Advancing Precision Medicine TA Webinar
July 23, 2018
1:00 PM – 2:00 PM ET

Coordinator: Good day and welcome to the Advancing Precision Medicine TA technical assistance webinar. Today's conference is being recorded. At this time, I would like to turn the call over to Shannon McDevitt. You may begin.

Shannon McDevitt: Thank you. Let me extend my welcome to the Advancing Precision Medicine TA webinar for the fiscal year 2018 in advancing precision supplemental funding opportunity. For convenience, I will call this APM. My name is Shannon, I’m the Medical Officer in the Bureau of Primary Health Care’s Office of Policy and Program Development. I am pleased to present APM to you today. This is a new, one-time, noncompetitive supplemental funding opportunity that supports health centers’ participation in the National Institute of Health All of US research program.

Submit your questions via the chat pod in the Adobe Connect webinar. At the end of the presentation, I will answer questions in the chat pod that apply broadly to today’s participants. As you think about questions that you would like to ask, remember that slides are available for download from the Adobe Connect webinar and the APM technical assistance website. The website URL is listed on the bottom of slide 1. A recording of today's presentation will be posted in a few days on the APM technical assistance website. The website provides an overview of APM and resources necessary to complete your grant application, including application instructions, required forms, sample documents. You must access the website to obtain the necessary application materials.
If you have a question today that is specific to your organization, or if we do not answer your question during today's webinar, please send your question via email to bphcsupplement@hrsa.gov. This email address is located on the bottom of this first slide.

The purpose of today's technical assistance webinar is to provide an overview of the APM instructions and ensure that you have the information that you need to successfully complete the application process. This funding opportunity is limited to 56 health centers that have demonstrated the health information technology readiness and organizational capacity to successfully complete the project requirements.

HRSA sent an EHB email to all 56 health centers on July 19. We are hopeful that all eligible health centers will apply for this noncompetitive funding.

Kicking us off is a brief presentation of All of US and the value of health centers partnering with this landmark research initiative. Then, I will provide a summary of the APM Instructions, including the key program and budget requirements, and specific details on how to complete the application forms and attachments.

I will conclude by offering you contacts and resources to help you complete and submit your application, and by answering questions submitted through the chat pod.

At this time, I would like to introduce Dr. Stephanie Devaney, the Deputy Director of the All of US Research Program. The NIH All of US team provided valuable consultation on the development of the APM funding opportunity.

Stephanie Devaney: Hi, thank you very much. I am getting ready to share my screen which you should very soon see my slides. First, I would like to convey my gratitude to our
colleagues at HRSA for working so closely with us on developing this opportunity for the federally qualified health centers. It has been one of the more rewarding partnerships we have had with the current federally qualified health centers that are part with our program already. And so we are just delighted to be working so closely with HRSA once again on this incredible opportunity.

Are you guys able to see my slides?

Shannon McDevitt: They are projecting well, Stephanie.

Stephanie Devaney: Wonderful. Thank you very much. So what I thought I would do, and I want to leave as much time for questions as possible, so what I want to do is give you a sense of what our program is so you understand the mission and structure of the All of US research program.

Myself and my colleagues Mark Calder and Ed Ramos who are also on the WebEx can answer questions along with our colleagues at HRSA. The All of US program has a pretty broad mission to accelerate research health research and biomedical breakthroughs enabling individualized prevention, care and treatment for All of US.

One of the most important access aspects is to develop relationships with a million or more individuals living in the United States who become participant partners in the program and agree to share information about themselves over their lifespan.

Enrolling and retaining these individuals is one of our primary objectives in helping to establish this resource. Ultimately, all of that information is collected and stored in our cloud environment that we are developing right now which is not yet open to researchers. All of the data is being stored centrally. Ultimately, our goal in 2019 is to open up access to the largest and richest biomedical data set
yet of a study like this to researchers of all types. Ultimately, we see our third primary objective under meeting our mission is to catalyze a robust ecosystem, which includes partnering with organizations like the federally qualified health centers as well as other partners and enabling technology that will support the collection of diverse data types on our participants so we truly can move the research community and answer questions we have not, to date, been able to answer given the way the data has been siloed across research study.

This slide just gives us a sense of our high level structure. We have data being held, as I mentioned, centrally in the Google cloud. That environment is being built by Vanderbilt Institute and they are working on making those data available through our research portal sometime in 2019 for researchers to query.

We have a bio bank at the Mayo Clinic where all of the specimens from our participants are stored for future assays and researchers ultimately to be able to refer back to the specimens. All of the aspects of our program, except for one in person visit at this moment, are digital, so the participants portal has been developed by Vibrant Health. Participants who want to join the study do so digitally and through our participant portal. The 3 blocks on the bottom are our different networks that are focused on enrolling our participants and maintaining—building out relationships with participants and helping to collect that the data that the program is asking for. So we have the center there, healthcare provider network which is made up of academic medical centers many of them connected under one award as well as federally qualified health centers, both the 6 that were part of our original pilot and qualified medical centers that are connected to academic medical centers. And the veterans health administration. We have 2 VA sites currently enrolling veterans in the program. We also have, on the sides, the direct volunteer network and that is -- in order for our program to reach All of US, we understood that we cannot just rely on enrolling individuals through individual health centers. Therefore, we need to come up with mechanisms by which we can enroll individuals from across the
country using their smart phones or even Internet connections at their local library or at home. Then we need a way to engage those individuals (in person) to a place where they can provide their blood specimens.

I will talk a little bit about the protocol in a moment to give you a sense of what it entails. On the right, the communications and community network, we have a number of community engagement partners that are helping us to build relationships and trust within their specific communities. As we attempt to enroll individuals that reflect a broad diversity of the United States, understanding we need to make connections with individual communities and we need to do that with a trusted intermediary. In some cases, those are the healthcare provider organizations, including FQHCs, and in some cases it is a community engagement partner that is helping us to build those relationships on the ground.

I mentioned, there are 2 ways to enroll in the study. One is directly through a healthcare provider organization and one is online from anywhere in the country, regardless of proximity to one of our funded healthcare providers. Individuals go through this general protocol. They first go through an electronic consent and authorize the sharing of their electronic health record with us. They say yes or no to that. We then asked them to sell out fill out a number of surveys. The goal is to collect demographic information, lifestyle information. Then to use the other digitally deployed surveys in the future as engagement methods but also to collect scientifically valid information. Another one we just released, another survey for health access. I forget what is called but it was around health access and one’s perceived health access as well as actual health access. We are going into personal health history and family medical health history as to upcoming service.

We then ask individuals to come in for an in person part of the protocol. For those who have said, yes, to sharing their electronic health record, we asked them to come in for physical measures, to provide a blood sample and urine sample, which then get stored at the Mayo Clinic. And ultimately we do want to start
incorporating more wearables and digital apps in our program, again trying to get to a model so we can be a national program and collect data where participants are to the extent that we can so we can efficiently be collecting information across all aspects of one’s health.

I want to talk about the direct volunteer capacity before I close out and open up for questions. This is an important functionality of the program. It might be the part of the program we leverage in the case of the funding opportunity. I mentioned we have healthcare provider organizations that are enrolling directly from their patient base and their local catchment areas into the program. They help us run those participants through the full protocol. In cases where there is no All of US research program healthcare provider organization available and someone wants to enroll online, we have been working with the organizations on the right-hand side of the screen including Walgreens, Qwest diagnostics, QTC and the national blood collaborative. All of them have a national reach and current infrastructure across the country that would allow us to, when we turn capacity on at those locations, would allow us to have trained staff at those locations that can take for us the physical measurements and collect blood samples and urine samples to be stored in Mayo so we would have participants who have gone through the full protocol from across the country.

We are, at the same time, developing capacity for collecting electronic health record information on those participants that come into our direct volunteer pathway as well as other types of data and figuring out ways that we can do this locally so it can be captured, the full suite of information on all participants regardless of where they live. I think we will get into electronic health record conversation more. But just to note, one of our primary objectives is to collect real-time critical data on all of our participants so we can match that to the information we are collecting from them to self-reports and surveys as well as genetic information and that is very tricky when we start thinking about how we will capture one's full health record outside of our – outside of the places where
we have a direct connection with one of these healthcare providers. We have launched a program called Sync for Science, that is in working with four large vendors, that has developed technology that allows, within the providers that deploy the technology, for a patient of those providers to enroll in our study and, through their patient portal, say, yes, I want to access, I want to share my health electronic record data with the All of US Research Program and to give that through the portal and those data come directly from the provider to the data research center that the All of US Research Program is maintaining. The Sync for Science capacity is one of the things that HRSA talked about in the funding opportunity. It would certainly be, we would be delighted of more providers have the capacity to share EHR data in that way, understanding how critically important that is for precision medicine research like the platform we are setting up. We would certainly be happy to talk more about that on this call.

I want to show this slide as my last slide and then I am happy to help answer questions. Just quick highlights here. We have about 88,000 participants that have signed up. We launched, opened up nationally just this past May. We are really emphasizing diversity, which is why our connection with FQHCs are so critical to us. Right now we have about 76% of individuals that have signed up are under-represented in biomedical research. We want to keep the number that high or higher. What we are working on over the next year are three major things in addition to this partnership with HRSA and those from across the country, opening up the research portal for researchers to begin enrolling children and to start generating data in 2019. I know that was a quick overview. I will stop here. We can surface any other questions or concerns you all have for this discussion.

Shannon McDevitt: Stephanie, will you be able to stay on for the next half hour while we cover the other…

Stephanie Devaney: Yes.
Shannon McDevitt: Great. Thank you so much for the generous giving of your time. We are so excited to continue our partnership with NIH and support All of US through this APM funding opportunity.

Let's dive into APM now. The purpose of APM non-competitive supplemental funding is to support health center participation in All of US and contribute to achievement of its central goal: to enroll 1 million individuals reflecting the nation’s rich diversity to produce meaningful health outcomes for communities across the country, including those historically underrepresented in biomedical research. Through APM, while helping health center patients enroll in All of US, health centers will also be investing in activities such as strengthening patient engagement and health information exchange, which address Health Center Program priorities. Additionally, health centers will be more prepared to participate in future research opportunities which may ultimately improve the health of their service areas.

APM eligibility is limited to 56 health centers. These health centers are currently receiving Health Center Program operational – or H80 –grant funding. They have demonstrated the health information technology readiness and organizational capacity necessary to increase community awareness of All of US and facilitate enrollment of health center patients in All of US.

Capacity and readiness were determined through two methods. First, 2017 Uniform Data System- or UDS- reports were analyzed using the criteria presented on slide 6, which considered patient-centered medical home status, staffing profiles, Meaningful Use attestation, and electronic health record characteristics.

Additionally, health centers currently participating in All of US may receive APM noncompetitive supplemental funding if they are identified in the application of currently funded All of US healthcare provider organizations in
response to NIH funding announcements as of May 1, 2018 and they propose new activities aligned with the APM purpose and requirements. The project directors authorizing officials of the 56 eligible health centers should have received an email on July 19 from HRSA's electronic handbooks or EHB. This email provides access to the APM EHB application module. The APM instructions and a hyperlink to the APM technical assistance website. The email also includes your specific sub-program funding proportions to help you complete the budget forms which I will discuss in more detail in a little bit.

Also, HRSA called the eligible health centers on July 20 to confirm your receipt of the email.

Let’s look closely at the APM funding details on slide 9.

Approximately $21 million is available to support APM in FY 2018. HRSA plans to award up to $375,000 to each of the 56 eligible health centers for the 2-year period of performance beginning September 1, 2018 and ending August 31, 2020. Depending on the number of approvable applications, HRSA may adjust award amounts consistent with available funds.

APM funding does not need to be requested in equal amounts in each year. For example, you may request $250,000 in year 1 and $125,000 in year 2. This flexibility allows for necessary hiring or consulting expenses, and/or equipment purchases necessary to initiate APM activities.

APM funding must be requested consistent with and, if approved, will be made available to each recipient in the same sub-program funding proportions as the existing H80 grant funding. Sub-program funding streams are community health center, migrant health center, health care for the homeless, and public housing primary care.
Recipients may use APM funding throughout their FY 2020 H80 budget period if they have HRSA-approved carryover requests, as permitted by program requirements and grants policy. APM funds should supplement and not supplant existing funding.

Let’s check in with you with an audience participation question.

True or false. APM funding is open to all organizations receiving H80 funding at the time of this funding opportunity release.

I will give you another second. We appreciate everyone checking in. It helps me know that you are following along. Let's go ahead and close the poll.

The majority of those participating in the poll question had the answer correct. It is false.

Eligibility is limited to 56 health centers, meeting specific criteria. Their H80 award recipient either fulfill the criteria or currently are All of US percent visit disparate participants. These 56 health centers were notified of their eligibility by an EHB email on July 19th. Refer back to slides 5 through 7 or Section III. Eligibility Information, in the APM Instructions document for eligibility details.

Let's transition to the details of your application. As you plan your project, keep in mind that HRSA will support funded help centers achievement of proposed APM supported activities through a new training and technical assistance contract. This contract is offered outside of this APM funding opportunity. HRSA will share more information about this contract later this summer.

Your proposal must demonstrate how you will use APM noncompetitive supplemental funding to achieve 3 project requirements. Increase the number of Health Center patients enrolled in All of US using the direct volunteer pathway,
enable patient participation in All of US, and create the ability to share data patient data with All of US. I will describe each of these in detail.

Health centers will increase community awareness of All of US and facilitate enrollment of Health Center patients using the direct volunteer pathway. All of US offers different options for patients to enroll and those are outlined. The options required by APM is for patients to enroll themselves during online application website or a call center. This is the direct volunteer pathway. Health centers can support them by offering access to support Internet connection, ASIC technical assistance such as creating an email account or a private space where they can access the All of US service and their personal information stored by All of US. Individuals enrolling through the Direct Volunteer Pathway will have their baseline physical measurement and bio-specimen collections facilitated by All of US and conducted at participating Walgreens stores, designated commercial laboratories, or the Journey Bus, which is a mobile unit that can facilitate all aspects of the All of US Research program. Health centers may use APM funding to enhance these activities through activities such as public transportation vouchers.

The next requirement, detailed on slide 15, is to enable patient participation in All of US. To achieve this, health centers will ensure that they have adopted the latest version of an Office of the National Coordinator for Health Information Technology, or ONC, certified EHR. EHRs should provide robust and user-friendly patient-facing health information technology, including patient portals. Health centers may use APM funding to upgrade their EHR to the most recent version to offer user-friendly patient portals and educate on how to acceptably use patient portals and other health information technology. APM's funding will also support the use of an application programming interface or API that supports health level VII, staff healthcare interoperability resources, also known as HL-7 FIRE, and includes Sync for Science. This will enable patients at a minimum to share the common clinical data set of their health information with All of US.
All of US provides a framework for researchers, healthcare providers and patients to work together to develop individualized care by securely exchanging electronic patient health information. Therefore, health centers may use APM funding to export patient data in a standard format such as the Observation Medical Outcomes Partnership also known as OMOP, common data model. APM funding may support changes necessary to allow patients enrolled in All of US to share their health information that comprises at a minimum, the common clinical data set designed by ONC.

There are 2 funding request requirements. Health centers must request APM funding to be used in part, for ONC certified EHR purposes or upgrades that will support participation in a data collaborative using the OMOP, data model and/or HL7 standards. If your EHR already have this capacity, demonstrate this in your application and explain how APM funding will be used to complete the other APM requirements. Attachments 6 and onward in the EHB application module would be appropriate places to provide this information.

The second funding request requirement is that your application must include funding for key APM project team members to travel to a 2 day meeting held by the training and technical assistance contractor. We anticipate this training will likely be held in Washington, DC around the time of another national Health Center meeting. The APM funding may not be used for clinical services, EHR purchases or upgrades that are not ONC certified, fundraising, support for lobbying or advocacy efforts, incentives such as gift cards or food, construction or renovation costs, facility or land purchases, and vehicle purchases. If your organization is unsure whether a cost is allowed, please contact our technical assistance team at bphcsupplement@hrsa.gov.
Progress toward achieving APM requirements will be monitored through required annual UDS and Budget Period Progress reports, as well as APM-specific progress reports that will be provided 3 times yearly.

The one aligned UDS measure is the number of patients the health center has engaged through health information technology, such as patient portals, kiosks, or secure messaging, such as secure email either through the EHR or through other technologies.

Progress reports will capture brief summaries of APM implementation progress and barriers. Health centers will report on measures including, but not limited to the number and demographics of health center patients enrolled in All of Us. Progress toward meeting HL7 and/or OMOP Common Data Model standards. For example, this could be demonstrated through a status update on EHR upgrades. And, an account of EHR data exchange with All of Us, including data as appropriate.

Emails were sent through EHB to eligible health centers’ project directors and authorizing officials on July 19th. Applications must be submitted in EHB by August 20th at 5 pm Eastern Time. The award start date is September 1st.

Although this is a relatively short application window, this is a streamlined application. HRSA has already established that the 56 eligible health centers have the capacity to achieve the project goals. What we need from your application is a plan for how you will achieve them.

Time for another audience participation question. True or false? APM funding must be used to enable patient precipitation in All of Us through all 3 strategies stated in the project requirements. The strategies are written out on slide 21 and in the poll box in the webinar room for your reference.
I will give you just a few seconds to answer. Thank you, everybody who is participating actively today. All right. 3 more seconds and here we go.

The correct answer is true.

Enabling patient participation in All of US will be accomplished through 3 required activities that enhance health information exchange using the latest version of an ONC certified EHR, increasing patient use of patient portals and other health information technology and using an application funding interface that supports HL7 FIRE, including Sync for Science. Remember, if your EHR already has one or more of these functionalities, your application must demonstrate that and you must describe how APM's funding will be used to achieve other APM requirements.

We have discussed the purpose, reporting requirements and key dates associated with your APM application. Now I will transition to an overview of the application components you will submit.

Slide 24 provides a list of essential application materials needed to assist in applying for APM and where to find them. The EHB email notification contains the unique application module URL and passcode as well as the subprogram funding proportions to help you complete the budget forms properly. The APM instructions are attached to the email to your convenience. On the APM technical assistance website, you will find APM instructions and user guides, forms required to be uploaded to the EHB application module and sample forms. It also provides technical resources for your reference.

APM applications will be completed and submitted in EHB. There is no grants.gov portion to this application. The APM technical assistance website provides resources necessary to complete your application. These include the steps for completing each section of the application and submitting it to the EHB.
The website also has the required forms that must be included in your application. Unlike other Health Center program funding applications, only the SF-424 Basic Information and Budget Forms are completed directly in EHB. All other forms are NOT structured in EHB and must be downloaded from the technical assistance website, completed, and uploaded into EHB.

There are 5 required documents that must be uploaded to the Attachments section of the EHB application module. Attachment 1 is the Federal Object Class Categories Form. Attachment 2 is the Budget Narrative. Attachment 3 is the Staffing Impact Form. Attachment 4 is the Project Narrative. And Attachment 5 is the Equipment List Form. Should you have additional documents to support your application, you may upload those beginning with Attachment 6.

For example, if you have an indirect cost rate agreement, include it here. If applicable, provide documentation demonstrating that your EHR currently possesses the described target capacities. For example, exporting patient data using the OMOP Common Data Model meets HL7 standards for the exchange, integration, sharing, and retrieval of electronic health information.

This is different than other Health Center program funding application so I will say again. These forms are required to be submitted as attachments. They are not already in EHB for you to fill out. If you are familiar with these forms, but not this process. Attach them to the EHB model. The forms and EHB user guide and additional resources are available on the APM technical assistance website.

Enter the required information on the SS 424 part 1 and part 2 as instructed on the APM user guide. Those that are not marked as required maybe left blank. Enter September 1, 2018 for the project period start date. And August 31, 2020 for the project period end date. You must upload a file to the “Project Description/Abstract” attachment field to move forward in the system, although a specific document is not required. There are two options. You may attach
something that summarizes your proposed project, which could be a brief narrative or a logic model. Alternatively, you may upload a blank document. Most required fields on the SF-424 form will be pre-populated with your organization’s existing information. Review the information and update as needed. Once you have completed the SF-424 Parts 1 and 2, proceed to the Budget Information.

Enter the total federal and non-federal project costs in Section A of the SF-424 Budget Information form. The total funding request may not exceed $375,000 and must be requested in the same sub-program funding proportions as existing H80 grant funding. Through an EHB email, HRSA provided each eligible health center the maximum funding request by sub-program funding proportions specific to their health center. The EHB User Guide provides steps to update the sub-programs presented on the form, if needed.

In Section C, provide any non-federal resources that will be used to support the proposed APM activities.

To complete the federal object cost category form enter federal and nonfederal expenses by object class category, all proposed activities by year. For example, personnel, equipment and supplies. The total funding request may not be spent in equal amounts in each year but keep in mind the total federal request across both years combined cannot exceed $375,000.

Slide 29 presents the Budget Narrative guidance. Complete a 2-year budget narrative that describes costs for all proposed activities. Clearly detail the federal and non-federal costs, if any, for each line item within each object class category of the Federal Object Class Categories Form and explain how each cost contributes to meeting the APM purpose. See Appendix B: Budget Narrative Instructions in the APM Instructions for detailed guidance. A sample Budget Narrative is provided on the APM Technical Assistance Website. If you propose
to hire contractors or consultants, explain how the contracted FTE estimate was developed and include details regarding the proposed contractual arrangements. If you intend to change an existing staff’s FTE to APM-specific activities, you must demonstrate a commensurate decrease in their current activities’ FTEs. For example, a full-time physician who will have 0.2 FTE dedicated to overseeing the adoption of APM-supported health information technology will become 0.8 FTE physician and 0.2 FTE chief information officer. You would explain this change in your Budget Narrative.

On the staffing impact form, enter the direct hire staff and/or contractor FTEs that will help achieve the APM project requirements according to the allowed position types listed on this form. Position descriptions are available in the 2018 UDF manual. Include staffing projections for the 2 year period of performance. Enter FTEs for direct hire staff and contact personnel separately. You must ensure appropriate oversight to any contractual arrangement.

The project narrative requires responses to 6 items. You will describe how your APM supported activities will increase the number of health center patients enrolled in All of US, community or populations, historically underrepresented in biomedical research. These committees include but are not limited to individuals with physical the abilities, racial or ethnic minorities, women, individuals from geographically isolated communities, economically disadvantaged individuals, and sexual and gender minorities.

You will also use your project narrative to describe how you will accomplish the following, use APM funding to support upgrades to your EHR, expert patient data in a format to support the use of OMOP common data model for sharing data with All of US, increase pacing use of portals and technology, enable patients to share at a minimum the common clinical data set, collect and report APM relevant measures not currently tracked through UDS. Finally, you will explain how
personnel supported with APM funding will support the successful achievement of APM activities.

If funding is requested in the equipment line item in the federal object class categories form, list the proposed equipment purchases on the equipment list form. Federal equipment means tangible property including information technology systems, having a useful life of more than 1 year and exceeds $5,000. See additional details in APM instructions and budget narrative instructions. The total on this form must equal the total amount requested on the equipment line item in that federal category form. If you are not requesting APM funding for equipment, enter no equipment to be purchase in the field. This must be included in the application.

Before we go on, let's take a moment for our final questions for the audience. This time, we focus on funding.

Identify the incorrect statement. All funding is awarded in September 2018, spending must be equal amounts in each year, you may use APM funding throughout your FY 2020 budget period with approved carryover request, or, you must request APM funding in the same subprogram proportions as your existing H80 award. Which one is incorrect?

Answer quickly. We will close this one quickly so we can get the questions.

All right, Jovaun, go ahead and close this one out. I think people are catching on.

As stated on slide 35, the incorrect statement is B. APM funding does not need to be requested and spent in equal amounts each year.

Before we jump into the questions you have posted, here are resources and reminders. Your entire application must be successfully submitted in EHB by 5
PM Eastern time on August 20, 2018. To submit your application, your organization must have an active SAM.gov registration. Please double check your status. There have been recent changes in Sam.gov. Slide 37 provides the URL link to the latest frequently asked questions.

Only the authorized official identified in EHB may submit the application. If the person who prepares the application is not the Authorizing Official, submit to AO button will display on the submit page. Be sure to leave adequate time for the AO to complete the submission process. You are encouraged to personally alert this individual that the application is awaiting their action.

You must meet key completeness eligibility and cost requirements when reviewed by HRSA. Awards will not be made if your health center has stopped receiving H80 grant funding, has 5 or more conditions related to the health center program requirement areas in the 60 day phase of aggressive action, or 1 or more conditions related to health center program requirement areas that are in the 30 day phase of progressive action. Eligibility is limited to health centers demonstrating health information technology readiness and organizational capacity necessary to increase community awareness of All of US and facilitate enrollment of Health Center patient using the direct volunteer pathway. Contact us at bphcsupplement@hrsa.gov with questions about allowable activities. Don’t forget to complete and submit your application now later on August 20 than 5pm ET.

Slide 41 provides main points of contact for developing an APM application. First and foremost, you must access the required forms on the APM technical assistance website. The slides and recording of this webinar will be posted to the website in a few days.

The APM Technical Assistance Team is available to respond to your application questions. Please contact us at bphcsupplement@hrsa.gov.
For budget related questions, contact our partner in the Division of Grants Management Operations, Joi Grymes-Johnson.

If you need technical assistance with the EHB, you should call the BPHC Helpline or submit a request via the BPHC Contact Form listed on this slide. Please remember to select “ Applicant” as the Requestor Type, and select “ Application / Progress Report: EHB System Questions” as the Issue Type.

Thank you for your participation in today's technical assistance webinar. We look forward to supporting you as you develop your APM application over the next few weeks.

We are ready to switch gears and answer some questions from the chat pod. If you have a question specific to your organization, or if we do not get to your question during today's session, follow up with us at bphcsupplement@hrsa.gov.

I am joined by my colleagues who will help me address your questions. At this time, I'm going to turn to Olivia Shockey, the expansion division director to get us started with some questions.

Olivia Shockey: Thanks, Shannon. We have a lot of questions in the chat pod. As Shannon stated, send your questions to bphcsupplement@hrsa.gov. If we do not get your question today.

We are going to start with general questions and we will transition to some questions I think Stephanie will be able to help us answer about the All of US research project in general.

The first is a request for Stephanie's slides. We are working on that for you. Stephanie, if you have not already received the request, we will reap this might be
requesting your slides. We will be posting the webinar. It is a short application window so going back and watching this may be helpful to you. We will try to get that up within the next few days at the latest.

There was request for a list of health centers that are eligible to enable collaboration on applications. Because it is a small list, we have not posted it to our website. Please note we will be sharing the list of awardees once all is said and done so you can collaborate with your project implementation and the TA contractor will be convening you for meetings and to work together so we can all strive on helping to reach that 1 million patient mark.

Shannon, I will start technical questions for you. Is the intention of the funding opportunity that the health centers will become actual All of US enrollment sites?

Shannon McDevitt: No, it is not. That is why the APM requires patient enrollment using the direct volunteer pathway. The health centers are playing a supportive role to the patient's, making sure they have online access, that they can have secure places where they can access their All of US portals for their information and that they complete their surveys that will be performed intermittently through the next 10 make years of their participation in the research protocol. The health centers through APM funding are not becoming healthcare provider organizations. We are helping health centers expand their capacity to assist their patients in participating in All of US and that includes their health information exchange capacity because patients that do participate in All of US will have the opportunity to share electronic health records, patient data with All of US so we want to help the health centers be positioned to support their patients in that function.

Olivia Shockey: It is clear that the funding supports facilitating the direct volunteer enrollment but what if my health center wants to partner with an HPO?
Shannon McDevitt: There is no prohibition on partnering with an HPO. That is something the technical assistance contractor could mediate. The healthcare provider organizations or HPO's are operating at full tilt, we understand some may have more capacity to take on more enrollment partners than others. This will be an individual conversation and arrangement. As we said, the technical assistance contractor has a lot of experience working with All of US and Health Center and so we know that between them and the guidance from All of US, that those would be negotiations we could help with you with.

Olivia Shockey: I want to clarify because I saw the question in the chat pod. Is there any possibility that the funding will continue beyond the 2 year window?

At this time, it does not the appear that will be the case. We know health centers are offering supplemental funding and if it is for hiring providers and doing things of that nature, we are often able to make that funding ongoing, pending progress and appropriation. This funding is a little different. It is 1 time and to drive the volunteers, your patients, to volunteer for and All of US program.

Shannon McDevitt: Olivia, if I could clarify, we have not announced the training and technical assistance provider yet. We are working hard to get that finalized and we look forward to sharing that information with you as soon as possible.

Olivia Shockey: Wonderful. Stephanie, just to put you on alert, the next few questions are going to be mostly questions that will need you to answer. There were a number of questions about data. They include what data will be collected, from the patient and for how long.

The answer to the question is that the types of data will be asking patients to share are the ones I talked about in my opening. We will be sharing those slides with HRSA so that you can access them. Ultimately, we plan to expand a type of data we collect from our participants over time as we see new scientific opportunities
for technical advances that allow us to collect additional data. For example, we imagine deploying surveys over time on specific health topics. Right now, the types of data requested are survey data, self-report data, electronic health data, and information that we are generating off of our assessments from our participants as well as baseline physical measurement data. We anticipate those types of data expanding and are asking our participants to engage with the program throughout their life with the understanding that people can withdraw at any time.

Olivia Shockey: How will the data that is collected be protected since de-identified data can also be re-identified?

Stephanie Devaney: All of the data is held in our secure cloud environment. It is in a raw data repository. The data that is ultimately made to researchers will be in a curated data repository. It will be stripped of obvious identifiers before anybody can access it. When it comes to access, researchers that want to access the data have to be approved by the program and they are to adhere to a code of conduct which explicitly includes, you must not attempt to re-identify any of the participants via the portal. Among other requirements that we expect our researchers to adhere to. It requires they undergo identity proofing, ethics training, and ultimately, every time they access data, it stays in the cloud environment. Researchers are not allowed to download individual level data to their local environment. When they are starting a project within the cloud, they have to publicly state what they are using the data for. That is a requirement in the 21st Century Cures Act that requires all current data use is publicly posted so that anyone can see what types of questions researchers are asking of the data.

Olivia Shockey: One last question for you, Stephanie. Are the surveys the patients will complete, are they available in multiple languages and if so, which ones?

Stephanie Devaney: We have all of the patient-facing material in our portal available in English and Spanish.
Olivia Shockey: Wonderful. I see we are getting close to time. I will focus on a few questions specific to the applications that the health centers will complete. If you have questions about All of US in general that did not get asked here, please do send them to the bphcsupplement@hrsa.gov and we will answer them.

Shannon, do APM Health Center participants have to seek IRB approval?

Shannon McDevitt: They are not conducting a research protocol. There is no need for IRB approval.

Olivia Shockey: Will Sync for Science work with other IP vendors such as GE Centricity?

Ed Ramos: I am happy to take that one. This is Ed from NIH All of US research program. I am the program officer forcing for Sync for Science. The technology is developed in coordination with the EHR vendors. We have mentioned 4 we have been working with to date. Part of the award would be an expansion of this collaboration so the EHR vendors would allow for customization of the API that works with their system. Part of moving forward would be an evaluation of the EHR vendors across the FQHCs and to map out a plan for collaboration with those vendors and developing a Sync for Science technology solution that would work for their systems.

Olivia Shockey: A few questions about allowable expenses. I see equipment and costs are allowable. Are IT or EHR licensing also allowable?

Shannon McDevitt: There is no exclusion for licensing cost. However, you need to remember this is a 1 time funding so it is the responsibility for the Health Center to identify how you will continue to support those licensing costs which we understand can be onerous, after the project period for the supplemental funding which will be August 31, 2020.
Olivia Shockey: I see in the narrative that I need to describe how I will help my patients enroll. Do I need to set specific enrollment targets in the narrative?

Shannon McDevitt: There is no requirement to set an enrollment target. That would certainly be helpful for monitoring your progress and creating your project work plan but understanding the extent to which some of the health information exchange capacity development and other requirements we wanted health centers to focus on those and enroll as many patients as possible, but without the accountability burden of having to reach an enrollment target likely require in other HRSA funded opportunities.

Olivia Shockey: We will do 2 more questions and then wrap up. There are a lot of questions we will not get to. Send them to bphcsupplement@hrsa.gov. We have Quest Labs working with our patients. Will Quest be an access point for collection of bio supplements?

Stephanie Devaney: Sure. We do have a partnership with Quest. That partnership is separate from any of our individual partnership request. We anticipate the awareness of a relationship with Qwest in your area, there is the opportunity to think about how we are going to build capacity across the country and at what time to leverage the partnership. That is not something we have determined yet.

Olivia Shockey: The last question is, how does All of US relate to NHANES?

Stephanie Devaney: We have talked with our colleagues who work on NHANES. We are fundamentally a different program. We are structured to collecting different types of information. Although we have had a number of conversations with other data
collectors a course different programs to think about where we might be interoperable in the future.

Shannon McDevitt: Stephanie, we cannot thank you and Ed for your in person support today of our technical assistance webinar enough. I am sure that your presence has impressed upon our participants today how much NIH values Health Center participation in the All of US research program and the close partnership that NIH are enjoying as we work on this together. We look forward to future conversations with you. Thank you to our participants in our webinar today. We hope many of you are applicants and I look forward to receiving your continued questions through our inbox, bphcsupplement@hrsa.gov.

If you have a budget-specific question, send that over to our colleague, Joy and all of those EHB questions can be sent to our specific question Help Line. Thank you for your participation and enjoy your week.

Coordinator: Thank you very much. Ladies and gentleman, this conference is now concluded. You may disconnect your phone lines and have a great week. Thank you.

END