 2) the second version was submitted since the last closed meeting by *Dr. Shekhar*.
- *Dr. Shekhar* summarized the language that he proposed adding in the 2nd version, which he submitted. He suggested that the Committee also consider broadening the language from biology and therapeutics and intrinsic studies to include disparities and preventive and health services research relevant to children’s cancer. *Dr. Shekhar* further suggested that broadening the language to include social determinants risk factors would be more egalitarian and allow more institutions to apply.
- *Dr. Davis* asked if the areas of need in the State not being heavily funded by outside sources (national, local and state) had been looked at for the topics that *Dr. Shekhar* raised. *Dr. Shekhar* responded that NIH funds traditional fundamental biology and clinical research. NIH does not fund non-fundamental research, such as how to improve access to cancer care, and such research shouldn’t be excluded. *Dr. Parmacek* stated that he favors broadening the language to include the disparities of care because it is a significant issue if the Committee is allowed to do so in terms of what is eligible. *Dr. Mascucci* suggested that the language begin at the highest level of specificity and then to least specificity to broaden the language to include cancer disparities and outcomes. *Dr. Shekhar* stated that the text needed to be broadened for addressing children’s cancer within the space given to the Committee [by the fiscal code].
- *Deputy Secretary Jared Shinabery* requested a motion to adopt the combination RFA language.
- *Dr. Masucci* moved to adopt the combination RFA to add language related to cancer disparities and circulate for Executive approval. Second by *Dr. Dwight Davis*. No discussion. No opposition or abstentions. The motion passed unanimously. The committee then agreed that legal should approve the combination draft after the meeting.
- *Deputy Secretary Jared Shinabery* opened the discussion regarding draft language for the Capital Equipment for Biotechnology priority.
- *Dr. Masucci* stated that the entire Committee approved the draft language for the Capital Equipment for Biotechnology priority, but HRAC is asking for help on use of embryonic stem cell usage from the Department. She further stated that the Certification forms may already cover use of embryonic stem cells. *Deputy Secretary Jared Shinabery* responded that legal will sign off on the RFA. *Dr. Shekhar* asked if the Capital Equipment for Biotechnology priority will be a 2nd RFA. *Deputy Secretary Jared Shinabery* affirmed that it would be a 2nd RFA. *Dr. Parmacek* asked if the original Act restricted how much funds can be used for infrastructure. *Dr. Parmacek* asked if it restricted to 50%? *Deputy Secretary Jared Shinabery* responded that the Department will need to confirm

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	<p>that. <i>Dr. Masucci</i> responded that the infrastructure restriction may apply to Formula grants, rather than Nonformula grants. <i>Dr. Shekhar</i> suggested that there may be legislative political attention to this language. <i>Dr. Parmacek</i> expressed agreement that much care must be taken in the wording due to the politically charged nature of human embryonic stem cell usage both now and in the past history of the Program. He further stated that HESCs could be excluded from the draft language, and the Committee must determine if HESCs should be left in or taken out of the draft language. <i>Dr. Davis</i> stated that the draft language needs the seal of approval of legal for use of HESCs. <i>Deputy Secretary Jared Shinabery</i> asked <i>Dr. Masucci</i> to send the most recent version of the draft language for the Capital Equipment for Biotechnology priority and <i>Dr. Masucci</i> sent an electronic copy of the draft language to <i>Deputy Secretary Jared Shinabery</i>. <i>Dr. Shekhar</i> suggested that the legislative affairs office should also look at the draft language.</p> <ul style="list-style-type: none"> ○ <i>Dr. Masucci</i> moved to adopt the draft language for the Capital Equipment for Biotechnology priority pending review through legal. <i>Dr. Shekhar</i> second. No discussion. No opposition or abstentions. The motion passed unanimously.
<p>5</p>	<p>Open Discussion</p> <ul style="list-style-type: none"> ○ <i>Deputy Secretary Jared Shinabery</i> noted the date of the next meeting as Monday, January 3rd from 10 to 11:30 AM, but suggested that it be moved due to closeness of the date to New Year’s Day holiday. After discussion, the date was moved to January 24th from 10 to 11:30AM. <i>Deputy Secretary Jared Shinabery</i> also noted that invitations will also be sent out for the rest of the meetings for all of 2022 for April 4th, July 11th and October 3rd from 10-11:3AM. <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. ○ <i>Dr. Davis</i> requested that the January 24th meeting should include a thoughtful conversation about the process moving forward including the original act as a review point with a legal interpretation of the fiscal code mandate. <i>Deputy Secretary Jared Shinabery</i> noted that the fiscal code will only apply to this year, and then will, presumably, go back to HRAC. <i>Dr. Davis</i> requested clarity for moving forward for the Committee from the legislature and Department regarding the operational rules for what HRAC is supposed to do. <i>Secretary Jared Shinabery</i> asked if <i>Dr. Davis</i> meant clarity related to the budget. <i>Dr. Davis</i> responded that clarity was needed regarding the cancelling of a project [priority] and the insertion of a new topic with no scientific background resulting in HRAC struggling to move forward. <i>Dr. Davis</i> went on to request that a discussion could be started in January relevant to the next budget (April) season. <i>Deputy Secretary Jared Shinabery</i> stated that it would be added to the agenda for the January 24th meeting. ○ <i>Mr. Tombros</i> stated that he would not be available for the January 24th meeting. <i>Deputy Secretary Jared Shinabery</i> suggested that the meeting times be discussed after the meeting and the Committee agreed to do this. ○ <i>Dr. Masucci</i> asked what the anticipated timeline was for releasing the RFA. <i>Will Cramer</i> stated the process usually takes 3 to 4 months, generally, but might take longer for this RFA. <i>Deputy Secretary Jared Shinabery</i> agreed that it would take a minimum of 3-4 months to get the RFA out on the streets.

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6	<p><i>Deputy Secretary Jared Shinabery</i> opened the floor for public comments and questions. No questions were asked by the public. <i>Dr. Davis</i> asked if several documents could be made available for the Committee for reference for the next meeting including a copy of the original Act and any amendments and the legal scenario that got the Committee to this point [Fiscal Code]. <i>Deputy Secretary Jared Shinabery</i> stated that the documents would be provided.</p>
7	<p><i>Deputy Secretary Jared Shinabery</i> expressed appreciation for the Committee's hard work on this RFA and discussion. He requested a motion to adjourn. <i>Dr. Shekhar</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 1:52 PM.</p>