ELC ENHANCING DETECTION

BACKGROUND AND PURPOSE

Over the past 25 years, the Centers for Disease Control and Prevention’s (CDC) Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) cooperative agreement has enhanced the capacity of each of our recipient jurisdictions’ public health capacity to cohesively and comprehensively address infectious disease needs. In addition to foundational support for epidemiology, laboratory, and health information systems, the ELC also supports disease-specific program areas (e.g., respiratory diseases; healthcare associated infections). The portfolio of ELC-supported activities at each jurisdiction is overseen by an ELC Governance Team with representation from epidemiology, laboratory, and health information systems. This structure has been successfully utilized by ELC recipients to manage activities and funding from special appropriations provided in response to a number of infectious disease emergencies (e.g., H1N1, Ebola, and Zika).

As part of the “Paycheck Protection Program and Health Care Enhancement Act of 2020 (P.L. 116-139, Title I)”, the ELC is awarding a total of $10.25 billion dollars to our recipient base in a program-initiated component funding under the Emerging Issues (E) Project of CK19-1904, henceforth, “ELC Enhancing Detection” supplement. These funds are broadly intended to provide critical resources to state, local, and territorial health departments in support of a broad range of COVID-19/SARS-CoV-2 testing and epidemiologic surveillance related activities. Direct recipients are limited to existing jurisdictions covered under CK19-1904. These resources should complement, not duplicate, existing funding provided to jurisdictions, including the ELC Community-based Surveillance and ELC CARES Act supplements. Additionally, recipients should leverage and 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. Ongoing monitoring of milestones and performance measures will be utilized to gauge progress toward successful completion of priority activities supported with these funds.

Resources provided via this award mechanism should support necessary expenses to implement and oversee expanded testing capacity for COVID-19/SARS-CoV-2, including the ability to process, manage, analyze, use, and report the increased data produced. Recipients will establish a robust SARS-CoV-2 testing program that ensures adequate testing is made available according to CDC priorities, including but not limited to: diagnostic tests, tests

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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 Paycheck Protection Program and Health Care Enhancement Act of 2020.
for contact tracing, and surveillance of asymptomatic persons to determine community spread. Recipients should assure that provisions are in place to meet future surge capacity testing needs including point of care or other rapid result testing for local outbreaks. Plans should include plans for testing at non-traditional sites (e.g., retail sites, community centers, residential medical facilities, or pharmacies); testing of at risk populations including elderly, disabled, those in congregate living facilities including prisons, racial and ethnic minorities, and other groups at risk due to high frequency of occupational or nonoccupational contacts; and should also address any essential partnerships with academic, commercial, and hospital laboratories to successfully meet testing demand. Plans should explicitly detail how a minimum of 2% of the state’s population will be tested each month beginning immediately; as well as plans to increase that number by Fall 2020. Plans should include a list of established and proposed laboratories that will be testing for SARS-CoV-2 in each state along with each laboratory’s available platforms and throughput, that are used for testing and indicate per laboratory, testing projections by month through December 31st, 2020.

In conjunction with optimizing testing and increasing test volumes for COVID-19/SARS-CoV-2, resources will support the establishment of modernized public health surveillance systems. These systems will support the public health response to COVID-19 and lay the foundation for the future of public health surveillance. 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, minimum required data elements will be specified by CDC for each reportable condition at a later date. These surveillance and data reporting systems must:

- 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 zipcode level with additional data fields as specified by CDC. This includes not only testing for the presence of virus (nucleic acid or antigen testing), but also serological testing documenting past infection.
- 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.
- Support the display of up-to-date, critical public health information relating to COVID-19 and future outbreaks at the county or zipcode level in visual dashboards 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 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 exposure within a community and determine appropriate mitigation strategies.

**FUNDING STRATEGY**

Funding by jurisdiction will be based on population and number of cases of COVID-19/SARS-CoV-2, as further provided in the legislative language for the Paycheck Protection Program and Health Care Enhancement Act of 2020 (https://www.congress.gov/bill/116th-congress/house-bill/266/). Direct Assistance is authorized under CK19-1904; 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 and the CDC Office of Grant Services (OGS).

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2Legislative Authority for CK19-1904: Sections 301 and 317 of the Public Health Service Act (PHS Act), 42 USC, 241 and 247b as amended; and Funding is appropriated under Affordable Care Act (PL 111-148), Title IV, Section 4002 (Prevention and Public Health Fund), Title IV, Section 4002
Recipients should consider requesting the following when developing budgets, in furtherance of award activities:

- Personnel (term, temporary, students, overtime, contract staff, etc.)
- Laboratory equipment and necessary maintenance contracts
- Collection supplies, test kits, reagents, consumables and other necessary supplies for existing testing or onboarding new platforms
- Courier service contracts (new or expansion of existing agreements)
- 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
- 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)
- Reporting and/or enrollment incentives
- Contracts with academic institutions, private laboratories, and/or commercial entities
- Laboratory renovations and minor construction (may be considered for unique cases where conditions do not currently allow for safe or effective testing)

*The above list is as an example and does not represent a full list of allowable costs. Any questions about specific budget items should be directed to the OGS and the ELC Project Officer.*

Support to Local Health Departments (LHD):
Recipients should work with their LHDs to determine how local needs can be addressed with the overall available resources. Direct ELC recipients may provide financial resources to LHDs within their jurisdiction by way of a contract or other mechanism(s) as available through their Health Department. In addition to financial resources, ELC direct recipients may provide support to LHDs through offering non-financial resources (personnel, supplies, etc.) to address COVID-19/SARS-CoV-2 surveillance, case detection, reporting, response, and prevention needs at the local level.

Supporting Management of Activities and Resources:
The ELC recommends that jurisdictions 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.

**PROCESS FOR WORKPLAN AND BUDGET SUBMISSION**

This funding should support ELC Health Care Enhancement activities and the necessary reporting for Budget Period 1 under CK19-1904; however, recipients are reminded that expanded authority\(^3\) applies, and activities are likely to take 30 months for completion due to the nature of COVID-19/SARS-CoV-2. Within 30 days of receipt of the Notice of Award (NOA), the recipient is required to submit a workplan and 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 jurisdiction and CDC and documented in REDCap and/or GrantSolutions as necessary.

To appropriately document workplans, budgets, and facilitate recipients meeting the 30-day requirement:

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\(^3\) Expanded Authority is provided to recipients through 45 CFR Part 75.308 which allows recipients to incur project costs 90 days prior to award, initiate one-time extension to project period, and carryover unobligated balances to subsequent budget periods.
1. Workplan entries will be completed in the ‘ELC Enhanced Detection’ portal, under ‘ELC COVID-19 Projects’, in REDCap; and
2. Revised budgets will be completed by using the template provided via GrantSolutions Grant Notes at time of NOA issuance.
   a. Funds will be awarded under the ‘Other’ cost category;
   b. Recipients will adjust the cost category allocations of awarded funds to reflect the areas where financial assistance is needed; and
   c. Recipients will upload the revised budget into GrantSolutions via a redirection amendment, with a courtesy copy into REDCap ‘ELC Enhanced Detection’ portal, by the 30-day post award deadline.
   d. ELC and OGS will process the redirection 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 have both contributed to and agreed upon the workplan and budget submitted, must be signed by all 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 Enhanced Detection’ funding will be used in coordination with funding from CDC’s Crisis COVID-19 Notice of Funding Opportunity (NOFO) and ELC CARES.
2. Specify the distinct new or enhanced activities made possible by ‘ELC Enhanced Detection’.
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 to support local entities.
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 plan, including populations and institutional settings. Plans should align to your jurisdictional testing plans for COVID-19 per legislation\(^4\). Plans for May – June must be submitted by May 30, 2020. Plans for July – December must be submitted by June 15, 2020. Details about testing plan submission will be shared with recipients via the ELC Program office.
6. Description of use of electronic health systems for surveillance, reporting, and public health action.

Of 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 Team as needed, for subject matter expertise and technical assistance to support States testing strategies.

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

1. Regular participation in calls with CDC/HHS for technical assistance and monitoring of activities supported through this cooperative agreement.
2. On-time submission of all requisite reporting. This may include but is not limited to reporting of performance measures and progress on milestones within REDCap or provision of financial updates.
3. Documentation of any necessary budget change/reallocation through REDCap and, as necessary, GrantSolutions.

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 team, etc.).

**ACTIVITIES**

*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. 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 to be determined and communicated at a later date, if such systems are not already in place. Such systems must support reporting for COVID-19, other conditions of public health significance.*

*Activities supported by these funds include but are not limited to the following:*

**Enhance Laboratory, Surveillance, Informatics and other Workforce Capacity**

1. Train and hire staff to improve laboratory workforce ability to address issues around laboratory safety, accessioning, 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 contact tracing) and other conditions of public health significance.
4. Build expertise to support management of the COVID-19 related activities within the jurisdiction and the 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 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 (which may build capacity to test for other pathogens with potential for broad community spread) among all symptomatic individuals, and secondarily expand capacity to achieve community-based surveillance, including testing of asymptomatic individuals.
   a. Develop systems to improve speed and efficiency of specimen submission to clinical and reference laboratories.
   b. Strengthen ability to quickly scale testing 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.
   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 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.
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e. Apply laboratory safety methods to ensure worker safety when managing and testing samples that may contain SARS-CoV-2/COVID-19.

2. Enhance laboratory testing capacity for SARS-CoV-2/COVID-19 outside of public health laboratories
   a. 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.
   b. Secure and/or utilize mobile laboratory units, or other methods to provide POC testing at public health-led clinics or non-traditional test sites (e.g., homeless shelters, food processing plants, prisons, Long Term Care Facilities (LTCF), etc.).

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.
   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.
   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, for data elements to be determined at a later date, is a requirement of accepting these funds.
1. Establish complete, up-to-date, automated reporting of morbidity and mortality to CDC and others due to COVID-19 and other 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 zipcode level to inform community mitigation strategies.

2. 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 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. Increase connectivity with laboratory and healthcare feeds for epidemiologic analysis (including using automated single CSV files).
   d. Expand eCR etc to include all conditions of public health significance

3. 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.

4. Enhance systems for flexible data collection, reporting, analysis, and visualization.
   a. Implement new/replacement systems where needed. Ensure systems are interoperable and that data are able to be linked across systems, including adding the capacity for lab data and other data to be used by the software/tools that are being deployed for contact tracing.
   b. Data must be made available at the local, state, and federal level.
   c. Make data on case, syndromic, laboratory tests, hospitalization, and healthcare capacity available on health department websites at the county/zip code level in a visual and tabular manner.

5. 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 zipcode, that allows for automated transmission of data to the CDC in a machine readable format.

a. Track and send 100% of emergency department and outpatient visits for COVID-like illness, as well as other syndromes/illnesses, to CDC.
b. Submit comprehensive syndromic surveillance data for all facilities in the jurisdiction.
c. Send deidentified copies of all admit, discharge, and transfer (ADT) messages to the CDC
d. 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.
f. 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 zipcode to the CDC-designated system.
g. Establish these systems in such a manner that they may be used on an ongoing basis for surveillance of, and reporting on, 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 case investigations, conduct contact tracing and follow up, and implement containment measures.
   a. Conduct necessary contact tracing including contact elicitation/identification, contact notification, and contact follow-up. Activities could include traditional contact tracing and/or proximity/location-based methods, as well as methods adapted for healthcare-specific and congregate 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 vulnerable populations to target mitigation strategies.
   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 employment settings (e.g., meat processing facilities), and congregate living settings (e.g., prisons, 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.

3. Implement prevention strategies in high-risk settings or within vulnerable populations (including tribal nations) including proactive monitoring for asymptomatic case detection.
   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. Increase Infection Prevention and Control (IPC) assessment capacity onsite using tele-ICAR.
   c. Perform preparedness assessment to ensure interventions are in place to protect high-risk populations.
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a. Coordinate as appropriate with federally funded entities responsible for providing health services to vulnerable 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 healthcare outbreak response expertise in 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 21 days of award. The ELC 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 practice, progress on 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 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.