Fiscal Year 2018 Advancing Precision Medicine Supplemental Funding Opportunity (APM)

HRSA-18-126
CFDA #: 93.224

Funding Opportunity Title:	Fiscal Year 2018 Advancing Precision Medicine (APM) Supplemental Funding Opportunity
Funding Opportunity Number:	HRSA-18-126
Application Opens:	July 19, 2018
Application Due Date:	August 20, 2018 by 5 p.m. ET
Anticipated Total Available Funding:	Approximately $21 million
Estimated Number of Awards:	Up to 56 awards
Estimated Award Amount:	Up to $375,000
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2018 to August 31, 2020
Eligible Applicants:	Eligible health centers that have demonstrated that they have the health information technology readiness and organizational capacity necessary to facilitate enrollment of health center patients in the All of Us Research Program.

TECHNICAL ASSISTANCE

HRSA will hold a pre-application technical assistance (TA) webinar for eligible health center applicants. The webinar will provide an overview of this funding opportunity and an opportunity to ask questions. Visit the APM technical assistance website at https://bphc.hrsa.gov/programopportunities/fundingopportunities/advancingprecisionmedicine/index.html for webinar details, required forms, sample documents, and other resources.

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I.   PROGRAM FUNDING OPPORTUNITY DESCRIPTION

1. Purpose

These instructions detail the fiscal year (FY) 2018 Advancing Precision Medicine (APM) Supplemental Funding Opportunity for certain existing Health Center Program (H80) award recipients (hereafter referred to as health centers).[1] The purpose of APM funding is to support health center participation in the National Institutes of Health's All of Us Research Program (AoU) 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.[2]

2. Authority

This funding opportunity is authorized by section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b), as amended, and Division E, Title IX, section 50901(b) of the Bipartisan Budget Act of 2018 (P.L. 115-123), which added subsection 330(r)(5) of the PHS Act.

3. Background

The mission of AoU is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care. AoU is the cornerstone of the federal Precision Medicine Initiative.[3] Precision medicine is an emerging approach to disease treatment and prevention that considers individual variability in lifestyle, environment, and biological makeup. For more information about AoU, go to https://allofus.nih.gov/.

Participation in AoU will provide health centers with unique experiences that will enhance their use and sharing of patient data, support the delivery of comprehensive and effective services, and improve capacity to participate in future research opportunities. AoU provides a framework for researchers, health care providers, and patients to work together to develop individualized care by securely exchanging electronic patient health information. APM funding may be used to support health centers in enhancing their interoperability capacity to exchange information with AoU. Additionally, health centers that attain interoperability functionality standards that support data sharing with AoU, such as Health Level Seven (HL7)[4] and Observation Medical Outcomes Partnership (OMOP) Common Data Model,[5] will be better prepared

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[1] For the purposes of this funding opportunity, the term "health center" means organizations funded under Section 330(e), (g), (h), and/or (i) of the Public Health Service Act, as amended (i.e., Health Center Program award recipients).

[2] For more information, see https://allofus.nih.gov/about/about-all-us-research-program.

[3] For more information, see https://ghr.nlm.nih.gov/primer/precisionmedicine/initiative.

[4] For more information, see http://www.hl7.org.

[5] For more information, see https://www.ohdsi.org/data-standardization/the-common-data-model/.

for their providers to be eligible for Centers of Medicare and Medicaid Services (CMS) interoperability incentive payments, newly renamed "Promoting Interoperability."[6]

By separate action, HRSA will also provide training and technical assistance (T/TA) specific to APM with the support of a new contract that will:

- Support health centers in maximizing the use of APM supplemental funding and accelerate their achievement of the APM requirements, and
- Provide Health Center Program-wide T/TA targeted to health centers not eligible for or not awarded APM supplemental funding, and health center strategic partners (e.g., National Cooperative Agreements, Primary Care Associations, Health Center Controlled Networks) to create awareness and support around a common understanding of the value of and opportunities for health center engagement in AoU.

II.   AWARD INFORMATION

1. Summary of Funding

Approximately $21 million is available to support APM in FY 2018, which will allow HRSA to award up to $375,000 in APM supplemental funding to approximately 56 recipients for a period of performance starting September 1, 2018 through the end of their respective budget periods in 2020. Recipients may use funding throughout the previously established FY 2020 Health Center Program operational grant (H80) budget period through HRSA-approved carryover requests to the extent permitted by other applicable requirements.

Depending on the number of approvable applications, HRSA may adjust award amounts consistent with available funds. Cost sharing or matching is not required. APM funding will be made available to recipients in the same sub-program funding proportions as the existing Health Center Program operational grant funding.[7]

III.   ELIGIBILITY INFORMATION

1. Eligible Applicants

Eligibility is limited to 56 health centers with the demonstrated health information technology readiness and organizational capacity necessary to increase community awareness of AoU and facilitate enrollment of health center patients. Capacity and readiness were determined through two methods: (1) analysis of 2017 Uniform Data System (UDS) reports, and (2) current participation in AoU.

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[6] For more information, see https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html.

[7] Health Center Program sub-program funding streams are: Community Health Centers (CHC), Migrant Health Centers (MHC), Health Care for the Homeless (HCH), and/or Public Housing Primary Care (PHPC).

Health centers currently participating in AoU may receive APM supplemental funding if they:

- Are identified in the applications of currently funded AoU health care provider organizations in response to NIH funding announcements as of May 1, 2018, and
- Propose new activities aligned with the APM purpose and requirements.

The following 2017 UDS metrics were used to identify additional health centers eligible to apply for APM funding:

- Patient-centered medical home (PCMH) recognition as of December 31, 2017;
- At least 2.5 patient/community education specialist full-time equivalents (FTEs);
- At least 20 physician FTEs;
- Attainment of CMS Meaningful Use Stage 2, with all eligible providers at all sites participating in CMS Meaningful Use; and
- Electronic health record (EHR) functionality that includes:
  o Electronic prescribing,
  o Clinical decision support,
  o Health information exchange with other providers and health care settings,
  o Patient engagement,
  o Electronic clinical summary, and
  o Coordinated enabling services.

2. Project Requirements

Your proposal must demonstrate how you will use APM funding to achieve the following:

- Increase the number of health center patients enrolled in AoU using the Direct Volunteer Pathway.[8]
- Enable patient participation in AoU by:[9]
  o Upgrading to the latest version of an Office of the National Coordinator for Health Information Technology (ONC)-certified EHR[10];
  o Increasing patient use of patient portals and other health information technology;[11] and

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[8] Individuals enrolling through the Direct Volunteer Pathway will enroll through an application, a website, or a toll-free call center. They will have their baseline physical measurement and biospecimen collections facilitated by AoU and conducted at participating Walgreens stores, designated commercial laboratories, or the Journey Bus (i.e., mobile unit that can facilitate all aspects of the program).

[9] Health information technology requirements to exchange patient information with AoU are described in the AoU protocol. This research protocol is provided as a resource only; APM does not require health centers to implement the AoU research protocol.

[10] CMS and ONC have established standards and other criteria for structured data. For additional information, refer to https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html.

[11] For more information, see https://www.healthit.gov/sites/default/files/170_315g7_application_access_patient_selection_v1_0_1_1.pdf.

- o Using an application programming interface (API) that supports HL7 Fast Healthcare Interoperability Resources (FHIR),[12] including Sync for Science,[13] to enable patients to share at a minimum the Common Clinical Data Set[14] of their health information with AoU.
- Create ability to export patient data in a format to support the use of OMOP Common Data Model for sharing data with AoU.

The funding request must:
- Demonstrate how the funding will be used, in part, for ONC-certified EHR purchases or upgrades that will support participation in a data collaborative using the OMOP Common Data Model and/or HL7 standards for the exchange, integration, sharing, and retrieval of electronic health information. If your EHR already has these capacities, your application must demonstrate this, as well as how APM funds will be utilized to achieve the other APM requirements.
- Include funding for key APM project team members to travel to a 2-day meeting held by the federal T/TA contractor.

3. Examples of Allowable APM Funding Uses

The following list of example allowable activities under this funding opportunity is not exhaustive. You may propose other activities that address the APM purpose and requirements.
- Establish and implement protocols to engage, educate, motivate, and facilitate the Direct Volunteer Pathway enrollment and retention of health center patients in AoU that target communities historically underrepresented in biomedical research and comply with the AoU research protocol.
- Recruit and hire staff and/or allocate FTEs to implement protocols, which may include physician champions,[15] outreach workers, patient/community education specialists, community health workers, and information technology staff.
- Purchase supplies to support the implementation of protocols, such as tablets, kiosks, and office furniture.
- Improve patients' health and digital literacy to support their enrollment and retention as participants in AoU.
- Improve patients' knowledge of precision medicine and AoU to support enrollment and retention as participants in AoU.
- Hire staff and/or contractors or consultants to support protocol development, training, and implementation; adoption of EHR enhancements; and patient data integration, use, and sharing.

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[12] For more information, see https://www.hl7.org/fhir/.
[13] For more information, see http://syncfor.science/.
[14] For more information, see https://www.healthit.gov/sites/default/files/commonclinicaldataset_ml_11-4-15.pdf.
[15] Champions are leaders who promote change and facilitate improvement efforts.

- Upgrade and/or enhance the in-use EHR to have patient data extracted and transformed in the AoU-specified OMOP Common Data Model for exporting to AoU.
- Upgrade to an ONC-certified EHR and/or tethered patient portal that allows patients to share their EHR's Common Clinical Data Set with applications of their choice.
- Upgrade to an API that supports the HL7 FHIR data standard and the OAuth 2 authorization standard of Sync for Science.[16]
- Enhance technical capacity to support the secure sharing of patient data with health care partners to enhance patient care continuity and efficiency, patient centered care, patient outcomes, and patient safety.
- Train health center staff and providers in using new protocols, new standard operating procedures, and health information technology enhancements, such as those to EHRs, patient portals, and health information exchange platforms.
- Establish standard operating procedures to effectively exchange health information to enhance patient care and treatment planning for patients partnering with AoU.

4. Partnership Resources

Health center strategic partners, including Primary Care Associations, Health Center Controlled Networks, and applicable National Cooperative Agreements, may be helpful resources to help you identify high impact and cost effective uses for APM funding in areas of their current work plans that align with APM and AoU-related activities.

5. Ineligible Costs

All proposed budget items must directly support the APM purpose and requirements as demonstrated in the Project Narrative and the Budget Narrative.

Examples of unallowable costs include, but are not limited to:
- Clinical services
- Purchase or upgrade of an EHR that is not certified by ONC[17]
- Fundraising
- Support for lobbying/advocacy efforts
- Incentives (e.g., gift cards, food)
- Construction/renovation costs
- Facility or land purchases
- Vehicle purchases

Pursuant to existing law, and consistent with Executive Order 13535 (75 FR 15599), health centers are prohibited from using federal funds to provide abortion services (except in cases of rape or incest, or when the life of the woman would be endangered).

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[16] For more information, see http://syncfor.science/use-case/clinical/.
[17] See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html.

This includes all funds awarded under this announcement and is consistent with past practice and long-standing requirements applicable to grant awards to health centers.

IV.   APPLICATION AND SUBMISSION INFORMATION

1.   Application Announcement, Deadline, and Award Notice

For all eligible health centers, HRSA sent an email notification through the HRSA Electronic Handbooks (EHB) to the Project Director and Authorizing Official, as listed in the EHB Health Center Program operational grant folder. This email specified the sub-program[18] funding proportions applicable to your application and provided details on how to access the application module in EHB.

Applications are due in EHB by **5 p.m. ET on August 20, 2018**. HRSA anticipates making awards in September 2018.

2.   Application Requirements

See Appendix A: Application Instructions for a detailed description of how to complete each application component. Refer to Appendix B: Budget Narrative Instructions for detailed Budget Narrative instructions.

3.   DUN and Bradstreet Universal Numbering System and System for Award Management

Every applicant is required to have a valid Dun and Bradstreet Universal Numbering System (DUNS) number, also known as the Unique Entity Identifier, and to maintain an active System for Award Management (SAM) registration at all times. HRSA may not make an award until you have complied with all applicable DUNS and SAM requirements. If you have not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that you are not qualified to receive an award.

UPDATED SAM.GOV ALERT: For your SAM.gov registration, you must submit a notarized letter appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018. Read the updated FAQs to learn more.

SAM.gov is experiencing high volume and delays. If you have tried to create or update your SAM.gov registration but have not been able to complete the process, you may not be able to apply for a HRSA funding opportunity via Grants.gov in a timely manner prior to the application deadline. If so, please email DGPwaivers@hrsa.gov, per the instructions in Section 3.6 of your HRSA Application Guide.

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[18] Health Center Program sub-program funding streams are: Community Health Centers (CHC), Migrant Health Centers (MHC), Health Care for the Homeless (HCH), and/or Public Housing Primary Care (PHPC).

4. Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

You certify, by submission of this proposal that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency. Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321.)

5. Financial Management and Accounting

You must have accounting structures and internal controls in place that provide accurate and complete information for costs associated with this award. HRSA funding must be tracked separately from other sources of support.

V. REPORTING REQUIREMENTS

1. Reporting and Additional Requirements

Health centers providing evidence of possessing the described target EHR capacities must demonstrate how APM funds will be used to address other APM requirements, including facilitating enrollment where needed.

Progress toward achieving APM requirements will be monitored through required annual UDS reports and APM-specific triannual progress reports. These reports will include data and a brief summary of APM implementation progress and barriers on measures including, but not limited to, the following:

- Number of patients the health center has engaged through health information technology, such as patient portals, kiosks, or secure messaging (i.e., secure email) either through the EHR or through other technologies.
- Number and demographics of health center patients enrolled in AoU.
- Progress toward meeting HL7 and/or OMOP Common Data Model standards (e.g., status of EHR upgrades, as applicable).
- EHR data exchange with AoU.

2. Application Reviews

HRSA will conduct reviews for completeness, eligibility, and allowable costs. HRSA reserves the right to request budget modifications and/or narrative revisions if an application is not fully responsive to the APM instructions or if ineligible activities or purchases are proposed.

Prior to award, HRSA will assess the Health Center Program award status of all applicants. You are not eligible to receive APM funding if you meet any of the following exclusionary criteria at the time of award:
- Have stopped receiving Health Center Program operational grant funding.

- Have five or more conditions on your Health Center Program operational grant related to Health Center Program requirement area(s) that are in the 60-day phase of Progressive Action.
- Have one or more conditions on your Health Center Program operational grant related to Health Center Program requirement area(s) that are in the 30-day phase of Progressive Action.

The Health Center Program is subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100. See Executive Order 12372 in the [HHS Grants Policy Statement](#). You must comply with applicable requirements of all other federal laws, executive orders, regulations, and policies governing the Health Center Program.

VII. AGENCY CONTACTS

For assistance completing the APM application, contact the appropriate resource below.

APM Points of Contact Table

HRSA EHB issues:	Technical assistance resources:
Bureau of Primary Health Care (BPHC) Helpline 1-877-974-BPHC (2742) (select option 3) Send email through Web Request Form	https://bphc.hrsa.gov/programopportunities/advancingprecisionmedicine/index.html Provides application instructions, required forms, sample documents, and other resources
Application and funding requirements questions:	**Budget and grant administration questions:**
APM technical assistance team bphcsupplement@hrsa.gov	**Joi M. Grymes-Johnson** Office of Federal Assistance Management Division of Grants Management Operations jgrymes@hrsa.gov

APPENDIX A: APPLICATION INSTRUCTIONS

APM applications will be completed and submitted in EHB. Below are instructions for each application component. The forms required to be submitted as attachments, an EHB User Guide, and additional resources are available on the APM technical assistance website at https://bphc.hrsa.gov/programopportunities/fundingopportunities/advancingprecisionmedicine/index.html.

<u>SF-424 Basic Information and Budget Forms</u>
Enter the required information on SF-424 Part 1 and Part 2. Fields that are not marked as required may be left blank. APM funding must be requested by and will be awarded in the same sub-program (i.e., CHC, MHC, HCH, PHPC) funding proportions as existing grant funding. 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 need not be spent in equal amounts in each year of the two-year period of performance. Through an EHB email, HRSA provided each eligible health center the maximum funding request by sub-program funding proportions.

<u>Project Description/Abstract (upload as attachment in SF-424A Part 2)</u>
The "Project Description/Abstract" attachment is not required for the APM application, but the EHB system requires an attachment in this area. You may elect to attach either a:
- Brief description or logic model that explains your proposed project, or
- Blank document.

<u>Attachment 1: Federal Object Class Categories Form</u>
Enter federal and non-federal expenses by object class category (e.g., personnel, equipment, supplies) for all proposed activities by year. The total funding request may not exceed $375,000 and need not be spent in equal amounts in each year.

<u>Attachment 2: Budget Narrative (upload attachment)</u>
Complete a 2-year budget narrative that describes costs for all proposed activities. Clearly detail the federal and non-federal costs (including program income, 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 for detailed instructions.

<u>Attachment 3: Staffing Impact Form</u>
Enter the direct hire staff and/or contractor FTEs that will help achieve the APM purpose and requirements according to the allowed position types listed on this form. Position descriptions are available in the 2018 UDS Manual.

If you propose to hire contractors or consultants, explain how the contracted FTE estimate was developed and include details regarding the proposed contractual arrangement(s) in the Budget Narrative. The contractual arrangements must be

appropriate for health center oversight of the proposed project, including any contractors and sub-recipients, or parent, affiliate, or subsidiary arrangements.

Attachment 4: Project Narrative
Provide a focused project narrative that describes how you will:

- Increase the number of health center patients enrolled in AoU through activities that focus on community/populations historically underrepresented in biomedical research, including but not limited to individuals with physical disabilities, racial or ethnic minorities, women, individuals from geographically isolated communities, economically disadvantaged individuals, and sexual and gender minorities.
- Upgrade your EHR to export patient data in a format to support the use of OMOP Common Data Model for sharing data with AoU.
- Increase patient use of patient portals and other health information technology.
- Enable patients to share, at a minimum, the Common Clinical Data Set of their health information with AoU via an API that supports HL7 FHIR, including Sync for Science.
- Collect and report APM-relevant measures not currently tracked through UDS. See additional details in Reporting and Additional Requirements.

In addition, the project narrative will describe how proposed direct hire staff and/or contractor(s) supported with APM funding will support APM activities.

Attachment 5: Equipment List Form
If funding is requested in the Equipment line item on the Federal Object Class Categories Form, list the proposed equipment purchases. Federal equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds $5,000. See additional details in Appendix B: Budget Narrative Instructions. The total on this form must equal the total amount of federal funding requested on the Equipment line item on the Federal Object Class Categories Form. Enter "0" and "N/A", as appropriate, if APM supplemental funding will not be used to purchase equipment.

Attachments 6 - 15: Additional Information
Attach additional documents to support your application, if desired.

- 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 (e.g., exports patient data using the OMOP Common Data Model; meets HL7 standards for the exchange, integration, sharing, and retrieval of electronic health information).

APPENDIX B: BUDGET NARRATIVE INSTRUCTIONS

Provide a Budget Narrative that outlines the federal and non-federal (if any) costs for each line item. Include the following for the entire requested funding (up to $375,000), regardless of whether it will be spent in the first or second year of the project. A sample Budget Narrative is available on the APM technical assistance website.

Your budget narrative must:
- Clearly detail calculations for how each line item is derived on the Federal Object Class Categories Form, including cost per unit.
- Explain how each cost contributes to meeting the APM requirements to help HRSA determine if costs are allowed.[19]

Cost Category	Budget Presentation Description
Personnel	List each direct hire staff member who will be supported by APM supplemental funding. Include the name (if possible), position title, FTE, and annual salary. Review the salary limit information provided below to develop the required Personnel Justification Table.
Fringe Benefits	List the components that comprise the fringe benefit rate (e.g., health insurance, taxes, unemployment insurance, life insurance, retirement plan, tuition reimbursement) for the proposed staff. The fringe benefits should be directly proportional to the portion of personnel costs allocated for this project.
Travel	The travel budget should reflect expenses associated with travel for consultants, direct hire staff, and/or contractors to attend trainings. List travel costs according to local and long distance travel. For local travel, include the mileage rate, number of miles, reason for travel, and individuals traveling. You must allocate funding for key APM project team members to travel to a 2-day meeting that will immediately precede or follow a national health center meeting to be held in Washington, DC.

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[19] Refer to the cost principles embedded in 45 CFR Part 75, see http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75 for details on allowable costs.

Cost Category	Budget Presentation Description
Equipment	Equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-federal entity for financial statement purposes, or $5,000. APM funding must be used, in part, for EHR upgrades that will support participation in a data collaborative using the OMOP Common Data Model and/or HL7 standards for the exchange, integration, sharing, and retrieval of electronic health information **unless** you document in Additional Information that your EHR already has these capacities.
Supplies	List the items necessary for implementing the proposed project. Items that do not meet the $5,000 threshold listed above for Equipment should be included here.
Contractual	Provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables. You are responsible for ensuring that your organization has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring contracts.
Other	Include all costs that do not fit into any other category and provide an explanation of each cost.

Salary Limitation Requirements

The Consolidated Appropriations Act, 2018 (P.L. 115-141) states that "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." The Executive Level II salary is currently set at $189,600. This salary limitation also applies to sub-awards/sub-contracts under a HRSA grant or cooperative agreement. Note that other salary limitations may apply in FY 2018, as required by law.

The information included in Personnel Justification Table, example below, must be provided for all direct hire staff and contractors proposed to be supported with APM supplemental funding. Direct hire staff and contractors supported entirely with non-federal funds do not require this level of information.

Example Personnel Justification Table for Proposed Personnel

Name	Position Title	Base Salary	Adjusted Annual Salary	% FTE	Federal Amount Requested
J. Smith	Physician champion:[20] 0.10 FTE x 200,000	$200,000	$189,600	10%	$18,960
R. Doe	Social Worker (enrollment facilitator): 0.25 FTE x 60,900	$60,900	No adjustment needed	25%	$15,225
D. Jones	Community health worker (outreach and recruitment): 1.0 FTE x 42,340	$42,340	No adjustment needed	100%	$42,340
	TOTAL				$76,525

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[20] Champions are leaders who promote change and facilitate improvement efforts.