

MP-CPI-20-004: Sickle Cell Disease Clinical Data Platform**Eligibility/Application**

Questions	Responses
Who is eligible to apply?	All applicants are eligible except for for-profit private institutions of higher education and for-profit organizations (including small businesses). Eligible applicants include: • State Governments • County Governments • City or township governments • Special district governments • Independent school districts • Public and State controlled institutions of higher education • Native American tribal governments (Federally recognized) • Public Housing authorities/Indian housing authorities • Native American tribal organizations (other than federally recognized tribal governments) • Nonprofits having 501(c)(3) status with the IRS, other than institutions of higher education • Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education • Private non-profit institutions of higher education • U.S. Territories
Are we required to provide cost sharing or matching?	You are not required to provide cost sharing or matching in your proposed budget.
Can we submit a proposed budget plan for just the first year of the project?	You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application that must cover all years (2) of the project period. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by "object class categories" identified on the SF-424A and justification of the costs.
Can we get an extension on the application deadline?	There are no current plans to extend the application deadline. Individual extensions on the application deadline will not be granted except as described in the funding opportunity announcement (FOA).

I represent a for-profit organization. If I have a non-profit partner that applies and receives the award, can I be a subrecipient?	No. OMH statutory authority limits recipients to public and non-profit entities. Subrecipients must also abide by the statutory limitation.
Who makes a determination concerning whether an entity is considered to be a subrecipient?	The HHS Uniform Administrative Requirements (UAR), 45 CFR 75.351, states that the recipient “must make case-by-case determinations whether each agreement it makes for the disbursement of Federal program funds casts the party receiving the funds in the role of a subrecipient or a contractor.” Characteristics which support the classification of the non-Federal entity as a subrecipient can be found at 45 CFR 75.351. The applicant should consult with its counsel for advice concerning the applicability of this section to its particular situation.
I’m having problems with the Grants.gov application platform. Can you help?	For assistance, you can reach GRANTS.GOV Applicant Support at 1-800-518-4726.
Can we use a biosketch instead of CV?	Yes.
Is there a reason why there is only 30 days to submit this application?	Fiscal Year 2020 funds are available to be awarded for this FOA until September 30, 2020. Applications are due to Grants.gov no later than August 18, 2020 at 6:00 pm Eastern to allow adequate time for objective review and administrative processes.

General Information

Questions	Responses
Is the award amount listed for 1 year or 2?	The award ceiling and floor amounts are listed per budget period (12 months). The project period is for 2 years. Please note that due to timing of award issuance or other administrative factors, funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, adequate stewardship of Federal funds, and the best interests of the Government.
When does the project start?	The anticipated start date is September 30, 2020.
Will this opportunity happen again?	This is first time that the funding opportunity announcement is being competed. At this time, there are no plans to compete this opportunity again.
Was there a planning grant previously awarded to develop the requirements in this FOA?	No.
How can I access the slides from the TA webinar?	You can download them from Grants.gov at: https://www.grants.gov/web/grants/view-opportunity.html?oppld=328140 A PDF file of the slides is available on the Related Documents tab on Grants.gov, at the page for this FOA.
When is the earliest date for the project to start?	The anticipated start date is September 30, 2020.

Programming

Questions	Responses
What is the target population?	The target population is healthcare providers who treat people with sickle cell disease (SCD).
To whom does the Technical Advisory Group provide advice?	The Technical Advisory Group (TAG) provides advice to the grantee. It does not provide advice to the Office of Minority Health (OMH). OMH will not manage or control the TAG, and any advice is expected to be given to the grantee.
There are a few places in the FOA that seem to imply that the evaluator will be external to the applicant organization. Is it a requirement that the evaluator be external?	No. However, page 24 of the FOA states: <i>"Please also describe the relationship between your evaluator and your organization and the degree of independence the evaluator will have."</i>
Is IRB approval required?	Recipients must comply with all HHS regulations, including those governing protection of human subjects. You may find more information online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html . To the extent the HHS regulation governing protection of human subjects applies, IRB approval is required prior to beginning any work with human subjects (Subpart A of 45 CFR Part 46).
What is the relationship between the awardee, the hub sites and the satellites?	OMH expects that the successful applicant will describe the process for identifying and recruiting hub sites and their satellite sites, and encouraging participation in the shared data collection platform and collaborative learning community. The successful applicant is also expected to describe the process for executing Memorandums of Agreement (MOA) with participating hub sites and state partners and any other organizations and entities that have been specifically named as a sub-recipient to carry out any aspect of the project. The signed MOA must clearly detail the specific role and resources (including in-kind) that each entity will bring to the project; state the duration and terms of the agreement; cover the entire project period; and be signed by an authorized representative. The organization's expertise, experience, and access to the targeted population(s) should also be described in the MOA. Hub sites may be sites such as academic health centers, including those that are or are in HBCUs, or health systems. Satellite sites may be sites such as community hospitals or federally qualified health centers.

Are there specific requirements for the data management plan mentioned in the FOA?	See Page 10 of the FOA for a description of the data management plan.
The FOA notes "OMH expects the MOA to include partnerships with relevant State Health Department(s) and/or State Medicaid Offices." Are there particular goals for this requirement?	The FOA does not specify specific goals for partnerships with State Health Departments and State Medicaid Offices
Do CE credits need to be offered during either the first or second-year period of performance to avoid losing evaluation points on the project plan? Or is it possible to score full points showing CE capability?	The FOA does not include expectations for when CE credits should be offered. Page 23 of the FOA states, "Describe the process for providing continuing education (CE) credits, Maintenance of Certification (MOC), and other educational incentives, as applicable".
Does the data platform need to differentiate between confirmed and probable cases? If so, will the platform need to include probabilistic matching features to assist in the determination of probable cases?	The FOA does not include this expectation.

Will evaluation points be added or deducted based on the number and quality of the letters of commitment to serve on the TAG?	Page 21 of the FOA states: “Describe how the technical advisory group (TAG) will be assembled, including identification and recruitment of potential members, development of TAG policies and protocols, and governance structures.” The application will be assessed for the degree to which the plan is adequate for recruiting and retaining the technical advisory group (TAG) with community members living with SCD or family members with SCD, as well as those knowledgeable of SCD patient care, clinical data platform development, SCD clinical trials networks, the CDC’s Sickle Cell Data Collection Program, private insurance and Medicaid reimbursement policies, patient/family engagement in care, and data security and privacy.
Should budgets include allocation for members of the learning community, including, but not limited to, hub and satellite members?	The requirements for the Budget Narrative and budget forms begin on page 25 of the FOA.
Is the expectation that the technical advisory group (TAG) structure be on a voluntary-basis, or should we build-in cost, including travel, for proposed TAG members?	Page 21 of the FOA states: “Describe how the technical advisory group (TAG) will be assembled, including identification and recruitment of potential members, development of TAG policies and protocols, and governance structures.” The requirements for the Budget Narrative and budget forms begin on page 25 of the FOA.
Where will be hosting done?	The FOA describes the requirements for the SCD data collection platform on pages 21-22.
Is there a minimum geography or population size necessary?	The FOA does not include a minimum geography or population size expectation.
Can we host on HIPAA compliant Microsoft or Google Servers?	The FOA describes the requirements for the SCD data collection platform on pages 21-22.
How is this coordinated with ASH Research Networks efforts?	The SCD Clinical Data Collection Platform initiative is a priority of the Office of the Assistant Secretary for Health. However, the ASH Research Network is not addressed in the FOA for this initiative.

Has OMH given consideration to make it a requirement that applicants include community based organizations as a required collaboration entity just as state health departments? Satellite sites such as FQHCs and community hospitals are listed (slide 10). Many times the role of non-clinical entities such as CBOs in working with patients and families to participate in projects such as the Data Collection Platform is overlooked. When granting agencies don't require specific collaboration, CBO participation is often relegated to participation on an advisory committee.	The expected collaborations are as specified in the FOA.
We generally use MS SQL Server. Is there a specific database server needed?	The FOA describes the requirements for the SCD data collection platform on pages 21-22.

Two requirements seem to suggest that the participating sites need not be recruited at the time of submission. Is that correct?	Page 22 of the FOA states: <i>“Describe the process for identifying and recruiting hub sites and their satellite sites, based on defined selection criteria and encouraging participation in the shared data collection platform and collaborative learning community.”</i> (Emphasis added.) Page 22 also states: <i>“Describe the process for executing Memorandums of Agreement (MOA) with participating hub sites and state partners.”</i> (Emphasis added.) If available at the time of submission, signed memoranda of agreement (MOAs) or signed Letters of Commitment (LOCs) may be submitted for each partner (or one signed MOA with all partners) and include specific roles, responsibilities, resources, and contributions of partner(s) to the project. MOAs signed by all partners are preferred as documentation to support the commitment of the partner organizations. If the applicant is unable to submit signed MOAs because of COVID-19 impacts, the applicant should submit an unsigned MOA(s). LOCs may be submitted at the time of application with the expectation that fully executed MOAs will be requested before an awarded project begins. The MOAs and signed LOCs must detail the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization’s expertise, experience, and access to the targeted population(s) should also be described in the LOC. Fully executed MOAs will be required within 30 days following the issuance of any award made under this announcement.
Is there a designated salary amount for this project? The presenter mentioned there was a typo on the amount listed on one of the slides.	Please see the funding restrictions on pages 42-43 of the FOA. The individual salary cap is based on the Federal Executive Pay Scale Executive Level II. As of January 2020, the Executive Level II salary is \$197,300 per annum. The amount must be prorated based on the level of effort (e.g., % of FTE) applied to the project as described in the FOA.