



**AMD SEQUENCING &
ANALYTICS
SUPPLEMENT GUIDANCE
4/21/2021**

Project E: Emerging Issues

Supported through the American Rescue Plan Act of 2021

CONTENTS

Background and Purpose 2

Funding Strategy 2

Allowable Costs 2

COVID-19 Terms and Conditions..... 3

Process for Workplan and Budget Submission..... 5

Required Tasks 6

Activities 7

Performance Measures 9

Summary of Reporting Requirements 9

Acknowledgement Letter: Due Within Five (5) Days of NOA Receipt 10

AMD SEQUENCING & ANALYTICS

PROJECT E: EMERGING ISSUES

BACKGROUND AND PURPOSE

The rapid emergence and global spread of SARS-CoV-2, the pathogen that causes COVID-19, highlights the threat posed by novel pathogens. One of the most versatile tools in understanding and guiding the response to these emergencies is genomic sequencing. While the ability to decode microbial genomes has existed since the 1970s, the advent of high-throughput DNA sequencing, also called next-generation sequencing, has greatly expanded the use of these technologies in public health.

The [Advanced Molecular Detection \(AMD\)](#) program is developing applications to protect America's health and building capacity in national, state and local public health laboratories. Modernizing infectious disease laboratories, training staff, and expanding the application of these new technologies will ensure that Americans have the strongest protection against infectious disease threats. The purpose of this announcement is to support sequencing and analytic capacity building in microbial genomics and bioinformatics as well as to further the development of AMD capacity in health departments.

In order for pathogen genomic sequence data to most effectively impact public health, the data need to be integrated with their corresponding epidemiologic or clinical data, analyzed together, and interpreted. While the AMD program has always supported activities that further this objective, with the funding described here, the program intends to accelerate progress by enabling state, territorial and local health departments to make the long-term investments in workforce and/or infrastructure that are necessary to achieve it. As such, data integration/genomic epidemiology is an explicitly objective of this announcement.

FUNDING STRATEGY

The **\$240,000,000**, under the *AMD SEQUENCING & ANALYTICS* award, will be awarded to the current 64 ELC recipients to cover a three (3) year project period, which will end on July 31, 2024. Funding will be awarded based on population according to a modification of the population-based formula used to allocate funds under the ELC Enhancing Detection awards using funds from the *American Rescue Plan Act of 2021, P.L. 117-2*. Funds may not be used for research or clinical care related to COVID-19. Financial expenditures will be monitored and assessed with recipients monthly.

ALLOWABLE COSTS

Recipients should consider requesting the following when developing the *AMD Sequencing & Analytics* budgets.

1. Personnel (term, temporary, students, overtime, contract staff, etc.).
 - a) Staff may be contracted through an academic partner or other organization; funding may be requested for the time, the costs of acquiring and implementing contract services for the personnel member.
 - b) Personnel should be specifically dedicated to implementing, enhancing, or expanding infectious disease sequencing and analytics capabilities. This may include sequencing laboratory scientists, bioinformatics staff, data scientists, or other staff directly working on establishing or expanding AMD sequencing and analytics capacity within the jurisdiction.
2. Laboratory equipment used for sequencing, automation, and bioinformatics and necessary maintenance contracts. Allowable equipment should be directly related to establishing, expanding, or enhancing sequencing and bioinformatics capacity.

3. Sequencing supplies, kits, reagents, consumables, and other necessary supplies for existing or new sequencing applications or onboarding new platforms to support sequencing. Allowable supplies should be directly related to establishing, expanding, or enhancing sequencing and bioinformatics capacity.
4. Hardware and software necessary for sequencing and bioinformatics.
5. Hardware and software necessary for integrating genomic and epidemiologic data.
6. Other costs associated with planning and implementing data integration for genomic epidemiology.
7. Cloud computing or computational resources to support bioinformatics needs, including, as necessary, third-party consultation and contract support.
8. Tools that assist in the rapid identification, electronic reporting, monitoring, analysis, and evaluation of control measures to reduce the spread of COVID-19, that may be translatable to other diseases (e.g., GIS software, visualization dashboards, cloud services).
9. Contracts with academic institutions, private laboratories, other non-commercial healthcare entities that may provide additional support for sequencing and analytics needs. Contracts should be specifically dedicated to implementing, enhancing, or expanding infectious disease sequencing and analytics capabilities.
10. Costs associated with introducing or extending the application of AMD technologies or improving AMD Capacity within the applicant's jurisdiction or affiliated laboratories.

The above list covers the anticipated, most relevant costs associated with achieving the activities in this guidance. This list does not represent a full list of allowable costs. Recipients are referred to the cost principles regulation found at [45 CFR Part 75 Subpart E – Cost Principles](#).

In determining if costs are allowable, consideration must be given to applicable regulations; the overall underlying cooperative agreement (CK19-1904); be considered necessary and reasonable; and be considered allocable (see: 45 [CFR 75.403](#)). Any questions about specific budget items should be directed to the Office of Grants Services (OGS) and the ELC Project Officer.

COVID-19 TERMS AND CONDITIONS

Coronavirus Disease 2019 (COVID-19) Funds: A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); the Consolidated Appropriations Act and the Coronavirus Response and Relief Supplement Appropriations Act, 2021 (P.L. 116-260) and/or the American Rescue Plan of 2021 (P.L. 117-2) agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

In addition, to the extent applicable, Recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC. HHS laboratory reporting guidance is posted at: <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.

This award is contingent upon agreement by the recipient to comply with existing and future guidance from the HHS Secretary regarding control of the spread of COVID-19. In addition, recipient is expected to flow down these terms to any subaward, to the extent applicable to activities set out in such subaward.

To achieve the public health objectives of ensuring the health, safety, and welfare of all Americans, Recipient must distribute or administer vaccine without discriminating on non-public-health grounds within a prioritized group.

Acknowledgement of Federal Funding: When issuing statements, press releases, publications, requests for proposal, and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter “statements”)-- describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

1. The percentage and dollar amount of the total costs of the program or project funded with federal money; and,
2. The percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the [full name of the **OPDIV/STAFFDIV**] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with 100 percent funded by [OPDIV/STAFFDIV]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [OPDIV/STAFFDIV]/HHS, or the U.S. Government. For more information, please visit [OPDIV/STAFFDIV website, if available].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the [full name of the **OPDIV/STAFFDIV**] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with XX percentage funded by [OPDIV/STAFFDIV]/HHS and \$XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [OPDIV/STAFFDIV]/HHS, or the U.S. Government. For more information, please visit [OPDIV/STAFFDIV website, if available].

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

Any amendments by the recipient to the acknowledgement statement must be coordinated with the HHS Awarding Agency.

If the recipient plans to issue a press release concerning the outcome of activities supported by HHS financial assistance, it should notify the HHS Awarding Agency in advance to allow for coordination.

Termination

This award may be terminated in whole or in part consistent with 45 CFR 75.372.

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

PROCESS FOR WORKPLAN AND BUDGET SUBMISSION

Within five (5) business days of receipt of this guidance, the recipient's Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions. The acknowledgement must be submitted on the recipient's official agency letterhead and utilize the 'Acknowledgement Letter for CK19-1904 – COVID Supplemental Funds' template provided at the end of this guidance document.

This funding will be awarded in the ELC Budget Period 2 (BP2) (i.e., August 1, 2020 – July 31, 2021) under CK19-1904. However, recipients should note that this supplemental funding is for a three (3) year project period which will end on July 31, 2024. The expanded project period coincides with the end of Budget Period 5 (BP5) of the ELC Cooperative Agreement (CK19-1904). Therefore, workplans and revised budgets should reflect activities and associated costs that will end on July 31, 2024.

Within 90 days of receipt of the Notice of Award (NOA), the recipient is required to submit a workplan and revised budget describing its proposed activities. Upon submission, budgets and workplans will be reviewed by CDC and feedback will be provided and discussed with the recipient. Any necessary or recommended changes may be agreed upon between the recipient and CDC and documented in REDCap; and any agreed upon changes must be captured in GrantSolutions, the system of record, as necessary.

To appropriately document workplans, budgets, and facilitate recipients meeting the 90-day requirement:

1. Workplan entries will be completed in the *AMD Sequencing & Analytics* page, under 'ELC COVID-19 Projects' portal, in REDCap; and
2. Revised budgets must be completed by using the Excel budget workbook template provided via GrantSolutions Grant Notes at time of NOA issuance. **Note:** If a recipient does not meet the 90-day submission requirement and has not received written approval for an extension from CDC, then the Payment Management System (PMS) account associated with this award will be restricted. The restriction will result in a manual drawdown process that requires CDC approval of each PMS charge. This restriction will remain in effect until the recipient satisfactorily meets the workplan and budget submission requirement.
 - a. Funds will be awarded under the 'Other' cost category and will be accessible in the Payment Management System (PMS) during the 90-day budget revision period for use in accomplishing activities outlined in this guidance.

- b. Recipients will adjust the cost category allocations of awarded funds to reflect the areas where financial assistance is needed.
 - c. Recipients will upload the revised budget into GrantSolutions via a budget revision amendment, with a courtesy copy into REDCap *AMD Sequencing & Analytics* page of the 'ELC COVID-19 Projects' portal, by the 90-day post award deadline; and
 - d. The ELC Project Officer and OGS will process the budget revision amendment in GrantSolutions and the recipient will receive a revised NOA reflecting the approved cost category allocations.
3. A letter, indicating that all ELC Governance Team members (i.e., Project Director, Epidemiology Lead, Laboratory Lead, Health Information Systems Lead, and Financial Lead) have both contributed to and agreed upon the workplan and revised budget submitted, must be signed by all Governance Team Members (hard copy or digital signature) and submitted with the documents in the REDCap portal.

GrantSolutions

Within 90 days of receipt of the NOA, the recipient is required to submit a '**Budget Revision Amendment**' as part of the recipient's current award (CK19-1904), Budget Period 2.

The 'budget revision amendment' must consist of the following documents:

1. **Budget Information: SF-424A**
 - a. Recipient can use the form generated by the ELC budget workbook.
 - b. Or, recipient can submit a PDF of this form.
 - c. Please do not use the **e-form in GrantSolutions** as it creates issues when processing the revised NOA.
2. **Cover Letter** signed by the Authorized Official of record in GrantSolutions.
3. **Completed revised budget** using the ELC budget workbook that was provided in GrantSolutions as a Grant Note.

Note: In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC responsibilities include but are not limited to:

1. Provide ongoing guidance, programmatic support (including guidance on evaluation, performance measurement, and workplan changes), technical assistance and subject matter expertise to the activities outlined in this supplemental funding announcement guidance.
2. Convene trainings, meetings, conference calls, and site visits with recipients.
3. Share best practices identified and provide national coordination of activities, where appropriate.

REQUIRED TASKS

Note: If a recipient does not meet the below required tasks and has not received written approval for an extension from CDC, recipient may have their funds restricted in the Payment Management System (PMS) for specific costs/activities. Recurring or repeat non-compliance may result in additional restrictions or other actions being taken, consistent with applicable grant regulations.

In addition to the programmatic activities noted below in further detail, recipient responsibilities include but are not limited to:

1. Within **five (5) business days** of receipt of this guidance the Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions. The acknowledgement must be submitted on the recipient's official agency letterhead and utilize the 'Acknowledgement Letter for CK19-1904 – COVID Supplemental Funds' template provided at the end of this guidance document.

2. Regular participation in calls with CDC for technical assistance and monitoring of activities supported through this cooperative agreement.
3. On-time submission of all requisite reporting. This may include but is not limited to reporting of performance measures, progress on milestones, and/or financial updates within REDCap.
4. Report expenditures and unliquidated obligations (ULOs) on a monthly basis. On the 5th day of the month, the expenditures and ULOs from the prior month shall be reported in the REDCap *AMD Sequencing & Analytics* page.
5. Documentation of any necessary budget change/reallocation through GrantSolutions and REDCap.

ACTIVITIES

This announcement will provide funding to health departments to support laboratories in efforts to introduce or extend AMD capacity within their laboratories or affiliated laboratories. These proposals may include equipment, supplies, services (such as cloud computing services) or personnel costs to cover AMD activities that are a priority to the state or locality and that are not covered elsewhere by the AMD program and not supported (e.g., ELC Enhancing Detection Expansion, etc.) by other funding opportunity announcements. Applicants should include justification for these activities (i.e., why developing capacity in this area is a priority for the state), including specific objectives and near-term (1 to 2 year) priorities. Funding under this announcement for these activities is expected to be executed over three years; and will end on July 31, 2024, which corresponds to the end of BP5 under CK19-1904.

The AMD Sequencing & Analytics award has three (3) required activities that are designed to enhance and expand sequencing and analytics capacity, data integration, and bioinformatics capacity.

Activity 1 – Enhance Sequencing and Bioinformatics Capacity in State, Local, and Territorial Health Agencies

1. Hire staff to improve capacity for sequencing including laboratory scientists and bioinformatics personnel to effectively increase sequencing capabilities for SARS-CoV-2 and other emerging infections and conditions of public health significance. *Funding for this activity may be limited to this funding opportunity.*
 - a. The intent of this section is to increase the workforce in public health laboratories for sequencing and genomic epidemiology. As such, the funding provided to hire staff or increase recipient workforce must be used to increase personnel, whether employees or contractors, who are or will be working in these areas. The funding may not be used to cover the costs of existing personnel such that funding may be diverted to other priorities.
 - b. Staffing awards have been allocated based on a minimum base funding using a population-based formula.
 - c. This position may be filled by new or existing personnel dedicated to sequencing and/or bioinformatics in related AMD projects.
 - d. This funding is for full-time personnel including wet-laboratory scientist, bioinformatician, and/or data scientist dedicated to infectious disease next-generation sequencing and analytics projects.

Jurisdiction Size	Activity 1: Seq/Bioinformatics Staff <i>(Awards are population based– includes fringe/indirect)</i>	Staff Per Site <i>(Population Based)</i>
Smallest (pop. < 0.06%)	\$1,400,000	1 per site (7 sites)/ year
Small (pop. < 0.95%)	\$6,000,000	2 per site (15 sites)/year
Medium (pop. < 2.00%)	\$15,600,000	3 per site (26 sites)/year
Large (pop. > 2.00%)	\$12,800,000	4 per site (16 sites)/year
Total (Years 1-3)	\$107,400,000	

2. This funding is not intended to support personnel who will not be performing tasks directly related to sequencing, bioinformatics, or other AMD related activities.
3. Recipients are encouraged to develop partnerships with academic, non-profit, or for-profit institutions to accomplish Activities 1 and 3. Recipients are not required to develop partnerships for any of the activities in this funding opportunity.

Activity 2 - Equipment and Supplies

1. Procure equipment to expand NGS, bioinformatics, and other AMD activities. Refer to allowable costs section.
 - a. May included but is not limited to sequencing instruments, liquid handling automation, or other equipment needed to carry out sequencing workflows.
2. Procure supplies including but not limited to, sequencing kits, reagents, consumables, and other necessary supplies for existing or new sequencing applications or onboarding new platforms to support sequencing.
3. Improve computational infrastructure, including network bandwidth and computing power, to support AMD sequencing and bioinformatics projects. These activities may make use of cloud infrastructure.
 - a. May include implementing or enhancing cloud-based services.
 - b. May include procuring software licenses for commercial genomic analysis software.
4. Funding may be used to support service contracts and maintenance agreements for equipment procured through this funding announcement.
5. This funding may be used to support cloud-based services. This may be a short-term expenditure during the project period when needed to accomplish a transition.
6. Software licenses may be funded where adequate justification is noted in the applicant’s workplan. The use of open-source software is encouraged where feasible. The AMD program may determine on a case-by-case basis to fund software licenses for commercial genomic analysis software, where a compelling case was made, especially where the packages are needed to making transitioning easier.
7. The AMD program will continue to support jurisdiction’s decisions to prioritize emerging pathogens and other pathogens of interest. This funding allows for some flexibility in deciding which pathogens are priority for sequencing in addition to SARS-CoV-2.
8. This funding does NOT cover routine office cost including office supplies, network access charges, utilities, ongoing infrastructure cost (i.e. Internet service fees) etc. that are not part of an indirect cost rate agreement.

Jurisdiction	Activity 2a: Equipment <i>(Awards are population Based)</i>	Notes- Activity 2a
Total Awards Year 1	\$48,000,000	Awards for new equipment
Total Awards Year 2-3	\$9,600,000	Awards for maintenance agreements

Jurisdiction	Activity 2b: Supplies <i>includes Activity 3 (Awards are Population based)</i>	Notes- Activities 2b & 3
TOTAL Awards Years 1-3	\$75,000,000	Data integration (Activity 3) costs bundled with supplies

Activity 3 - Data Integration

1. Integrate epidemiologic data with NGS and AMD data. Applicants should address specific plans to implement data integration to support genomic epidemiology.
2. Develop capacity within the health department to integrate genomic and epidemiologic data so that it can more effectively contribute to response to the pandemic. This could include developing a system for integrating genomic and epidemiologic data with tools such as Microbetrace or Nextstrain, which are both open-source, non-commercial products, or other software, so that the data may more effectively be used to accomplish public-health objectives. This may include modifying epidemiologic data systems to integrate information more effectively from pathogen sequencing. It may include hiring data scientists or other staff with skills useful for integrating epidemiologic data, integrating that data with genomic data, and analyzing both types of data together.
3. Otherwise enable the use of genomic data to support public health action.

PERFORMANCE MEASURES

1. Number of next-generation sequencing (NGS) or whole genome sequencing (WGS) systems in the lab (including equipment not previously purchased with AMD funding, but is available for various AMD-related testing).
 - a. Number and proportion of applicants who are actively using NGS protocols to process samples and/or bioinformatics pipelines to manage data analysis for the following public health priorities.
 - i. SARS-CoV-2
 - ii. Bacterial foodborne illness (i.e., through PulseNet)
 - iii. Antimicrobial-resistant hospital-acquired pathogens
 - iv. Influenza
 - v. Hepatitis C (i.e., using the GHOST system)
 - vi. Legionella
 - vii. Streptococcal pathogens
 - viii. Mycobacterium tuberculosis
 - ix. Other emerging pathogens
2. Number of laboratory or microbiology staff dedicated to NGS or WGS.
 - a. Number of new laboratory staff hired under this funding opportunity.
3. Number of bioinformatics staff dedicated to AMD applications including NGS, data integration, and bioinformatics pipelines.
 - a. Number of new bioinformatics staff hired under this funding opportunity.
 - b. Number of new data science staff hired under this funding opportunity.

SUMMARY OF REPORTING REQUIREMENTS

The following is a summary of the reporting requirements for the *AMD Sequencing & Analytics*.

1. Within five (5) business days of receipt of this guidance, the Authorized Official is required to acknowledge receipt of this guidance by submitting a Grant Note in GrantSolutions.
2. Quarterly progress reports on milestones in approved workplans via REDCap.
3. Monthly fiscal reports (beginning 30 days after NOAs are issued).
4. Performance measure data.
5. CDC may require recipients to develop annual progress reports (APRs). CDC will provide APR guidance and optional templates should they be required.

ACKNOWLEDGEMENT LETTER: DUE WITHIN FIVE (5) DAYS OF NOA RECEIPT

AMD Sequencing & Analytics

Date:

Organization Name:

Subject: Acknowledgement Letter for CK19-1904 – COVID-19 Supplemental Funds – AMD Sequencing & Analytics

Reference: Guidance for the use of supplemental funding (April 2021) for CK19-1904 AMD Sequencing & Analytics through the American Rescue Plan Act of 2021.

This is to acknowledge that I have received, reviewed, and understand the requirements in the attached programmatic guidance.

The federal funding received will be in support of the supplemental funding referenced herein and will be spent in accordance with the legislation and programmatic guidance.

Authorized Official