Information Call for Funding Opportunity Announcement

Strengthening the U.S. Response to Resistant Gonorrhea (SURRG)

ELC Cooperative Agreement (CK19-1904), Project S

March 9, 2021

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of Sexually Transmitted Disease Prevention

CDC

Speakers

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SURRG Project Lead

Division of STD Prevention

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Division of STD Prevention

Laboratory Reference & Research Branch

Call Goal and Objectives

❑ <u>Goal</u>: Assist applicants with their application process for ELC Cooperative Agreement, CK19-1904, Project S.

❑ <u>Objectives</u>:

1. Provide an overview of the content of application guidance

2. Provide an opportunity for questions and answers

Both technical questions about the webinar and questions for the speakers can be entered into the chat.

Agenda

- ❑ SURRG background

- ❑ Overview of strategies and activities

- ❑ Overview of reporting requirements

- ❑ Award eligibility and application review process

- ❑ Funding strategy and budget guidance

- ❑ Staffing and Workplan guidance

- ❑ Q&A session

SURRG Background

❑ Program out of CDC's Division of STD Prevention

❑ Federal Antibiotic Resistance Initiative funding

❑ Supports 2020-2025 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB)

  ▪ Slow the emergence and spread of resistant bacteria/infections

  ▪ Advance use of rapid and innovative diagnostic tests for identification of resistant bacteria

❑ Build local capacity for antibiotic resistant gonorrhea rapid detection and response

SURRG — STRENGTHENING THE U.S. RESPONSE TO RESISTANT GONORRHEA

SURRG Background

❑ Administered through the ELC Cooperative Agreement

❑ ELC 5-year cycles <u>do not</u> match SURRG 5-year cycles

❑ SURRG Cycle 1, 2016-2021 (awardees reapplied each year):
  ▪ ELC BP3-5 of ELC CK14-1401
  ▪ ELC BP1-2 of ELC CK19-1904

❑ SURRG Cycle 2, 2021-2026: (awardees reapply each year):
  ▪ ELC BP3-5 of ELC CK19-1904
  ▪ ELC BP1-2 of ELC (Num. TBD)

❑ Funding beyond 2021-2022 not guaranteed

❑ SURRG application includes:
  ▪ 5 required strategies with 29 required activities (Component 1)
  ▪ 1 optional strategy (Component 2)

SURRG Strategies

❑ <u>Strategy 1</u>: Strengthen local resistant GC threat coordination and epi capacity through protocol and workforce development

❑ <u>Strategy 2</u>: Strengthen specimen collection and local processes for robust and timely detection of resistant GC threats.

❑ <u>Strategy 3</u>: Conduct enhanced SURRG GC case investigations and outbreak response

❑ <u>Strategy 4</u>: Strengthen public health lab capacity for timely detection of ARGC surveillance, reporting, and response

❑ <u>Strategy 5</u>: Collect, clean and submit data to CDC. Conduct ongoing monitoring, quality improvement activities and epi analyses

❑ <u>Strategy 6 (Component 2 - *Optional*)</u>: Pilot demonstration and evaluation projects to address critical gaps in U.S. capacity to respond to ARGC and establish best practices

Strategy 1: Strengthen local resistant GC threat coordination and epi capacity through protocol and workforce development

a. Staffing
b. Develop and implement project protocols
c. Modify and enhance data systems
d. Develop state/local ARGC outbreak response plan
e. Establish state protocol for provider reporting of and PH response to suspected treatment failure cases
f. Establish a statewide ARGC preparedness and response Center of Excellence
g. Contact tracing effectiveness outreach

Strategy 2: Strengthen specimen collection and local processes for robust and timely detection of resistant GC threats

a. Collaborate with health centers for robust collection of genital, pharyngeal and rectal GC specimens

   ➢ at least 1 STD clinic(s) in ≥1 local jurisdiction
   ➢ at least 2 community-based non-STD health centers
      ➢ High morbidity
      ➢ Reach different populations than STD clinic (e.g. women, ERs)

b. Address protocol development, patient flow, specimen collection supplies, staff training, data collection, specimen courier, etc.

Strategy 2 (continued):

c. Goal: collect enough specimens to perform antibiotic susceptibility testing (AST) on 15% or more of local GC cases

➤ or 1,000 isolates if jurisdiction has >7,000 GC cases per year

➤ Anticipate culture positivity to be much less than specimen collection

d. Provide routine data monitoring and feedback reports to partnering clinics

Strategy 3: Conduct enhanced SURRG GC case investigations and outbreak response

a. Conduct partner services investigations and facilitate Test of Cure for patients with infections with reduced cefixime or ceftriaxone susceptibility

b. Modify DIS database and/or data collection to capture required SURRG investigation data

c. Train DIS staff on SURRG investigations

Strategy 4:
Strengthen PH lab capacity for timely detection of ARGC surveillance, reporting, and response

a. Build lab culture and AST capacity
   - Protocols, training, CLIA certification, LIMS modifications
   - CDC will provide culture and AST SOP
   - CDC can provide remote or in-person Etest training

b. Conduct timely culture and AST (using Etest®)
   - Etest for ceftriaxone and cefixime
   - Goal: On average, AST results within 5 days of specimen collection

c. As needed, validate GC specimen collection and transport techniques

d. Routinely submit isolates to assigned regional lab for expanded AST and WGS

Strategy 4 (continued):

e.   Pilot running a molecular assay using a real-time PCR
   ➢ CDC will provide SOP
   ➢ ≥ 20 specimens

f.   Establish access to remnant GC+ NAATs for molecular testing in the event of an outbreak
   ➢ from a health system, lab or patient population not already participating in SURRG

g.   Develop state or local lab procedures for accepting/processing suspected treatment failure specimens from non-SURRG providers

Strategy 5: Collect, clean and submit data to CDC; Conduct ongoing monitoring, quality improvement activities and epi analyses

a. Routinely extract, clean and submit data from systems (LIMS, EMR, surveillance and partner services databases)
   - ➤ monthly aggregate metric reporting
   - ➤ ~quarterly line-listed data submissions to CDC

b. Conduct routine process and outcome monitoring and evaluation activities

c. Conduct ≥1 SURRG-related quality improvement project

d. Conduct analysis of local data

e. Collaborate with CDC efforts to pilot use of genomic data for public health action (CDC-led)

Strategy 6 (Component 2 – Optional): Pilot demonstration and evaluation projects to address critical gaps in U.S. capacity for respond to ARGC and establish best practices

> Note:
> Component 2 funds are to pilot and evaluate innovative approaches, not to fund provision and evaluation of recommended or routine practices

a. Establish TOC best practices

b. Establish contact tracing/partner services best practices

c. Establish GC transport media best practices

Strategy 6 (continued):

d. Enhance local capacity for implementation of molecular assays to detect markers of cephalosporin resistance in GC/conduct on-going molecular surveillance

e. Enhance ARGC lab reporting (reporting of AST results from non-PH labs)

f. Other ARGC pilot demonstration and evaluation project

Reporting Requirements

1. <u>Directly reported</u> to CDC <u>on ELC renewal application</u>
   - Project staffing

2. <u>Monthly and annual metric reports</u>:
   - # specimens collected and positive cultures by anatomic site and clinic
   - Numbers of GC-positive NAATs by anatomic site (<u>for STD clinics only</u>)
   - Aggregate time for processing cultures and AST

3. <u>Line-listed data</u> (submitted ~quarterly)
   - Per CDC protocol: clinic, lab and investigation data in SAS files

4. Other <u>annual</u> <u>submissions directly to CDC SURRG team</u>:
   - Project protocols
   - ARGC outbreak response plan
   - Brief summary of monitoring activities, epi analyses, and QI activities
   - Written summary and webinar presentation for any funded Component 2 projects.

Eligibility

❑ ELC recipients to partner with:

- ▪ 1-3 local high GC risk jurisdictions:
  - ➢ High GC morbidity
  - ➢ History of emerging GC resistance
  - ➢ Access to large numbers of MSM
- ▪ ≥ 1 STD clinic (Dx ≥ 200 GC cases per year)
- ▪ ≥ 2 high GC morbidity non-STD community health centers
  - ➢ can collect ≥ 20 specimens per month
- ▪ ≥ 1 proximate state or local laboratory
  - ➢ Can propose different lab for molecular activities

❑ With staffing, experience, leadership and data systems capacity and commitment to implement scope of work

Application Review Process

- ❑ Each SURRG application will be reviewed by multiple staff from DSTDP

- ❑ Decisions will be based on factors outlined in the guidance (p. 183)

Application Review: SURRG and GISP

❑ Applications for SURRG (Project S) and GISP (Project T) will be reviewed separately

- NOTE: All funded SURRG sites will participate in GISP: AST data from isolates from the first 25 males/month with symptomatic urethritis from participating STD clinic(s) will be incorporated into GISP surveillance data

  HOWEVER…

- Applicants CANNOT be funded for SURRG and GISP for the same jurisdiction.

- Applicants that want to be considered for GISP in the event they are not funded for SURRG, must submit a separate GISP application

- Applying only to SURRG (and not GISP for the same jurisdiction) will not increase your chances of being a SURRG awardee.

- ELC applicants can apply for GISP for >1 jurisdiction

  • GISP may make funding decisions based on geographic diversity

Funding Strategy

- ❏ ~$6,000,000 available for BP4 (SURRG cycle 2, year 1)
    - ▪ Estimated 6-8 awardees for Component 1
        - • *Estimated average award for Component 1: $650,000*
    - ▪ Estimated 4-5 awardees will also be funded for Component 2
        - • *Estimated average award for Component 2: $150,000*

- ❏ Budget decisions based on scope of work, available funding, and proposed budget

- ❏ Awardees will reapply annually

Funding Component 1 and 2

- Funding for Component 2 will only be considered for applicants funded for Component 1

- Applicants can request funding for/be awarded funding for more than one activity/project in Component 2

- Component 2 proposals can be 1-year or multi-year proposals, however if funded:
  - funding is not guaranteed beyond ELC BP3
  - proposed workplan must include an evaluation component to be completed within ELC BP3

Budget Request Guidance

- Budget requests should be sufficiently detailed to guide funding decisions

- Refer to guidance (p. 183) for allowable expenses

- Use "budget justification" cells to provide detail
  - <u>Personnel</u>: use to describe key SURRG roles and responsibilities AND % FTE for any component 2 activities
  - <u>Supplies and equipment</u>: use to itemize laboratory supply requests (per unit cost, # of units)
  - <u>Travel</u>: use to describe key per unit costs: $/mile, airfare, per diem

- If request for LHD funds is included as a contract:
  - Include <u>detail</u> on positions, salaries, fringe, overhead, supplies, equipment and travel costs in the "budget justification" cell
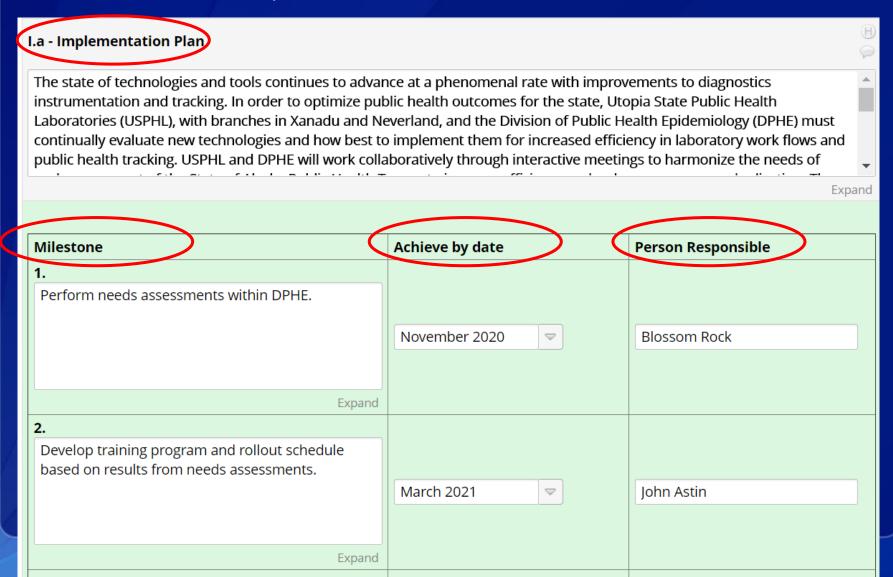 - Encouraged to submit the LHD contract budget as an appendix

Budget Requests

- **Personnel: Using dropdown tab, indicate up to 4 key activities for each personnel request and other budget line items (new)**

Workplan Guidance

❑ For each activity (≥29) applicants will complete:

I.a - Implementation Plan

The state of technologies and tools continues to advance at a phenomenal rate with improvements to diagnostics instrumentation and tracking. In order to optimize public health outcomes for the state, Utopia State Public Health Laboratories (USPHL), with branches in Xanadu and Neverland, and the Division of Public Health Epidemiology (DPHE) must continually evaluate new technologies and how best to implement them for increased efficiency in laboratory work flows and public health tracking. USPHL and DPHE will work collaboratively through interactive meetings to harmonize the needs of

Expand

Milestone	Achieve by date	Person Responsible
1. Perform needs assessments within DPHE.	November 2020	Blossom Rock
2. Develop training program and rollout schedule based on results from needs assessments.	March 2021	John Astin

Workplan Guidance: Implementation Plan

❑ There is no "*Approach*" section this year
- No problem statement
- No justification section
- No applicant capacity section
- No evaluation plan

❑ Therefore – you are encouraged to **insert applicant capacity into "implementation plan" cells as relevant** (local morbidity, staff/HD experience and skillset, staffing, infrastructure, modifiable data systems, leadership investment, etc.)

Workplan Guidance: Milestones

❑ Milestones are discrete points in an activity that mark the completion of one phase and entry into the subsequent phase (not individual steps to get to the discrete outcome)

❑ They allow for quarterly monitoring of activity progress to determine if ahead of schedule, on schedule, or behind

❑ Written in active voice; some examples include:
   ➢ Build feedback report; Modify data systems
   ➢ Hire staff; Establish lab Etest capacity; Develop clinic protocols

❑ Avoid vague milestones:

❑ Avoid ongoing, routine activities:

❑ Use realistic and staggered complete by dates
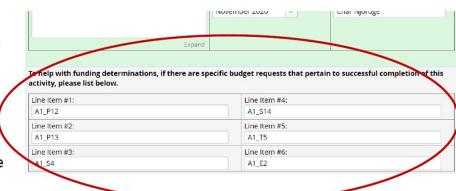
Workplan Guidance: Linking to Budget

- (New) Can assign up to the 6 most important budget line items to accomplish each activity

- Format: Project tab name_cost category+line #

- Example: **S.1_P13**

- Cost categories:

  – Personnel "P"

  – Supplies "S"

  – Equipment "E"

  – Travel "T"

  – Other "O"

Epidemiology *and* Laboratory Capacity *for* Prevention *and* Control *of* Emerging Infectious Diseases | Preventing Infectious Disease Threats by Strengthening U.S. Health Departments

Linking Workplan to Budget

- New section for BP3 that allows mapping activities to line items in the budget workbook.

- There are complimentary fields in the BP3 budget workbook that allow linkage to activities.

November 2020 | Char Njoroge

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To help with funding determinations, if there are specific budget requests that pertain to successful completion of this activity, please list below.

Line Item #1:	Line Item #4:
A1_P12	A1_S14
Line Item #2:	Line Item #5:
A1_P13	A1_T5
Line Item #3:	Line Item #6:
A1_S4	A1_E2

- Using these fields can help CDC program staff with funding determinations and understand potential impact of not providing financial support, as requested, when doing budget markups.

Staffing Considerations

- Staffing guidance p. 183 and 185

- Key roles/program positions:
  - Project Director/Principal Investigator
  - Laboratory Lead
  - **Epi Coordinator/Project manager**
  - Bench laboratorian
  - Data Manager
  - Epidemiologist
  - Clinical lead
  - DIS or DIS Supervisor

- Staffing structure may differ based on proposed workplan

- Individuals can serve in more than one role if appropriate

Staffing Considerations

❑ Percent FTE request should match anticipated FTE needed to complete activities in workplan.

❑ Anticipated many positions will not require full FTE

- Epi Coordinator and bench laboratorian: likely 100% FTE

- PI and/or clinical lead, laboratory lead, data manager, epi analyst, and disease investigator, etc. likely will not need to be 100% FTE

- DIS work-load anticipated to be much less in SURRG, cycle 2

❑ Consider where to best house positions based on role

Application Submission Process

❑ Due date: May 1, 2021

❑ Work with your local ELC administrator to determine local deadlines and additional application instructions

Additional Information

- Please contact:

  - Karen Schlanger, khs4@cdc.gov with overall questions

  - Cau Pham, whi4@cdc.gov with lab-specific questions

- Slides and a transcript from today's call will be available at: **www.cdc.gov/std/funding/default.htm**

Questions?

Call Adjourned