

**RFA-HS-23-012: Implementing and Evaluating New Models for
Delivering Comprehensive, Coordinated, Person-Centered Care to
People with Long COVID (U18)**

Frequently Asked Questions

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General Application Process

1. **Where can we access slides from the pre-application technical assistance call held on May 1st?**

The slides are available on AHRQ's [Notice of Funding Opportunities](#) page or you can download them directly at [HS-23-012-webinar-slides.pptx](#).

2. **On the PHS 398 Research Plan Form, is #2 - Specific Aims under the Research Plan Section required for this submission?**

Yes, a Specific Aims page is required for this submission.

3. **Where should the required application elements “Description of Current Clinic” and “Proposed Project Description” be included in the application?**

These elements should be included in the PHS 398 Research Plan Form in the Research Strategy section (#3).

4. **What information should we include in the 12-page Research Strategy section on the PHS 398 Research Plan Form? Should we use the standard NIH grant application structure for this submission?**

The 12-page Research Strategy section should include the required application elements, “Description of Current Clinic” and “Proposed Project Description” (see RFA [Section I. Funding Opportunity Description](#)). Applicants may structure the Research Strategy section as they see fit, as long as all required elements are included. However, many applicants choose to follow the general format suggested in the application guide. Applicants should consider whether reviewers will be able to easily find the information required for them to evaluate the proposal (see RFA [Section V: Application Review Information](#)).

5. **Can an organization submit multiple applications?**

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. We urge applicants to work with other clinics or departments within their organizations that may be applying for this opportunity to coordinate, prioritize, and avoid duplicate efforts.

6. **The RFA states that applicants must follow the SF424 guidance for R mechanisms, which lists items such as Specific Aims and Facilities and Equipment as mandatory. Are these required for this submission (U18 mechanism)? The only required files in ASSIST are the Project Summary/Abstract, Project Narrative, Research Strategy (for which there is additional guidance) and budget justification.**

As the RFA indicates in [Section IV: Application and Submission Information](#), it is important to follow the Research (R) Instructions in the [SF424 \(R&R\) Application Guide](#), except where instructed in this notice of funding opportunity or another Guide Notice to do otherwise. ASSIST and other systems only run validations for a subset of required application components, not all. If applications are submitted without required information, they may be considered non-responsive and not undergo scientific review.

7. Can you clarify the Data Management Plan requirements?

Data Management Plans (DMPs) are required for all applications to this RFA. DMPs should describe what data will be generated (e.g., for evaluation activities) and how the recipient will manage, store, and disseminate data generated. Please review the RFA DMP section and the “[AHRQ Data Management Plan Policy](#)” for additional details.

The DMP should be submitted under the Resource Sharing Plan section of a grant application. Please see [NOT-HS-23-012: Notice of Change](#). DMPs do not count toward page limits.

8. Are letters of support required from all senior/key personnel and other significant contributors?

Provide letters of support from partnering organizations or clinicians, where possible. Letters of support may also be submitted to demonstrate the support of consortium participants (if applicable) and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. The letters’ text should demonstrate their specific commitment and summarize any agreements in place to support the proposed project.

Eligibility

9. Are VA clinics eligible to apply for this RFA?

Possibly, provided they meet all other eligibility criteria. Federal institutions are generally eligible for this RFA, but there are unique requirements and budget considerations for federal applicants to other federal funding agencies that should be discussed with the applicant’s institutional official.

10. Are there any special considerations if the applicant organization is a university and the participating Long COVID clinic is a VA site?

In this scenario, there are no special program or budget considerations beyond those specified in the [HHS Grants Policy](#) and [45 CFR Part 75](#) (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards).

11. Are Federally Qualified Health Centers (FQHCs) eligible for this RFA?

Yes, FQHCs are eligible for this RFA provided they meet all other eligibility criteria.

- 12. We currently have a post-COVID research clinic. We collect healthcare data and offer testing such as EKG and ECHO. We refer patients with any significant findings to their primary care physician for follow-up. Do you consider a research clinic to be eligible for funding?**

The definition of an existing, multidisciplinary Long COVID clinic is provided in the RFA. Applications that do not meet this criterion will not be considered for funding.

- 13. If our Long COVID clinic is newly operational in May, will it meet the criterion of “existing clinic?”**

If the clinic is up and running by the application due date, it would meet the basic criterion of “existing clinic”. If your institution also meets other eligibility criteria, you would be eligible to apply. Please consider whether you can adequately report on the current care delivery model and challenges, as these aspects are included in the application Scored Review Criteria (see [Section V. Application Review Information](#)).

- 14. If our clinic or partners have funding from NIH or other public or private funders for Long COVID research, are we eligible to apply for this RFA?**

Yes, provided the purpose of the other funding does not conflict with the goals of this RFA and there is no overlap (“double-dipping”) in funding.

Multiple Organizations and Consortium Arrangements

- 15. Can two or more Long COVID clinics apply together in this U18 to eliminate overlapping offers?**

Yes, as long as the primary applicant meets the eligibility criteria and the proposed activities meet the RFA requirements. The total budget cap remains the same regardless of the number of clinics involved in the application. The total page limit (12 pages) also remains the same for describing the current clinic and proposed projects (if different) of multiple, unaffiliated clinics.

- 16. Can the organization implementing the care delivery model be a subcontractor to an independent entity that serves as the recipient of the grant funding, if a majority of funds awarded are allotted to the delivery model’s implementation?**

Possibly. As stated in RFA [Section III. Eligibility Information](#), the [HHS Grants Policy](#) requires that the grant recipient perform a substantive role in the conduct of the planned project and not merely serve as a conduit of funds to another party. If consortium activities represent a significant portion of the overall project, the applicant must justify why the applicant

organization, rather than the party performing this portion of the overall project, should be the recipient and what substantive role the applicant organization will play.

17. Should participating Long COVID clinics be treated as subawards in the budget?

Clinics may either be the applicant organization (or part of it) or subawardees. Please contact the Office of Sponsored Projects within your organization to determine an appropriate designation of the clinic in the budget. In general, organizations collaborating with a grant applicant are considered subawardees and a grant applicant should establish consortium agreements with collaborating organizations. However, please discuss this matter with your Office of Sponsored Projects.

The [HHS Grants Policy](#) (Page B-4) defines consortium agreement as follows: “A formal agreement whereby a project is carried out by a recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned project or program activity and not merely serve as a conduit of funds to another party or parties. Consortium agreements are considered subawards for purposes of this policy statement.”

18. For applications that involve PDs/PIs from multiple organizations, will funds awarded be passed solely to the applicant organization and is it expected that other organizations will receive their apportioned allotment from the applicant organization? Is it permissible for two organizations, each with a PD/PI, to enter into a cooperative agreement and receive their apportioned allotment directly from AHRQ?

There can only be one applicant organization per application. AHRQ will authorize funds solely to the applicant organization. If multiple organizations are proposed in the application, the applicant organization is responsible for establishing consortia agreements with partnering organizations to create subawards and transfer a portion of the authorized funds to those organizations to conduct the research.

The [HHS Grants Policy](#) (Page B-4) defines consortium agreement as follows: “A formal agreement whereby a project is carried out by a recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned project or program activity and not merely serve as a conduit of funds to another party or parties. Consortium agreements are considered subawards for purposes of this policy statement.”

19. Does AHRQ prefer that the applicant clinic work with their state public health, behavioral health, and Medicaid programs for expansion of community resources and primary care? Is the state government one of the community-based organizations with which applicants should have a partnership?

There are no requirements for specific types of partnerships. Applicants should propose partners that will help the applicant meet the goals of the RFA.

20. Are there small business subcontracting requirements?

No. Since this is not a contract opportunity, there are no subcontracting requirements.

Personnel

21. How many PDs/PIs are allowed for this project?

There is no specific requirement related to the number of PDs/PIs allowed. As stated in RFA [Section III. Eligibility Information](#), “For institutions/organizations proposing multiple PDs/PIs, visit the Multiple PD/PI Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide. The AHRQ multiple PDs/PIs policy can be found at <https://grants.nih.gov/grants/guide/notice-files/NOT-HS-16-018.html>. A single PD/PI, or the multiple PD(s)/PI(s) combined, must devote at least 20% minimum FTE (i.e., at least 8 hours per week) in each given year of the project. If any effort is in-kind, this should be explained in the budget justification, and a letter of support from an authorized institutional official is required.”

22. Will an application with an Early-Stage Investigator (ESI) proposed as PD/PI be considered competitive? If a PD/PI currently is an Early-Stage Investigator and is awarded funding, does that mean ESI status cannot be applied to future NIH grants?

AHRQ does not consider Early-Stage Investigator status in application scoring or funding. Please direct any questions about ESI status for NIH opportunities to NIH.

23. Are there any requirements related to seniority status or number of years of experience for PDs/PIs, key personnel, or other investigators?

There are no requirements related to seniority or years of experience for personnel. However, your application must demonstrate that the proposed investigator team, including key personnel, has the necessary qualifications to perform their assigned roles. Please review requirements related to “Investigator(s) and Organization(s)” under “B. Proposed Project Description” in RFA [Section I. Funding Opportunity Description](#) and review criteria for “Investigator(s)” under “Scored Review Criteria” in RFA [Section V. Application Review Information](#).

24. Can someone be a co-PI without having a track record of publications related to Long COVID?

There is no specific requirement for PDs/PIs or other key personnel to have Long COVID-related publications. However, your application must demonstrate that key personnel have the necessary qualifications to perform their assigned roles. Please review requirements related to

“Investigator(s) and Organization(s)” under “B. Proposed Project Description” in RFA [Section I. Funding Opportunity Description](#) and review criteria for “Investigator(s)” under “Scored Review Criteria” in RFA [Section V. Application Review Information](#).

25. Is the level of effort (i.e., FTE) listed for the PD/PI and other key personnel in the application and Notice of Award (if the application is funded) fixed?

No, the level of effort for the PD/PI or other key personnel proposed in the application and listed in the Notice of Award is not fixed. However, reductions in effort greater than 25% from the level that was approved at the time of award for key personnel would require written prior approval from AHRQ. See the [HHS Grants Policy](#) section on “Change in Status, including Absence, of Principal Investigator/Project Director and Other Key Personnel” (Page II-54). Further, any reduction that would cause the PD/PI to devote less than 20% FTE to the project would require written prior approval of AHRQ. Applicants may also propose varying levels of effort across project years, provided RFA requirements are met.

Budget

26. May we request an exception to the budget limits in the RFA? Do we need to seek AHRQ approval for funding requests with direct costs more than \$500,000?

There is no direct cost limit for this RFA, only a total cost limit. Total costs include both direct and indirect costs. Cost structure (i.e., direct and indirect cost breakdown) within the total cost limit should be discussed with your institution. AHRQ will not consider requests above the total cost limits described in the RFA (\$1,000,000 in any given year and \$5,000,000 for the entire project period).

27. How much should we budget for travel and other costs related to the grantee Learning Community?

Applicants must budget for up to two key personnel to travel to the Washington, DC area once each year for a one- or two-day annual Learning Community meeting. Applicants will also be required to participate in monthly virtual Learning Community meetings and other minor Learning Community activities (that do not involve travel), as needed. Applicants must budget for these activities accordingly.

28. If an individual does not have insurance or has a gap in coverage, can the grant provide funding for the uninsured individual to receive care at the Long COVID clinic? Should we limit such use of funds to some percentage of total funds, i.e., is there a maximum amount allowed for use for such patient care costs?

Applicants may potentially propose to use funds to cover patient care for people without insurance. However, as stated in the RFA, AHRQ funding is not intended to replace existing

sources of funding for care and services provided. For example, if a clinic/hospital receives state or Federal funding to provide charity care, AHRQ funding may not replace this funding. In addition, applicants could propose strategies to connect uninsured patients with insurance coverage as part of their effort to increase access and comprehensiveness of care.

While there is no specified budget limit in the RFA for use of funds for patient care costs, the overall application must be responsive to all RFA goals and the budget should be designed accordingly, since subsidizing care can quickly use up the funds available. Any applicants requesting a significant budget (i.e., more than \$100,000 in any single budget period) for patient care costs should review the [HHS Grants Policy Statement](#) (Page I-25) for information regarding “research patient care” costs. Note that funds may be used only for those expenses that are directly related and necessary to the project.

29. Can PDs/PIs, co-investigators, and other key personnel not attribute their time/FTE/required funding to this award if their primary work already includes the NOFO aims, to allow the funds to be used elsewhere to implement award activities? Do we need to include senior/key personnel on the budget form if funding is not being requested for their salaries?

All personnel from the applicant organization dedicating effort to the project should be listed on the personnel budget with their base salary and effort, even if they are not requesting salary support. Describe the in-kind arrangement in the budget justification and include a letter of support from the institution confirming the commitment to have protected time for the individual to work on the project.

30. Do we need to submit a 5-year timeline or 1-year timeline?

The application & budget need to address the full proposed project period (up to 5 years).

31. How do we include other personnel not yet hired if funding will be requested for their salaries?

“To Be Determined” personnel may be included in grant budgets along with an estimate of their salary and level of effort. The role of these personnel should be described in the Budget Justification section of the application. In general, key personnel should not be TBD.

32. Can grant funds be used for resources outside the healthcare system needed to help patients access clinic services (e.g., for transportation services that are not reimbursed)?

Yes. The [HHS Grants Policy Statement](#) (Page II-43) says: “If patient care, including research patient care, or other direct health or social services are approved activities of the grant-supported project or program, the costs of transporting individuals participating in the program

or project to the site where services are being provided, including costs of public transportation, are allowable.”

Note that funds may be used only for those expenses that are directly related and necessary to the project. AHRQ funding is intended to supplement, not displace, current sources of funding (e.g., insurance reimbursement, services provided by nonprofits or government agencies) for care and services provided.

33. Can grant funds be used to provide services outside the Long COVID clinic (e.g., home-based care, social services)?

Yes. As stated in the RFA, access/referral to social services and community-based organizations, for patients who need them, are required care delivery model components.

The RFA also provides the following as an example of responsive strategies to increase access and serve more people with Long COVID: “Expanding services to new regions and/or populations, particularly underserved, rural, vulnerable, or minority populations, through telehealth, satellite or mobile clinics, clinician-to-clinician consultative services (e.g., e-consults), in-home services, partnerships with rural clinicians, language assistance (e.g., through certified medical interpreters), lengthening hours of operation, or other strategies.”

Any applicants requesting a significant budget (i.e., more than \$100,000 in any single budget period) for patient care costs should review the [HHS Grants Policy Statement](#) (Page I-25) for information regarding “research patient care” costs.

34. Could funds be used to support clinical personnel? Can the PD/PI effort include clinical practice seeing patients with Long COVID? Can grant funds be used to support salaries of neuropsychologists, rehabilitation providers, and social workers who are not currently reimbursed by insurance?

Yes, if the clinical activities are specific to this project, delivered to patients with Long COVID only, and not covered by existing sources of funding. AHRQ funding is intended to supplement, not displace, current sources of funding (e.g., insurance reimbursement) for care and services provided. Funds may be used only for those expenses that are directly related and necessary to the project.

35. Can AHRQ funds be used to purchase equipment (e.g., tilt table to diagnose POTS)?

Possibly. Funds may be used only for those expenses that are directly related and necessary to the project, so any equipment should be specifically for this project and not general institutional support.

Evaluation

36. What is included in the 20% funding allocation limit for evaluation activities? Does it include personnel FTE, including evaluation liaison FTE, for the cross-grantee evaluation led by AHRQ's contractor?

The 20% funding limit for evaluation activities is intended to signal that AHRQ funding should primarily be dedicated to demonstration/implementation of Long COVID care models and not research activities. The 20% funding allocation includes both direct and indirect costs associated with evaluation activities. The evaluation-related activities may include personnel time, including the evaluation liaison ($\geq 5\%$ FTE) and other participation in the cross-grantee evaluation, and any materials or other costs associated with evaluation-related activities. AHRQ does not expect to see a budget line item for evaluation nor expects to assess the percent of funding allocated to evaluation unless reviewers or program staff raise concerns about a particular applicant's budget allocation. However, the allocation of time and resources to various project activities should be clearly described in the budget justification section of the proposal.

37. Is there any guidance on who should be selected as "evaluation liaison"? Would this typically be a faculty member or senior research staff or someone else? Are there any specific requirements or skills for the evaluation liaison?

There are no specific requirements about the academic appointment or job title for the evaluation liaison. The evaluation liaison must be someone very familiar with the evaluation approach and progress. The RFA requires that applicants assign an evaluation liaison (ideally the PD/PI or dedicated evaluation lead) with expertise across the project to serve as a chief informant and coordinator with the contractor. The RFA also requires that the evaluation liaison be qualified to provide meaningful input on cross-recipient evaluation strategies (e.g., methodology, harmonized cross-recipient metrics), represent the recipient's perspective in communications across AHRQ, contractor, and recipient teams, and implement group recommendations in the recipient's individual project. These requirements are described in the "Evaluation Approach" and "Investigator(s) and Organization(s)" sections of the Proposed Project Description in the RFA.

38. Does AHRQ recommend any specific questionnaires or survey instruments for data collection?

No, but in general, AHRQ recommends using existing, validated instruments, when possible, rather than developing new instruments.

39. Do activities related to patient advisory councils or other patient engagement strategies, or participation in the grantee Learning Community fall into the 20% allowable allocation for evaluation?

Patient engagement strategies, such as advisory councils, do not account towards the 20% allowable allocation for evaluation unless the applicant proposes these activities as part of their evaluation strategy. While the overall participation in the Learning Community coordinated by AHRQ's contractor does not count towards the allowable allocation for evaluation, note that some Learning Community meetings may discuss cross-grantee evaluation topics.

40. Is the NOFO advocating for a Learning Health System approach with rapid cycle improvements over time?

Please see the requirements for “Learning Approach” and “Evaluation Approach” under Proposed Project Description in the RFA. Applicants are required to regularly track progress and adapt implementation approaches throughout the period of support based on the latest evidence and best practices in Long COVID management, internal tracking and evaluation data, and knowledge gained from participation in the Learning Community.

41. Can you elaborate on options for the mixed-model method of evaluation on this project?

The mixed-methods evaluation should include both quantitative and qualitative evaluation strategies and formative and summative approaches. Applicants should propose evaluation designs that meet the RFA requirements described in the “Evaluation Approach” section of the Proposed Project Description.

42. Is this NOFO funding or not funding research?

The purpose of this funding opportunity is primarily to expand access to comprehensive, coordinated, person-centered Long COVID care. It is not intended to support rigorous research (e.g., experimental or quasi-experimental designs) on the effectiveness of particular Long COVID treatments or care models. As indicated in the RFA, while applicants are expected to evaluate the results of their care models and participate in a cross-grantee evaluation, they must allocate no more than 20% of funding to evaluation/research-type activities.

Other

43. Can we propose to include adaptations to our implementation strategies and activities based on feedback from the community, such as patients and providers?

Yes, it is expected that implementation strategies and activities, including care delivery models, may change or be adapted during the project based on emerging evidence and knowledge gained from internal and external sources. Adapting implementation strategies based on community feedback from patients or providers is appropriate. It is also expected that recipients will adapt and modify strategies, as needed, based on the latest evidence and best practices for Long COVID management, findings from ongoing internal tracking and evaluation, and knowledge gained from participation in the Learning Community. Please see the “Learning Approach” and

“Evaluation Approach” sections of the Proposed Project Description and Scored Review Criteria for “Learning Approach” and “Evaluation Approach” in the RFA for further detail on related requirements and review criteria.

44. Is there an expectation that proposals include a patient or community advisory board?

This is not an RFA requirement. However, you may propose an advisory board if it strengthens your application and project.

45. Regarding the primary care education and support requirement, the RFA suggests modeling after Project ECHO. As Project ECHO already has a Long COVID learning collaborative, are recipients expected to join the existing Project ECHO Long COVID collaborative and expand on the existing collaborative? Can applicants propose a primary care education and support program that is separate from the Project ECHO Long COVID collaborative, including a local or regional program?

The RFA lists Project ECHO-like models as an example of primary care education and support strategies. Grant recipients are not required to join the existing Project ECHO Long COVID learning collaborative but can choose to do so. Applicants can propose primary care education and support strategies of their choice with supporting rationale. It would be appropriate to focus primary care education and support locally or regionally to best address the gaps and challenges faced in your clinic’s service area.

46. Can you provide additional information about the national collaboration component? Will there be a requirement for standard data collection forms across organizations? Will we have to share data with other grant recipients?

Grant recipients will be required to participate in a cross-grantee Learning Community and evaluation led by AHRQ’s contractor. AHRQ and its contractor will work with recipients to establish standard data reporting expectations and harmonize a core set of evaluation metrics across grantees, to the extent possible. Recipients will be required to submit data to AHRQ’s contractor using standard data submission templates, harmonized across recipients to the extent possible. The RFA does not require data sharing with other recipients.

Please refer to the “Required Participation in AHRQ’s Broader Initiative” section of the RFA for further details.

47. Our Long COVID clinic serves a vulnerable inner-city, minority population. However, we have no detailed data on their social determinants of health to document their vulnerability status. Is this acceptable?

There are no specific requirements for the patient population served either currently or under the proposed model of care using AHRQ funding. Applicants are required to describe the

sociodemographic profile of patients served, to the extent possible. If applicants do not have specific data on any required element, they must present best estimates (indicating that they are estimates) and describe their ability and plan to collect these elements if funded.

48. Will there be a restriction on how many grants are funded in a specific region?

No, but as stated in the RFA, [Section V. Application Review Information](#), AHRQ will consider overall programmatic and geographic balance of the proposed projects to program priorities in the funding decision process.

49. Could you clarify the final merit criterion of "Environment"? Is that the clinical setting type?

Please refer to RFA [Section V. Application Review Information](#) for review criteria for Environment.

50. Are any examples available for funded grants from AHRQ?

You can search for and view all AHRQ-funded grants on the [NIH RePORTER website](#).

51. How does AHRQ define a "warm hand off" to a primary care provider?

You can learn more about warm handoffs at [Warm Handoff: Intervention | Agency for Healthcare Research and Quality \(ahrq.gov\)](#).

52. Would development of clinical decision support (CDS) software or other health information technology (HIT) be an acceptable use of funds?

Developing and implementing CDS or other HIT applications could potentially be a part of your application if it is in the broader context of achieving the aims of the funding opportunity. Developing CDS or HIT alone would not meet the aims of the funding opportunity.

53. The RFA states that a contractor will help manage a learning community and conduct an evaluation of the overall initiative. Can you provide any additional details on this contract?

Unfortunately, there is no additional information that can be shared at this time. If AHRQ solicits contract applications, additional details will be publicly available at that time.

54. What timeframe is allowable for developing and implementing the proposed Long COVID care delivery model with all required components?

There is no specified timeframe for developing and implementing the proposed care delivery model components, but applicants are required to describe their timeline and approach in the application. Grantees will be required to assess and report their progress on required

performance measures throughout the period of support (see “Evaluation Approach” and “Program Planning and Performance Reporting Requirements” sections of the RFA).