Centers for Disease Control and Prevention (CDC)
Office of Financial Resources

Instructions for Preparing an Annual Performance Report (APR)
Catalog of Federal Domestic Assistance (CFDA): 93.116
Notice of Funding Opportunity Number (NOFO): CDC-RFA-PS20-200103CONT22

Tuberculosis Elimination and Laboratory Cooperative Agreement
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention,

Division of TB Elimination

Eligibility:

This award will be a continuation of funds intended only for recipients previously awarded under **CDC-RFA-PS20-2001, Tuberculosis Elimination and Laboratory.**

For this award, the award amount has been uploaded to GrantSolutions as a separate correspondence and reflects the anticipated funding level for Budget Year 03, Fiscal Year 2022, Budget Period 01/01/2022 – 12/31/2022.

Application Submission:

CDC requires recipients to submit their Annual Performance Reports (APR), which serves as the non-competing continuation application, through www.grantsolutions.gov no later than 120 days prior to the end of the budget period.

If you encounter any difficulties submitting your annual performance report through www.grantsolutions.gov, please contact the GrantSolutions helpdesk at 866-577-0771 or email help@grantsolutions.gov prior to the submission deadline. If you need further information regarding the annual performance report process, please contact Romero Stokes, Grants Management Specialist, at lnj0@cdc.gov. For programmatic information, please contact Martha Boisseau, Project Officer, at 770.488.6261.

Reports must be submitted by 08/31/2021***, 11:59 p.m. Eastern Standard Time on*** www.grantsolutions.gov for Reporting Period(s) **1/1/2020 – 12/31/2020 and 1/1/2021 – 6/30/2021**. Late or incomplete reports could result in an enforcement action such as a delay in the award or a reduction in funds. CDC will accept requests for a deadline extension on rare occasions and after adequate justification has been provided.

Annual Federal Financial Report Submission

The Annual Federal Financial report (FFR) SF-425 is required and must be submitted through the Payment Management System (PMS) no later than 90 days after the end of the budget period. If a budget period is greater than 12 months, at a minimum annual FFRs are submitted for each 12-month period. The annual FFR for this Budget Period 01/01/2021-12/31/2021 is due in PMS by 03/31/2022.

General Application Packet Tips:

- Properly label each item of the application packet
- Each section should use 1.5 spacing with one-inch margins

- Number all pages
- This report must not exceed 45 pages excluding administrative reporting. Web links are allowed.
- Where the instructions on the forms conflict with these instructions, follow these instructions.
- GrantSolutions allows several file types to be uploaded within the system. Refer to GrantSolutions help support for a list of the file types.

Checklist of required contents of application packet:

1. Performance Progress and Monitoring Report (PPMR)
2. SF-424A Budget Information-Non-Construction (online form)
3. Budget Justification (attachment)
4. Indirect Cost Rate Agreement (attachment)
5. Performance Narrative
6. SF-LLL Disclosure of Lobbying Activities (online form and instructions), if applicable[1], are located at https://www.grants.gov/web/grants/forms/post-award-reporting-forms.html
7. SF-424B Assurances Non-Construction (online form)
8. Certifications and Assurances (online form)
9. Interim Federal Financial Report (FFR) SF-425 instructions are located at https://www.grants.gov/forms/post-award-reporting-forms.html
10. Additional Program Requirements, if applicable

1. Performance Progress and Monitoring Report:

- PPMR instructions are attached to the form located at https://www.cdc.gov/grants/documents/Performance-Progress-and-Monitoring-Report-PPMR.pdf.

2. SF-424A Budget Information and Justification:

- Instructions for completing SF-424A Budget Information-Non-Construction online form are located at https://www.grantsolutions.gov/gs/pdf/ophs-1_SF424A_Instruction.pdf

  SPECIAL NOTE: In the SF-424A Budget Information section, recipients should fill out column (a) – "Grant Program Function or Activity," under "Section A – Budget Summary" for each proposed component. Under "Section B - Budget Categories," each column should reflect requested funds for each component. The "Object Class Categories" totals under Section B should match what is being requested in your budget narrative. Column (5) – "Total" should be a cumulative total of all requested funds.

- Analysis of Remaining Time and Funds
  1. If it appears there will be insufficient funds, provide detailed justification of the shortfall. List the actions taken to bring the obligations in line with the authorized funding level.
  2. Based on the current rate of obligation, if it appears there will be un-obligated funds at the end of the current budget period, provide detailed actions that will be taken to obligate this amount or use the process below to get access to unused funds.

[1] The form has instructions that indicate when the form is required.

Recipients Approved for Expanded Authority

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 (FFR). If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the recipient's authority to automatically carryover unobligated balances in the future, use the balance to reduce or offset CDC funding for a subsequent budget period, or use a combination of these actions.

In addition to reporting use of unobligated funds in the annual FRR, program requests the submission of an **interim FFR** as part of the APR submission. Submit an interim **hardcopy** FFR as an attachment and title: "Interim FFR" Federal Financial Report (FFR), Standard Form-425, available on the internet at https://www.grants.gov/web/grants/forms/post-award-reporting-forms.html.

- The estimated un-obligated balance should be realistic to be consistent with the annual FFR to be submitted following the end of the budget period.
- The proposed budget should be based on the federal funding level, which is stated on page one of this document (Anticipated Funding Level).
- In a separate narrative, provide a detailed, line-item budget justification of the funding amount requested, including any request to use unobligated funds, to support the activities to be carried out with those funds. Attach and title it "Budget Narrative".
- The budget justification must be prepared in the general form, format, and to the level of detail as described in the CDC Budget Preparation Guidelines. The budget guidance is provided on CDC's internet at: http://www.cdc.gov/grants/applying/application-resources.html and the GrantSolutions application control checklist.
- For any new, proposed subcontracts, provide the information specified in the Budget Guidance.
- When non-federal matching is required, provide a line-item list of non-federal contributions including source, amount, and/or value of third-party contributions proposed to meet a matching requirement.

3. **Indirect Cost Rate Agreement (This is not applicable to institutions of higher education. The rates applied are based on the agreement in effect from the first year of award.):**
   A. If indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those recipients under such a plan.
   B. Clearly describe the method used to calculate indirect costs. Make sure the method is consistent with the Indirect Cost Rate Agreement.
   C. To be entitled to use indirect cost rates, a rate agreement must be in effect at the start of the budget period.
   D. If there is no Indirect Cost Rate Agreement or the agreement has expired, indirect costs may be charged as direct if (1) this practice is consist with the recipient's/applicant's approved accounting practices; and (2) if the costs are adequately supported and justified.
   E. If applicable, attach and name the document, "Indirect Cost Rate."
   F. If applicable, the recipient's indirect costs are based on a rate of ten percent of modified total direct costs (MTDC) as defined in 45 CFR Part 75.2.
   G. For institutions of higher education, indirect costs are based on the negotiated indirect cost rate agreement used for the first year award, and rates in that agreement are to be used for the remainder of the competitive segment in accordance with 45 CFR Part 75. Indirect cost/facilities and administration

rates for subcontracts will be treated in the same manner as those for the recipient if the subcontractor is covered by 45 CFR Part 75.

H. For grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S., indirect costs are based on a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000.

4. Performance Narrative:

Section I. Current Budget Period Progress:

Provide a brief report addressing the following elements of each objective or activity. See Additional Program Requirements in number 4 below for specific guidance.

The annual performance report must include the following:

- **Performance Measures** (including outcomes) – Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results** – Recipients must report evaluation results for the work completed to date (including any data about the effects of the program).
- **Work Plan** – Recipients must update work plan each budget period.
- **Data management Plan** – Projects that involve collection or generation of new public health data are required to develop a Data Management Plan (DMP) and update throughout the life cycle of the data. Recipients must report updates to the DMP. Recipients should submit an updated DMP only if there are changes to the previously submitted 5-year DMP.
- **Successes**
    - Recipients must report progress on completing activities outlined in the work plan.
    - Recipients must describe any additional successes (e.g., identified through evaluation results or lessons learned) achieved in the past year.
    - Recipients must describe success stories.
- **Challenges**
    - Recipients must describe any challenges that might affect their ability to achieve annual and project-period outcomes, conduct performance measures, or complete the activities in the work plan.
    - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**
    - Recipients must describe how CDC could help them overcome challenges to achieving annual and project-period outcomes and performance measures, and completing activities outlined in the work plan.

Section II. New Budget Period Proposed Objectives and Activities:

A. List proposed objectives for the upcoming budget period. These objectives must support the intent of the original Notice of Funding Opportunity (NOFO).

B. Each objective and activity must contain a performance or outcome measure that assesses the effectiveness of the project.

C. For each objective:
    1. List activities that will be implemented.
    2. Provide a timeline for accomplishment.

3. Identify and justify any redirection of activities; and
4. Explain the methods you will use to implement the new, redirected activities.

D. In addition to this information, include comments pertaining to budgetary issues that might hamper the success or completion of the project as originally proposed and approved. Please utilize the work plan format in the original work plan, if applicable.

5. Additional Program Requirements

Awardees have a 65-page limit for the APR. Within the 65-page limit, excluding administrative reporting (i.e., SF-424A, budget narrative, and indirect cost rate agreement). Recipients should use a maximum of 40 pages for P&C; 10 pages for HRD; and 15 pages for Laboratory Strengthening to cover performance reporting and continuation funding application. Attachments are not allowed except for administrative reporting, but weblinks are allowed.

The APR will be due 8/31/2021 for activities performed January 1, 2020 through December 31, 2020 (complete year of Budget Period 01) and January 1, 2021 through June 30, 2021 (1st half of Budget Period 02). These reports should be distinguishable from one another.

Note: To meet CDC requirements for this NOFO, reports should include performance and outcome reporting specific to each component as follows:

Prevention and Control (P&C):

- One-page summary report on National TB Program Objectives using NTIP system including a description of which objectives were met and what the impediments were to meet the objectives.
- Report priority level activities highlighting successful outcomes, including development of benchmarks for specific activities.
- Report barriers and challenges to program implementation of the proposed priority level strategies/activities encountered; how was the planned program modified to accommodate them?
- Report specific strategies and collaborations related to addressing co-morbidities and health disparities.

Program Planning, Evaluation, and Improvement:

- Annually, describe program evaluation results from the program evaluation plan outlined in the prior year's APR, remediation strategies identified to promote performance improvement, and a new program evaluation plan for the coming year. The program evaluation section annual report must include the following:

i. Results and conclusions of the prior years' program evaluation (awardee can refer to the evaluation plan included in the last APR instead of repeating the plan):

1. Describe status of implementation of the prior year's program evaluation plan, including rationale for plan revisions, and challenges to plan completion.
2. Report findings, including barriers, facilitators, limitations, and lessons learned, related to reaching performance targets.

ii. Remediation plan based on the prior year's program evaluation:

1. Describe how findings and lessons learned will be applied to improve program performance (i.e. new or revised strategies, sharing of findings and lessons learned).
2. Outline a plan and timeline to evaluate the effectiveness of remediation efforts.

iii. Background for the coming years' program evaluation focus area:

1. Describe the rationale for selecting the focus area (identify which NTIP indicator or other data source was used to determine the focus area and why this area was chosen).
2. Describe how the applicant intends to use findings to improve the program.

iv. Program Evaluation Plan for the coming year

1. Define evaluation objectives and\or key evaluation questions. Each objective should be Specific, Measurable, Achievable, Realistic and Time-bound (SMART).
2. For each program evaluation objective, describe data sources, methods, and timelines for data collection and analyses.

- **Annually, each applicant/recipient must identify their Designated Program Evaluation Focal Point, including the following information:**
  Name:

  Job title:

  Mailing address:

  Telephone:

  Email:

- **Cohort Review Reports: Grantees should report progress on conducting cohort reviews, including**
  Number of cases discussed,

  Key issues identified during the reviews, and

  Recommendations provided.

Format for Cohort Review Reporting:	
Element	**Progress**
Date(s) of cohort review(s)	
Number of cases discussed (per review/total)	
Summary of review process	
Key issues identified and resolved	
Recommendations	
New tools or trainings	

Human Resource Development (HRD):

Recipients should report on progress of HRD activities and achievements for the previous year. The report should include, but is not limited to the following:

- A description of how HRD funds were used.
- Training courses provided.
- Training courses attended.
- Educational resources purchased or leased.
- Educational materials developed.
- Description of collaboration with partners, such has those serving high risk populations.
- Attendance at the TB ETN conference and focal point meeting; and
- Salary for training and education personnel.

HRD Progress Report should also include a description of how needs were identified and addressed, as well as barriers and opportunities identified in TB HRD.

Annually, the HRD focal point should be identified in the application, including:
Name, Title, and contact information.

New for this application: the program's medical consultant should be identified in the application, including: Name, Title, and contact information. (Note: If the applicant does not have an identified medical consultant and uses the Centers of Excellence as their consultant, please state so).

Public Health Laboratory Strengthening:
The recipient's APR for the Laboratory Component should include:

- An organizational chart of personnel performing TB laboratory testing including names of staff in each position. Include a designated laboratory point of contact with contact information.
- A brief description of the methods used in the laboratory and/or access through referral, including those for specimen processing, direct detection, AFB smear, culture, identification, DST and IGRA as applicable and a brief overview of the overall laboratory testing algorithm. Testing methods should be stated and specific instrument used for testing included (i.e., Bruker or Vitek MALDI-TOF). The concise description should include information on overall flow of specimens in the laboratory, how testing is reflexed, referral practices, reporting protocols, electronic test ordering and reporting and number of days per week testing is performed. A visual testing algorithm may also be included. Plans to implement new technologies (e.g., IGRA, WGS) should be discussed here.
- An updated Work Plan to include progress on Laboratory Elements 1, 2 and 3 activities, updated timelines and encountered barriers to potential completion. The updated Excel laboratory work plan can be found at **https://www.cdc.gov/tb/education/SampleWorkPlans.htm**

Laboratory Element 1: Ensure availability of high-quality and prompt core laboratory services for TB.

All laboratories, regardless of volume, should provide a narrative on laboratory activities related to improving each of the national benchmark turnaround time (TAT) recommendations to include:

- Laboratory-specific measurable goals for improving each TAT (specimen receipt, AFB smear, ID, DST and NAAT). Laboratory-specific goals should be chosen to achieve or exceed national benchmarks. If the laboratory is currently meeting national targets, maintaining the current TAT or a new measurable goal should be listed.
- Updates in subsequent annual performance reports should describe progress made towards achieving previously stated goals.
- Description of specific strategies and activities for achieving the stated goals.
- Explanation of potential obstacles to meeting the stated goals.
- Using PDF data forms, report the laboratory's data for each of the following workload and TAT indicators for the full year 2020 and 2021 year-to-date (January - June). These data should reflect testing for your jurisdiction only (i.e., not work performed for another state).

Turnaround Times (TAT)

Report the calculated TAT for each recommendation as described below. Calculations should be in calendar days. Current performance targets and instructions on how to calculate TATs can be found at https://www.aphl.org/programs/infectious_disease/tuberculosis/Pages/Cooperative-Agreement-Toolkit.aspx.

- Promote rapid delivery of specimens to the laboratory. Benchmark is receipt within 1 day of specimen collection. Report cumulative percent received within 1, 2 and 3 calendar days.
- Use fluorescent acid-fast staining and promptly transmit results. Benchmark is report within 1 day from receipt of specimen. Report cumulative percent transmitted within 1, 2 and 3 calendar days.
- Reduce the average time for a laboratory to confirm and report tuberculosis cases using NAAT. Benchmark is 2 days from receipt of clinical specimen for 77% of cases that are later culture confirmed. Report the percent of MTBC culture-confirmed patients with a positive NAAT or other direct detection method that was reported within 48 hours of specimen receipt.
- Use rapid methods to identify and report isolates as MTBC as soon as possible. Benchmark is report within 14-21 days from receipt of specimen. Report percent of MTBC isolates identified from initial diagnostic specimens within 21 calendar days.
- Determine the susceptibilities of initial MTBC isolates to first-line drugs in a rapid culture system and report results promptly. Report percent rifampin results reported for initial diagnostic specimens within 17 days of identification of MTBC from culture. Do not include molecular testing data.
- Consider performing **in-house** molecular methods for the detection of mutations associated with drug resistance, as appropriate. Not every public health laboratory will have sufficient volume or capacity to perform this testing. TAT benchmarks using molecular methods for susceptibility testing have not been determined. Data is requested from those performing in-house molecular testing to establish a baseline for separate TATs for clinical specimens/sediments and isolates. Data from both probe-based and sequencing methodologies should be included. If more than one method is performed, stratify TAT by method. This indicator may have some redundancy with the NAAT indicator if the methodology used also detects MTBC.

- For **in-house** molecular DST, report the mean and range TAT (in days) for clinical specimens/processed sediments from specimen receipt until final report. Please stratify TAT by each method used.
- For **in-house** molecular DST, report the mean and range TAT (in days) for MTBC isolates from date of receipt (if a referred isolate) or date of ID (if ID is performed in-house) until final report. Please stratify TAT by each method used.
- If IGRA is performed in-house (within the PHL), report the mean number of days between specimen collection and test result for an IGRA result to be reported.

Workload Data

Report the workload volume indicators listed below:

1) Total number of clinical specimens processed for smear and culture. Do not include isolates referred from another laboratory.

2) Number of individual patients for whom a clinical specimen was processed for smear and culture.

   a. Of these, report the number of individual patients for whom at least one culture was positive for MTBC.

   b. Of these individuals positive for MTBC by culture, report the number initially positive by NAAT from a clinical specimen in your laboratory. Note: This number should not include specimens or processed sediments referred for NAAT only.

   c. Of those individuals positive for MTBC by culture who had a positive NAAT from the clinical specimen, report the **number** of individual patients for whom the laboratory report of MTBC was provided within 48 hours of clinical specimen receipt.

3) Number of individual patients for whom a clinical specimen was tested directly with a NAAT. (This includes testing performed in-house and referred testing.) Do not include data for rapid species identification tests performed on isolates (e.g., ACCUPROBE).

   a. Of these, report the number of individual patients for whom a NAAT result was positive for MTBC. Note: For labs that accept referred specimens or sediments for NAAT-only, this number may be higher than data reported for 2b above.

4) Number of individual patients for whom a reference isolate was received to rule out or confirm the identification of MTBC. This should not include known nontuberculous mycobacteria.

   a. Of these, report the number of individual patients that had at least one reference isolate identified as MTBC.

5) Number of individual patients for whom growth-based MTBC first-line DST was performed and/or, if DST was not performed in-house, for whom an isolate was referred to another laboratory for DST.

6) If applicable, number of individual patients for whom in-house molecular DST was performed. Molecular DST method(s) should be described in the narrative section.

   a. Number of individual patients for whom in-house molecular DST was performed for clinical specimens/sediments.

   b. Number of individual patients for whom in-house molecular DST was performed for MTBC isolates.

7) Number of individual patients for whom the laboratory referred an isolate of MTBC for genotyping.

8) If applicable, provide the total number of IGRAs performed in-house.

Volume Considerations for Addressing Laboratory Elements 2 and 3
Laboratories receiving ≤ 1,000 clinical specimens each year should provide at least one measurable objective for both Elements 2 and 3 as described below. Those laboratories receiving 1,001–5,000 clinical specimens each year should provide at least two measurable objectives and those receiving ≥ 5,001 clinical specimens each year should provide at least three measurable objectives for Elements 2 and 3.

Laboratory Element 2:

Laboratories will implement process improvements during the 5-year project period and report on gained efficiencies from these changes in practice in Annual Performance Reports.

To improve laboratory efficiency and quality assurance, local data (i.e., your laboratory-specific data) should be monitored, frequently reviewed and analyzed to explore opportunities for process improvements specific to laboratory testing volume and services for continual quality improvement (e.g., contamination rate, workload and turnaround numbers/percentages over time, testing algorithms, equipment improvements/challenges).
Report on the following information below:

- Measurable objectives appropriate for your laboratory testing volume and level of service should be chosen and described.
- Specific strategies and activities related to improvements should be described.
- Progress, obstacles, and outcomes related to gained efficiencies to previously stated objectives should be updated in subsequent annual performance reports.
- Once objectives are achieved, either the next phase of the objective or a new objective must be chosen for the upcoming year.

Laboratory Element 3:

Laboratories will communicate and collaborate with partners (e.g., healthcare providers, TB Programs, TB Nurses, and other laboratories) to ensure optimal use of laboratory services and timely flow of information. Laboratories should initiate plans for increased communication or educational opportunities for specimen collection and submission with TB Programs and other laboratories, find opportunities to apply evidence-based local practices within the broader public health system and collaborate with TB Programs and local hospitals to improve awareness and understanding of laboratory services (e.g., development of specimen collection guidelines or promotion of available in-house or reference laboratory services).
Report on the following information below:

- Measurable objectives appropriate for your laboratory testing volume and level of service should be chosen and described.
- Specific strategies and activities to improve communication and collaboration should be described.
- Progress, obstacles, and outcomes related to previously stated objectives should be updated in subsequent annual performance reports.
- Once objectives are achieved, either the next phase of the objective or a new objective must be chosen for the upcoming year.

Performance Measure Reporting (optional)

Recipients will meet this annual requirement to report on performance measures with the submission of an Annual Performance Report. **However, CDC will request an additional report, the Performance Measure Report, in certain instances such as a jurisdiction's response to a large TB outbreak.**

Performance Measure Reports should at minimum include:

- Report on the activities completed
- Outcomes achieved
- Challenges experienced
- Program improvements as applicable
- Additional support (if any) requested from CDC

Awardees submitting Performance Measure Reports for response to large TB outbreaks should provide a report **90 days following the response** and **quarterly thereafter** for the first year of outbreak response, and at least semiannually thereafter until the outbreak subsides.

Aggregate Report for Program Evaluation (ARPE)

The ARPE report is due each year:	By March 31.
The Final ARPE report is due:	For the current year minus two (for example, in 2022, the Final report is due for year 2020).
The Preliminary ARPE report is due:	For the current year minus one (for example, in 2022, the Preliminary report is due for year 2021).

The report deadline was moved back from August 15 to March 31 to allow more current data to be used with the funding formula. The due dates for the Targeted Testing report for high morbidity areas follows the same schedule as the Contact Investigation report. Low morbidity areas are encouraged to report as indicated in Strategy 2c.

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30341-3724

Date: 6/30/21

Reference: Conversion of Funds from FA to DA
NOFO: CDC-RFA-PS20-2001-02

Dear Applicant:

If you would like to request the conversion of awarded funds from FA to DA, please create a memo with this request and include it with your continuation application.

Please upload this memo as a miscellaneous attachment addressed to your Program Officer.