ELC ENHANCING DETECTION THROUGH CORONAVIRUS RESPONSE AND RELIEF (CRR) SUPPLEMENTAL FUNDS

Project E: Emerging Issues Funding for the Enhanced Detection, Response, Surveillance, and Prevention of COVID-19 Supported through the Coronavirus Response and Relief Supplemental Appropriations Act of 2021

CONTENTS

ELC ENHANCING DETECTION EXPANSION
PROJECT E: EMERGING ISSUES

BACKGROUND AND PURPOSE

Note: *As the 'ELC Enhancing Detection Expansion' guidance is intended to build upon the prior work supported under 'ELC Enhancing Detection', this guidance contains the language from the 'ELC Enhancing Detection' guidance.*

This guidance is intended to provide details regarding $19.11 billion from the *Coronavirus Response and Relief Supplemental Appropriations Act of 2021,* P.L. 116-260, that will be provided to ELC recipients early in 2021. While the activities largely build upon those under *Enhancing Detection*, specific details of the guidance should be reviewed in total for important context and clarification.

As part of the CARES Act and Paycheck Protection Program and Health Care Enhancement Act supplements, the ELC awarded approximately $11 billion in 2020 to help address the domestic response to COVID-19. To provide additional critical support to jurisdictions as they continue to address COVID-19 within their communities, $19.11 billion from the *Coronavirus Response and Relief Supplemental Appropriations Act of 2021,* P.L. 116-260, will be provided to ELC recipients. These additional resources, by law, are intended to "prevent, prepare for, and respond to coronavirus" by supporting testing, case investigation and contact tracing, surveillance, containment, and mitigation. Such activities may include support for workforce, epidemiology, use by employers, elementary and secondary schools, child care facilities, institutions of higher education, long-term care facilities, or in other settings, scale up of testing by public health, academic, commercial, and hospital laboratories, and community-based testing sites, mobile testing units, health care facilities, and other entities engaged in COVID–19 testing, and other activities related to COVID–19 testing, case investigation and contact tracing, surveillance, containment, and mitigation (including interstate compacts or other mutual aid agreements for such purposes).

As with the previous awards, direct recipients are limited to existing jurisdictions covered under CK19-1904[1]. Recipients should continue to build upon existing ELC infrastructure that emphasizes the coordination and critical integration of laboratory with epidemiology and health information systems in order to maximize the public health impact of available resources. It is the role of the recipient's ELC Project Director to ensure funds are used to achieve the required activities in this guidance; and to guarantee these new funds do not duplicate financial support through prior awards. These funds are intended to complement and not duplicate resources from any other federal source, including those previously awarded via the ELC Cooperative Agreement. Similarly, these resources are not intended to be applied without foresight, consideration for, and planning to address future infectious disease events.

Ongoing monitoring of milestones and performance measures will be utilized to gauge progress toward successful completion of priority activities supported with these funds. Recipients will again be required to complete and submit Jurisdictional Testing, Case Investigation, and Contact Tracing Plans (please note that these may be published on the HHS website: https://www.hhs.gov/coronavirus/testing-plans/index.html. The following guidance outlines other specific details and requirements accompanying the resources.

JURISDICTIONAL TESTING, CASE INVESTIGATION, AND CONTACT TRACING PLANS

Utilizing the provided template, located in REDCap, recipients will update information regarding the overall testing landscape within their jurisdiction. This exercise should be done in partnership with state/jurisdictional leadership (e.g., public health, emergency management, State Health Official, local health departments, etc.) and should reflect the approach to testing at a broad jurisdictional level, including tribal needs as appropriate. For example, testing done at public health, clinical and/or commercial labs should be included as well as approaches for reaching communities placed at greater risk for COVID-19, and the application and use of various types of testing for detection and/or surveillance (antigen, molecular, and serology) and inform contact investigation and tracing efforts. These plans should include aspects of advanced molecular detection (AMD) technologies to inform and drive investigations utilizing molecular epidemiology techniques.

Jurisdictions must provide details regarding their robust SARS-CoV-2 testing, case investigation, and contact tracing program that ensures adequate testing is made available according to CDC priorities, including but not limited to: diagnostic tests, tests for close contacts of cases, and expanded screening testing for asymptomatic persons to identify and isolate infectious individuals and monitor community spread. Recipients should assure that provisions are in place to meet future surge capacity testing needs including point-of-care or other rapid testing for outbreaks. Plans should include provisions for testing at, and reporting from, non-traditional sites (e.g., schools, retail sites, community centers, residential medical facilities, or pharmacies); testing of populations at higher risk of becoming infected with SARS-CoV-2 due to high frequency of residential, occupational or nonoccupational contacts; and should also address any essential partnerships with academic, commercial, and hospital laboratories to successfully meet testing demand.

In conjunction with optimizing testing and increasing test volumes for COVID-19/SARS-CoV-2, resources will support the establishment of modernized, timely (real-time) public health surveillance (e.g., to help support case investigation and contact tracing) and health information systems. These systems will support the public health response to COVID-19 and lay the foundation for the future of public health surveillance.

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[1] Only current ELC recipients are eligible to receive awards associated with the supplement described in this guidance. While tribal nations are not included in these awards, other federal support is provided in the *Coronavirus Response and Relief Supplemental Appropriations Act of 2021*.

Establishing systems and processes to report the data categories described in this document on a daily, automated basis to state and federal health systems is a requirement of accepting these funds, if such systems are not already in place. These systems must be transparent and visible to communities through an open website. For each data category, data elements will be specified by CDC for each reportable condition (e.g., race/ethnicity) at a later date. Both existing and newly established surveillance and data reporting systems must:

1. Ensure that real-time, at least daily, complete and accurate test orders and results can be exchanged within the healthcare/public health system and simultaneously reported to CDC and others via automated systems in a machine-readable format. These systems must support reporting of test results at the county or zip code level with additional data fields as specified by CDC [e.g., Ask on Entry (AOE) questions]. This includes not only testing for the presence of virus (nucleic acid or antigen testing), but also serological testing documenting past infection.
2. Ensure real-time, at least daily, complete, automated reporting in a machine-readable format for the following data categories: case, hospitalization and death reporting; emergency department syndromic surveillance; and capacity, resources, and patient impact at healthcare facilities through electronic reporting.
3. Support the display of up-to-date, critical public health information relating to COVID-19 and future outbreaks at the county or zip code level in visual dashboards or tables on county or state websites, including case data and syndromic surveillance data.

Enhancements to epidemiologic activities resulting from additional test data are also fundamental to controlling the spread of COVID-19. Recipients must accelerate efforts to conduct robust case investigation and contact tracing and then identify and isolate new cases of COVID-19 among symptomatic or asymptomatic individuals. This information should be further utilized to understand COVID-19/SARS-CoV-2 transmission within a community and determine appropriate mitigation strategies.

FUNDING STRATEGY

Funding by jurisdiction will be based on population, as provided in the legislative language for the *Coronavirus Response and Relief Supplemental Appropriations Act of 2021* (https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-116HR133SA-RCP-116-68.pdf).

Direct Assistance is authorized under CK19-1904[2]; however, should opportunities for direct assistance be made available, these will be shared broadly with our recipient base and options for providing direct assistance in lieu of financial assistance may be discussed and coordinated with the ELC Project Officer and the CDC Office of Grant Services (OGS).

ALLOWABLE COSTS

Recipients should consider requesting the following when developing budgets, in furtherance of award activities. The financial resources provided are required, by law, to support activities intended to address prevention and response to COVID-19.

1. Personnel (term, temporary, students, overtime, contract staff, etc.).
2. Laboratory equipment and necessary maintenance contracts.

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[2]Legislative Authority for CK19-1904: Sections 301 and 317 of the Public Health Service Act (PHS Act), 42 USC sections 241 and 247b, as amended; and funding is, in part, appropriated under Affordable Care Act (PL 111-148), Title IV, Section 4002 (Prevention and Public Health Fund), Title IV, Section 4002.

3. Collection supplies, test kits, reagents, consumables and other necessary supplies for existing testing or onboarding new platforms.
4. Courier service contracts (new or expansion of existing agreements).
5. Hardware and software necessary for robust implementation of electronic laboratory and surveillance data exchange between recipient and other entities, including healthcare entities, jurisdictional public health and CDC.
6. Tools that assist in the rapid identification, electronic reporting, monitoring, analysis, and evaluation of control measures to reduce the spread of disease (e.g. GIS software, visualization dashboards, cloud services).
7. Contracts with academic institutions, private laboratories, other non-commercial healthcare entities, and/or commercial entities.
8. Renovations and minor construction (e.g., alteration of less than 50% total square footage of an existing structure; installation of a concrete slab for modular laboratory units; etc.) may be considered for unique cases where conditions do not currently allow for safe or effective testing and/or delivery of effective public health services.
9. Leasing/purchasing vehicles (e.g., mobile testing, providing public health services in underserved areas, etc.). **Note:** Recipients will need to submit quotes with their revised budgets that are due within 60 days of award issuance and receive prior approval from OGS. After the revised NOA is issued, any further request for leasing/purchasing must be made through GrantSolutions and include the necessary quotes.
10. Software or systems to assist with laboratory resource management (e.g., software for inventory management, temperature notifications, etc.), quality management, biosafety or training needs.
11. Quarantine and isolation support necessary for preventing the spread of COVID-19 (including wraparound services such as hoteling, food, laundry, mental health services, etc.).
12. Stipends/incentives may be considered to encourage participation in testing and/or vaccination coverage for those put at higher risk for COVID-19 (individual level) or for facilities/agencies to enroll and/or report data to the health department (institutional level). Recipients interested in exploring this option (individual and/or institutional) must submit a plan that covers all of the following elements: (a) justification, (b) cost savings [e.g., how it will defray costs or have a positive return on investment], (c) defined amount, (d) qualifications for issuance, and (e) method of tracking. When submitting the revised budget within 60 days of award issuance, stipend/incentive plans must be included in the 'budget justification' section of the ELC budget workbook and receive CDC approval before implementation. After the revised NOA is issued, any subsequent requests for using funds to support stipends/incentives must be made in GrantSolutions, including the stipend/incentive plan, and receive CDC approval before implementation.
13. Resources to complement, but not duplicate, other CDC vaccine delivery efforts (e.g., those activities covered under IP19-1901). Costs can include infrastructure needs (e.g., staff, contractors, call centers, storage, space, etc.) that support testing as well as vaccination operations.
14. Health communications materials and health education services to inform and protect communities are allowable, if they do not duplicate activities covered by other CDC funding mechanisms (e.g., IP21-2106, IP21-2107). Recipients are reminded to be cognizant of the statutory and policy requirements for acknowledging the HHS/CDC funding when issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents. In accordance with CDC General Terms and Conditions for Non-research Awards - Acknowledgement of Federal Funding, in your base award. (https://www.cdc.gov/grants/documents/General-Terms-and-Conditions-Non-Research-Awards.pdf)
15. Expenses associated with outreach and assistance (e.g., support provided through community-based organizations) for those put at higher risk for COVID-19.

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 grant 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 OGS and the ELC Project Officer.

SUPPORT TO LOCAL HEALTH DEPARTMENTS (LHD)

As with previous support provided for COVID-19 activities, recipients should work with their local health departments (LHDs) to determine how local needs will be addressed with the overall available resources. Direct ELC recipients are strongly encouraged to provide financial resources to LHDs within their jurisdiction by way of a contract or other mechanism(s) that may be available through their health department. In addition to financial resources, directly funded recipients may also provide support to LHDs through offering non-financial resources (personnel, supplies, etc.) to address COVID-19/SARS-CoV-2 testing, surveillance, case detection, reporting, response, and prevention needs at the local level. When completing the revised budget, in the ELC budget workbook, there is a state/local health department allocation section that must be completed accurately to allow tracking of direct and indirect support to LHDs. During the quarterly workplan milestone progress reporting, recipients must provide reports, in the REDCap monitoring portal, on progress in supporting LHDs (e.g., on-track or barriers and proposed remedies, etc.) along with amount of funding (direct and/or indirect) to LHDs at time of reporting.

The ELC Program Office will continue to monitor spending and programmatic performance, which will be reported to CDC and HHS leadership, and others as appropriate and necessary, on progress and barriers experienced by recipients (see HHS regulation on performance measurement 45 CFR 75.301). Information regarding resources provided to local jurisdictions should be made available to the ELC Project Officer during regular monitoring calls and if issues arise that require action on the part of the recipient or CDC (e.g., significant delays by a local health department when submitting documentation to the state for reimbursement). In circumstances where CDC finds lessons learned from programmatic performance, such as successful or unsuccessful strategies, these may be shared with other recipients.

SUPPORTING MANAGEMENT OF ACTIVITIES AND RESOURCES

The ELC Program Office strongly recommends that recipients ensure ELC leadership staff at the recipient level are adequate for the management of this award and its integration with the recipient's overall portfolio of ELC funded activities. A minimum of 1 program manager and 1 budget staff (or equivalents) is suggested for the effective management and implementation of the recipients' proposed activities. Depending on the recipient's current capacity for managing both existing COVID-19 funds and these funds associated with this award, the program manager and budget staff may consist of full-time or additional part-time support to achieve the necessary monitoring and management requirements.

PROCESS FOR WORKPLAN AND BUDGET SUBMISSION

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.

This funding should support activities and the necessary reporting for Budget Period 2 (BP2) under CK19-1904. This supplemental funding is for a 30 ½ month project period and will end on July 31, 2023. The expanded project period coincides with the end of Budget Period 4 (BP4) of the ELC Cooperative Agreement (CK19-1904); therefore, workplans and revised budgets should reflect activities and associated costs that will end on July 31, 2023. Recipients are reminded

that expanded authority[3] applies, and funding may be extended to subsequent budget periods to cover the activities until July 31, 2023. Within 60 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 60-day requirement:

1. Workplan entries will be completed in the ELC Enhancing Detection Expansion 'ELC ED Expansion' 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 60-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 60-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 'ELC ED Expansion Financials' page of the 'ELC COVID-19 Projects' portal, by the 60-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 requested 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 <u>all</u> Governance Team Members (hard copy or digital signature) and submitted with the documents in the REDCap portal.

Workplan detail

Additional workplan guidance will be provided to recipients post-award; they will be required to provide a clear and concise description of the time-bound strategies and activities they will use to achieve the project's outcomes, including:

1. Description of how 'ELC Enhancing Detection Expansion' funding will be used in coordination with funding from CDC's Crisis COVID-19 Notice of Funding Opportunity (NOFO), Immunization and Vaccines for Children cooperative agreement (IP19-1901, original and any COVID-19 supplemental awards), and all other ELC COVID-19 funding previously awarded.
2. Specify the distinct new or enhanced activities made possible by 'ELC ED Expansion'.
3. Plans for how the ELC recipient will work with local jurisdictions to meet local needs that support the entire jurisdiction. These plans must include: description of activities to be supported at the local level, identification of local partners and localities to be supported, methods to assess local needs, and description of funding mechanisms

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[3] Expanded Authority is provided to recipients through 45 CFR Part 75.308, which allows carryover of unobligated balances from one budget period to a subsequent budget period. Unobligated funds may be used for purposes within the scope of the project as originally approved. Recipients will report use, or intended use, of unobligated funds in Section 12 "Remarks" of the annual Federal Financial Report.

to support local entities, and estimated amount of support (monetary and in-kind) including to local health departments.

4. Description of expected mechanisms and frequency of interactions between the health department and/or public health laboratory with academic/hospital and commercial laboratories.

5. Description of testing and case investigation and contact tracing plan, including populations and institutional settings. Plans should align to your Jurisdictional Testing, Case Investigation, and Contact Tracing plans for COVID-19 per legislation[4]. Plans for January 2021 – December 2021 must be submitted by March 18, 2021; and cover a 1-year period. The testing and case investigation and contact tracing plan will then be updated, on a quarterly basis, to reflect substantive changes and/or progress. Details about testing and case investigation and contact tracing plan submission will be shared with recipients via the ELC Program Office.

   a. Please note that HHS and/or CDC may work with recipients to transfer activities and associated costs (e.g., community- based testing sites, large test kit purchases (OASH), etc.) to these funds where appropriate and necessary.

   b. To the extent that there are existing Federal (HHS) contracts for testing supplies, HHS and/or CDC may work with recipients to consider allowing recipients to buy into those existing contracts, as may be possible under applicable law.

6. Description of use of electronic health systems for surveillance, reporting, and public health action.

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.

4. Coordinate with the HHS Testing and Diagnostics Working Group, as needed, to support States testing strategies.

Within 60 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, no later than **March 18, 2021**.

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.

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[4] Link to bill stating that there is to be a plan and the elements for incorporation: https://www.congress.gov/bill/116th-congress/house-bill/266/ CDC will provide a template in REDCap for recipients to complete to provide additional guidance and ensure all necessary elements are addressed.

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 PMS for specific cost/activities. Recurring or repeat non-compliance may result in additional restrictions or other actions being taken.

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/HHS 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 'ELC ED Expansion Financial Reporting' page.
5. Documentation of any necessary budget change/reallocation through REDCap and, as necessary, GrantSolutions.
6. If implementing new or replacement systems, develop an implementation plan, including:
   a. Rationale for acquiring a new/replacement health information surveillance system and information used to make the decision, such as
      i. gaps in existing system
      ii. options explored prior to making the decision.
   b. Tasks and efforts required (appropriate milestones).
   c. Timeline for completion.
   d. Person responsible for these activities.
   Implementation plans must be submitted to EDX@cdc.gov, with a copy uploaded into REDCap. Plans will be reviewed and must receive programmatic support from CDC prior to start of implementation. (See Activities section below for specific activities requiring implementation plan and approval.)
7. Schedule a required call (at least 60 minutes) with CDC ELC Health Information Systems (HIS) team to review HIS related activities and milestones described in this workplan.
8. No later than April 30, 2021, have a call with the ELC Project Officer, which will include the recipient representatives to review proposed workplan activities and revised budget submission.
9. Recipient must establish/maintain electronic reporting of SARS-CoV2/COVID-19 laboratory data to CDC daily per the guidance provided by CDC (e.g., CELR). This includes all testing (e.g., positive/negative, PCR, Point-of-Care, etc.) and complete data elements (e.g., race/ethnicity) per CARES legislation and ELC performance measures.

Both CDC and recipients should appropriately coordinate with points of contact in relevant stakeholder organizations to maximize the impact of federal dollars [e.g., tribal nations, Health Resources and Services Administration (HRSA), HHS Testing and Diagnostics Working Group, etc.].

ACTIVITIES

Data collected as a part of the Activities supported with these funds shall be reported to CDC in the form and fashion determined by CDC. Recipients are required to establish electronic reporting systems to support comprehensive, timely,

automated reporting of these data to LHD, CDC and others, at a frequency determined by CDC, if such systems are not already in place. Such systems must support reporting for COVID-19, other conditions of public health significance.

Note: These additional resources are intended to be directed toward testing, case investigation and contact tracing, surveillance, containment, and mitigation, including support for workforce, epidemiology, use by employers, elementary and secondary schools, child care facilities, institutions of higher education, long-term care facilities, or in other settings, scale up of testing by public health, academic, commercial, and hospital laboratories, and community-based testing sites, mobile testing units, health care facilities, and other entities engaged in COVID–19 testing, and other related activities related to COVID–19 testing, case investigation and contact tracing, surveillance, containment, and mitigation which may include interstate compacts or other mutual aid agreements for such purposes.

The following programmatic workplan activities are <u>required</u> and must be completed by the public health department and/or public health laboratory. **Note:** If a recipient does not address all the required activities in the workplan, then the workplan will be considered incomplete. If the workplan is not complete by the 60-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 requirement.

The 'ELC Enhancing Detection Expansion' workplans will be started in REDCap for recipients through use of the 'ELC Enhancing Detection' workplans. Recipients will then build upon the workplans, in REDCap, to establish their 'ELC Enhancing Detection Expansion' workplans. If activities were not previously addressed in 'ELC Enhancing Detection' workplans, recipients are required to update 'ELC Enhancing Detection Expansion' workplans and respond to all activities. Certain activities or purchases will require recipients to work with ELC HIS prior to the start of implementation.

Enhance Laboratory, Surveillance, Informatics and other Workforce Capacity

1. Train and hire staff to improve laboratory workforce ability to address issues around laboratory safety, quality management, inventory management, specimen management, diagnostic and surveillance testing and reporting results.
2. Build expertise for healthcare and community outbreak response and infection prevention and control (IPC) among local health departments.
3. Train and hire staff to improve the capacities of the epidemiology and informatics workforce to effectively conduct surveillance and response of COVID-19 (including case investigation and contact tracing) and other emerging infections and conditions of public health significance. This should include staff who can address unique cultural needs of those put at higher risk for COVID-19.
4. Build expertise to support management of the COVID-19 related activities within the jurisdiction and integrate into the broader ELC portfolio of activities (e.g., additional leadership, program and project managers, budget staff, etc.).
5. Increase capacity for timely data management, analysis, and reporting for COVID-19 and other emerging coronavirus and other infections and conditions of public health significance.

Strengthen Laboratory Testing

1. Establish or expand capacity to quickly, accurately and safely test for SARS-CoV-2/COVID-19 and build infectious disease preparedness for future coronavirus and other events involving other pathogens with potential for broad community spread.
   a. Develop systems to improve speed and efficiency of specimen submission to clinical and reference laboratories.
   b. Strengthen ability to quickly scale testing [e.g., nucleic acid amplification test (NAAT), antigen, etc.] as necessary to ensure that optimal utilization of existing and new testing platforms can be supported to help

meet increases in testing demand in a timely manner. Laboratories are strongly encouraged to diversify their testing platforms to enable them to pivot depending on reagent and supply availabilities.

c. Perform serology testing with an FDA EUA authorized serological assay in order to conduct surveillance for past infection and monitor community exposure.

d. Work with LHDs, including through sub-awards, to build local capacity for testing of COVID-19/SARS-CoV-2 including within high-risk settings or in vulnerable populations that reside in their communities.

e. Apply laboratory safety methods to ensure worker safety when managing and testing samples that may contain SARS-CoV-2/COVID-19.

f. Implement alternative surveillance methods, including sequencing, wastewater surveillance, regional testing centers for surveillance and screening, etc. and link with other relevant surveillance systems (e.g., immunization registry). [This activity is optional and should complement other already funded activities.]

g. Augment or add specificity to existing laboratory response plans for future coronavirus and other outbreak responses caused by an infectious disease.

h. Support national surveillance for SARS-CoV-2 by submitting representative, deidentified samples to CDC for sequencing through the National SARS-CoV-2 Strain Surveillance (NS3) program.
    Note: CDC has issued guidance elsewhere on specifics of the submission of samples and metadata (see https://www.aphl.org/sars2seq), but in general: unless otherwise indicated, samples submitted for NS3 should be from separate cases, unrelated to each other and that represent typical cases of COVID-19 in the jurisdiction. The number of samples requested is reflective of a minimum number of samples needed for long term surveillance, with adjustments for population and other factors. Please work with the CDC NS3 surveillance team to develop a sustainable sampling plan for your jurisdiction.

i. Expand the use of SARS-CoV-2 genomic sequencing and molecular epidemiology for state and local surveillance and response.
    Note: Timely access to viral genomic sequence data can be a critically important tool in responding to outbreaks; assessing transmission pathways, mechanisms and risk; determining the effectiveness of public health control measures; positioning state and local public health resources; and in supporting policy decisions. CDC encourages the expanded role of sequence data in support of state, local and regional public health priorities, especially when they are done in coordination with national sequencing efforts such as SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES). These efforts could include rapid sequencing and analysis of SARS-CoV-2 genomes by contractors and staff within the public health laboratory itself, through the expansion of laboratory capacity, workforce or bioinformatics capabilities (including improved access to cloud computing resources), or through the establishment or expansion of partnerships with academia and the private sector.

2. Enhance laboratory testing capacity for SARS-CoV-2/COVID-19 outside of public health laboratories

a. Conduct surveillance of all SARS-CoV-2/COVID-19 testing resources and map the jurisdictional testing resources that exist outside the public health arena (e.g., point of care, private, academic, etc.).

b. Establish or expand capacity to coordinate with public/private laboratory testing providers, including those that assist with surge and with testing for high-risk environments.

c. Secure and/or utilize mobile laboratory units, or other methods to provide POC testing (including antigen testing) at public health-led clinics or non-traditional test sites including but not limited to shelters or other places of congregate housing, food processing plants, correctional facilities, Long Term Care Facilities (LTCF), elementary and secondary schools, child care facilities, and institutions of higher education.

d. Ensure public/private laboratory testing providers, including those providing POC testing at public health-led clinics or non-traditional test sites, are provided biosafety resources for SARS-CoV-2 specimen collection and/or testing.

3. Enhance data management and analytic capacity in public health laboratories to help improve efficiencies in operations, management, testing, and data sharing.

a. Improve efficiencies in laboratory operations and management using data from throughput, staffing, billing, supplies, and orders. Ensure ability to track inventory of testing reagents by device/platform, among other things.

b. Improve the capacity to analyze laboratory data to help understand and make informed decisions about issues such as gaps in testing and community mitigation efforts. Data elements such as tests ordered and completed (including by device/platform), rates of positivity, source of samples, specimen collection sites, and test type will be used to create data visualizations that will be shared with the public, local health departments, and federal partners.

Advance Electronic Data Exchange at Public Health Labs

1. Enhance and expand laboratory information infrastructure, to improve jurisdictional visibility on laboratory data (tests performed) from all testing sites and enable faster and more complete data exchange and reporting.

    a. Employ a well-functioning Laboratory Information Management System (LIMS) system to support efficient data flows within the PHL and its partners. This includes expanding existing capacity of the current LIMS to improve data exchange and increase data flows through LIMS maintenance, new configurations/modules, and enhancements. Implement new/replacement LIMS where needed.
        Note: If implementing new or replacement systems, develop an implementation plan, including appropriate milestones and timeline to completion. Implementation plans will be reviewed and approved for consistency with the activities set forth in the ELC awards by CDC prior to start of implementation.

    b. Ensure ability to administer LIMS. Ensure the ability to configure all tests that are in LIMS, including new tests, EUAs, etc., in a timely manner. Ensure expanding needs for administration and management of LIMS system are covered through dedicated staff.

    c. Interface diagnostic equipment to directly report laboratory results into LIMS.

    d. Put a web portal in place to support online ordering and reporting. Integrate the web portal into the LIMS.
        Note: If implementing new or replacement systems, develop an implementation plan, including appropriate milestones and timeline to completion. Implementation plans will be reviewed and approved for consistency with the activities set forth in the ELC awards by CDC prior to start of implementation.

    e. Enhance laboratory test ordering and reporting capability.
        i. Implement or improve capacity to consume and produce electronic HL7 test orders and result reporting (ETOR) to allow laboratories and healthcare providers to directly exchange standardized test orders and results across different facilities and electronic information systems using agreed upon standards.
        ii. 100% of results must be reported with key demographic variables including age/gender/race.
        iii. Report all testing to the health department and CDC using HL7 ELR.

Improve Surveillance and Reporting of Electronic Health Data

Conducting the activities in this section to enable comprehensive, automated, daily reporting to the CDC and others in a machine-readable format, is a requirement of accepting these funds. See CDC website(s) for required data elements. Websites will be amended as requirements are updated.

A. *Lab Reporting: https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#what-to-report*
B. *Case Reporting: https://www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html.*

1. Establish complete, up-to-date, timely, automated reporting of morbidity and mortality to CDC and others due to COVID-19 and other coronavirus and other emerging infections which impact conditions of public health significance, with required associated data fields in a machine-readable format, by:
    a. Establishing or enhancing community-based surveillance, including surveillance of vulnerable populations, individuals without severe illness, those with recent travel to high-risk locations, or who are contacts to known cases.
    b. Monitoring changes to daily incidence rates of COVID-19 and other conditions of public health significance at the county or zip code level to inform community mitigation strategies.
2. Establish additional and on-going surveillance methods (e.g. sentinel surveillance) for COVID-19 and other conditions of public health significance.
3. Establish complete, up-to-date, timely, automated reporting of individual-level data through electronic case reporting to CDC and others in a machine-readable format (ensuring LHD have access to data that is reported):
    a. At the health department, enhance capacity to work with testing facilities to onboard and improve electronic laboratory reporting (ELR), including to receive data from new or non-traditional testing settings. Use alternative data flows (e.g., reporting portals) and file formats (e.g., CSV or XLS) to help automate where appropriate. In addition to other reportable results, this should include all COVID-19/SARS-CoV-2-related testing data (i.e., tests to detect SAR-CoV-2 including serology testing).
    b. Automate receiving EHR data, including eCR and FHIR-base eCR Now, to generate initial case report as specified by CDC for the reportable disease within 24 hours and to update over time within 24 hours of a change in information contained in the CDC-directed case report, including death. Utilize eCR data to ensure data completeness, establish comprehensive morbidity and mortality surveillance, and help monitor the health of the community and inform decisions for the delivery of public health services.
    c. Develop a project plan for the automated processing of the Electronic Initial Case Report (eICR) and Reportability Response (RR) into health information systems. Prior to implementation of eICR and RR for a specific disease or disease group, plan how data will be used for surveillance workflows (e.g. negative COVID-19 reports from providers), draft reporting specifications, and consumption, as appropriate.
        Note: As an interim solution, while health information system capacity is being developed, convert to a human readable format and provide for use by appropriate surveillance program personnel.
    d. Increase connectivity with laboratory and healthcare feeds for epidemiologic analysis (including using automated single CSV files).
    e. Expand electronic reporting mechanism (e.g., eCR, ELR) to include all conditions of public health significance.
4. Improve understanding of capacity, resources, and patient impact at healthcare facilities through electronic reporting.
    a. Required expansion of reporting facility capacity, resources, and patient impact information, such as patients admitted and hospitalized, in an electronic, machine-readable, as well as human-readable visual, and tabular manner, to achieve 100% coverage in jurisdiction and include daily data from all acute care, long-term care, and ambulatory care settings. Use these data to monitor facilities with confirmed cases of COVID-19/SARS-CoV-2 infection or with COVID-like illness among staff or residents and facilities at high risk of acquiring COVID-19/SARS-CoV-2 cases and COVID-like illness among staff or residents.
    b. Increase ADT messaging and use to achieve comprehensive surveillance of emergency room visits, hospital admissions, facility and department transfers, and discharges to provide an early warning signal, to monitor the impact on hospitals, and to understand the growth of serious cases requiring admission.
5. Enhance systems for flexible data collection, reporting, analysis, and visualization.

    a. Implement new/replacement systems where needed. Ensure systems are interoperable and that data can be linked across systems (e.g., public health, healthcare, private labs), including adding the capacity for lab data and other data to be used by the software/tools that are being deployed for case investigation and contact tracing.

Note:

1. If implementing new or replacement systems, develop an implementation plan, including:

    a. Rationale for acquiring a new/replacement health information surveillance system and information used to make the decision, such as
        i. gaps in existing system
        ii. options explored prior to making the decision.
    b. Tasks and efforts required (appropriate milestones).
    c. Timeline for completion.
    d. Person responsible for these activities.

    Implementation plans must be submitted to EDX@cdc.gov, with a copy uploaded into REDCap. Plans will be reviewed and must receive programmatic support from CDC prior to start of implementation.

2. Examples for data linkages and/or interoperability across systems include case surveillance data, vaccination data, vital records, etc.
3. If implementing or expanding immunizations related information technology systems (e.g., registries, data lake, VAMS, vaccine finder, etc.), recipient should work with Immunization Cooperative Agreement Project Officer for long-term support. Once COVID funds are exhausted, ELC Cooperative Agreement will not have resources for ongoing financial assistance with these registries.

    b. Update/Enhance/Modernize infrastructure to handle large data streams and properly process, triage, and retain data. For example, receiving large numbers of negative test results, triage, process, and use as appropriate. Consider scalable storage (e.g. data lake).

    c. Data must be made available at the local, state, and federal level.

    d. Make data on cases, syndromic surveillance, laboratory tests, hospitalization, and healthcare capacity available on health department websites at the county/zip code level in a visual and tabular manner.

6. Establish or improve systems to ensure complete, accurate and immediate (within 24 hrs.) data transmission to a system and open website available to local health officials and the public by county and zip code, that allows for automated transmission of data to the CDC in a machine readable format.

    a. Increase coverage (Target for emergency departments (ED): 100%) and number of facilities submitting syndromic surveillance data to the National Syndromic Surveillance Program (NSSP) [https://www.cdc.gov/nssp/index.html] for emergency department (ED) and urgent care facilities for syndromes and illnesses with messages that include the NSSP priority 1 and 2 data elements.

    b. Submit all case reports in an immediate, automated way to CDC for COVID-19/SARS-CoV-2 and other conditions of public health significance with associated required data fields in a machine-readable format.

    c. Provide accurate accounting of COVID-19/SARS-CoV-2 associated deaths. Establish electronic, automated, immediate death reporting to CDC with associated required data fields in a machine-readable format.

    d. Report requested COVID-19/SARS-CoV-2-related data, including line level testing data (negatives, positives, indeterminants, serology, antigen, nucleic acid) daily by county or zip code to the CDC-designated system.

    e. Establish these systems in such a manner that they may be used on an ongoing basis for surveillance of, and reporting on, routine and other threats to the public health and conditions of public health significance.

Use Laboratory Data to Enhance Investigation, Response and Prevention

1. Use laboratory data to initiate and conduct case investigation and contact tracing and follow up; and implement containment measures.
   a. Conduct necessary case investigation and contact tracing including contact elicitation/identification, contact notification, contact testing, and follow-up. Activities could include traditional case investigation and contact tracing and/or proximity/location-based methods, as well as methods adapted for healthcare-specific contexts, employers, elementary and secondary schools, childcare facilities, institutions of higher education, long-term care facilities, or in other settings.
   b. Utilize tools (e.g., geographic information systems and methods) that assist in the rapid mapping and tracking of disease cases for timely and effective epidemic monitoring and response, incorporating laboratory testing results and other data sources.
2. Identify cases and exposure to COVID-19 in high-risk settings or within populations at increased risk of severe illness or death to target mitigation strategies and referral for therapies (for example, monoclonal antibodies) to prevent hospitalization.
   a. Assess and monitor infections in healthcare workers across the healthcare spectrum.
   b. Monitor cases and exposure to COVID-19 to identify need for targeted mitigation strategies to isolate and prevent further spread within high-risk healthcare facilities (e.g., hospitals, dialysis clinics, cancer clinics, nursing homes, and other long-term care facilities, etc.).
   c. Monitor cases and exposure to COVID-19 to identify need for targeted mitigation strategies to isolate and prevent further spread within high-risk occupational settings (e.g., meat processing facilities), and congregate living settings (e.g., correctional facilities, youth homes, shelters).
   d. Work with LHDs to build local capacity for reporting, rapid containment and prevention of COVID-19/SARS-CoV-2 within high-risk settings or in vulnerable populations that reside in their communities.
   e. Jurisdictions should ensure systems are in place to link test results to relevant public health strategies, including prevention and treatment.
      Note: Additional resources

      Treatment: https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html

      Public health strategies: https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e2.htm

3. Implement prevention strategies in high-risk settings or within vulnerable populations (including tribal nations as appropriate) including proactive monitoring for asymptomatic case detection.
   Note: These additional resources are intended to be directed toward testing, case investigation and contact tracing, surveillance, containment, and mitigation, including support for workforce, epidemiology, use by employers, elementary and secondary schools, child care facilities, institutions of higher education, long-term care facilities, or in other settings, scale up of testing by public health, academic, commercial, and hospital laboratories, and community-based testing sites, mobile testing units, health care facilities, and other entities engaged in COVID–19 testing, and other related activities related to COVID–19 testing, case investigation and contact tracing, surveillance, containment, and mitigation which may include interstate compacts or other mutual aid agreements for such purposes.
   a. Build capacity for infection prevention and control in LTCFs (e.g., at least one Infection Preventionist (IP) for every facility) and outpatient settings.

     i. Build capacity to safely house and isolate infected and exposed residents of LTCFs and other congregate settings.
    ii. Develop interoperable patient safety information exchange systems.
   iii. Assist with enrollment of all LTCFs into NHSN and provision of related user support.
  b. Build capacity for infection prevention and control in elementary and secondary schools, childcare facilities, and/or institutions of higher education.
  c. Increase Infection Prevention and Control (IPC) assessment capacity onsite using tele-ICAR.
  d. Perform preparedness assessment to ensure interventions are in place to protect high-risk populations.
  e. Coordinate as appropriate with federally funded entities responsible for providing health services to higher-risk populations (e.g., tribal nations and federally qualified health centers).

Coordinate and Engage with Partners

1. Partner with LHDs to establish or enhance testing for COVID-19/SARS-CoV-2.
   a. Support appropriate LHDs with acquiring equipment and staffing to conduct testing for COVID-19/SARS-CoV-2.
   b. Support LHDs to conduct appropriate specimen collection and/or testing within their jurisdictions.
2. Partner with local, regional, or national organizations or academic institutions to enhance capacity for infection control and prevention of COVID-19/SARS-CoV-2.
   a. Build infection prevention and control and outbreak response expertise in local health departments (LHDs).
   b. Partner with academic medical centers and schools of public health to develop regional centers for IPC consultation and support services.

PERFORMANCE MEASURES AND REPORTING

Performance Measures: In addition to the metrics and deliverable indicated above, performance measures specific to COVID-19-related activities will be finalized and provided to recipients within approximately 45 days of award. The ELC Program Office will utilize existing data sources whenever possible to reduce the reporting burden on recipients and, where appropriate, existing ELC performance measures may be used. While more frequent reporting may be employed within the first year of this supplement, these requirements may be adjusted as circumstances allow. Where it is possible, reporting will be aligned to current performance measure reporting timelines.

Consistent with current ELC Program Office practice, progress on workplan milestones will be reported on a quarterly basis utilizing REDCap. Recipients will be provided 2 weeks to update their progress and note any challenges encountered since the previous update. Financial reporting requirements shall be noted and, as necessary, updated in the Terms and Conditions of the award. The ELC Program Office will work with OGS to limit the administrative burden on recipients.

Summary of Reporting Requirements:
1. Quarterly progress reports on milestones in approved workplans via REDCap.
2. Monthly fiscal reports (beginning 60 days after NOAs are issued).
3. Performance measure data.
4. CDC may require recipients to develop annual progress reports (APRs). CDC will provide APR guidance and optional templates should they be required.

Please also note: Data collected as a part of the activities supported with these funds shall be reported to CDC in a form and fashion to be determined and communicated at a later date.

ELC Enhancing Detection Expansion

Date:

Organization Name:

Subject: Acknowledgement Letter for CK19-1904 – COVID-19 Supplemental Funds

Reference: Guidance for the use of supplemental funding (January 2021) for CK19-1904 ELC Enhancing Detection Through Coronavirus Response and Relief (CRR).

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