Purpose and Instructions

The purpose of this form is to learn about upcoming CSTLTS data collections to ensure compliance with human subjects research and Paperwork Reduction Act (PRA) regulations. Complete this form when planning:

- Data collection activities involving non-Federal respondents
- Research that is conducted or supported by CDC

In other words, this form should be completed well before any data collection activities begin. Contact Cori Wigington (jgi2@cdc.gov) with questions.

Section 1: Program Information

1. **Date of Form Completion:** *8/15/2019*
2. **Project Officer / Investigator / Point of Contact Name:** *Liza Corso*
3. **CDC Email:** *lcorso@cdc.gov*
4. **Phone:** *404-498-0313*
5. **Organizational Unit** (e.g., OSTLTS/DPHPI/ASREB): *OSTLTS*
6. **Data Collection Project Title:** *Public Health Accreditation Board (PHAB): Assessment of Processes and Outcomes*
7. **Funding mechanism (select all that apply):**

   ☐ Contract; announcement number: *Click here to enter text.*

   ☒ Cooperative Agreement; announcement number: *NU90OT000229-02-00*

   ☐ Grant; announcement number: *Click here to enter text.*

   ☐ Task Order/Purchase Order; announcement number: *Click here to enter text.*

   ☐ Other: *Click here to enter text.*

Section 2: Data Collection Summary

8. **Purpose:**

   ☐ The purpose of this project is to develop or contribute to the generalizable knowledge to improve public health practice related to Click here to enter text.

   ☒ The purpose of this project is to assess and / or improve the following public health service program/ service by *assessing the public health department accreditation program and its efforts to strengthen organizational capacity.*

   ☐ The purpose of this project is to prevent or control disease or injury by *Click here to enter text.*

9. **Brief description of the data collection:** *Health departments participating in the accreditation program will respond to a series of surveys (no more than one survey a year per health department) designed to capture their impressions of the program and how their health department has changed at various points in time.*

10. **Estimated number of respondents:** *300 annually*

11. **Respondent population / study participants: (check all that apply)**
    - ☐Federal employees
    - ☐Contractors to the federal government (e.g., Northrop Grumman, Deloitte)
    - ☒State health department staff
    - ☒Local health department staff
    - ☒Tribal governmental / coalitions staff
    - ☒Territorial health department staff
    - ☐State elected or appointed official (e.g., governor)
    - ☐Local elected or appointed official
    - ☐Legislative staff
    - ☐Clinical practitioner and/or healthcare staff (e.g., physician, hospital administrator, etc.)
    - ☐Community member
    - ☐Partner organization staff
    - ☐University faculty / staff
    - ☐Study/program participant
    - ☐Other individual, please specify: *Click here to enter text.*

12. **Data collection methods: (check all that apply)**
    - ☒Questionnaire / Survey Instrument
    - ☐Interim and/or Annual Progress Report
    - ☐Focus Group
    - ☐Key Informant Interview
    - ☐Other, please specify: Click here to enter text.

13. **Intended use: (check all that apply)**
    - ☐ On-going data collection for program management and involving the collection of minimal, standard data elements of all sites receiving CDC funds for program implementation
    - ☐ Provide formative information before implementing a new, modified, or previously untested intervention
    - ☐ Provide formative information on how to tailor a proven-effective intervention, service or program in a specific setting or context
    - ☒ Assess the success of an established program in achieving its objectives in a specific population where information gained will be used to provide feedback to that program
    - ☐ Test a new, modified, or previously untested intervention, service, or program to determine if it is effective

☐ Manage public health program through regular, ongoing collection and analysis of health-related data for disease or event notification, please specify program:
☒ Longitudinal data collection allowing for hypothesis testing
☐ Identify, characterize, and/or solve an immediate health problem which will benefit those participants involved in the investigation or their communities
☐ Systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs
☐ Other, please specify: *Click here to enter text.*

14. **Will the data collection be <u>conducted</u> by CDC/ATSDR?**
    ☐ Yes
    ☒ No

15. **Will the data collection be <u>sponsored</u> by CDC/ATSDR?** *For more information visit: Internal CDC Guidance on Sponsorship Determination*
    ☒ Yes
    ☐ No

16. **Briefly describe CDC/ATSDR's role**: *CDC has contributed to the instrument design and will provide guidance on the analysis, interpretation, and dissemination of findings.*

17. **Anticipated start date of data collection:** January 2020

Section 3: Self-Determination of Research & Paperwork Reduction Act Applicability

In the following section, identify if you think this data collection is a) research or non-research and b) subject to the paperwork reduction act. All self-determinations will be reviewed by the OSTLTS Human Subjects Contact and Paperwork Reduction Act (PRA) Contact for official determinations.

Research / Non-Research

45 CFR 46.102(d) regulations state "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" where "generalizable knowledge" is defined as new information that has relevance beyond the population or program from with it was collected, or information that is added to the scientific literature), then the project is considered to be research. For more information, visit: Human Research Protection Office's.

Research / Non-research Self Determination

☒ Non-research
☐ Research

a. Is this activity research involving human participants?
☐ No
☐ Yes

Paperwork Reduction Act

CSTLTS Data Collection Determination Form
Public health research / Non-research & Paperwork Reduction Act

The Paperwork Reduction Act (PRA) requires that Federal agencies submit Information Collection Requests to the Office of Management and Budget (OMB) for approval for federally sponsored data collections involving ten (10) or more respondents. For more information visit: Information Collection Review Office.

PRA Self Determination:

☐ PRA does not apply
☒ PRA does apply

Send Completed form to Cori Wigington (jgi2@cdc.gov), PRA Contact / Human Subjects Contact

To be completed by the OSTLTS PRA Contact & Human Subjects Contact only

Official Research Determination:

☒ Non-research
☐ Research

a. Is this activity research involving human participants?

☒ No
☐ Yes

Official PRA Determination:

☐ PRA does not apply
☒ PRA does apply

NOTES:

Non-research/PRA does apply.

Cori Wigington — 08.15.19
PRA Contact (or designee) — **Date**

Laura Colman — 08.15.19
Human Subjects Contact (or designee) — **Date**