Purpose and Instructions

The purpose of this form is to learn about upcoming OSTLTS 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:** *7/26/2018*
2. **Project Officer / Investigator / Point of Contact Name:** *Cassandra Frazier*
3. **CDC Email:** *bkx9@cdc.gov*
4. **Phone:** *404-498-0581*
5. **Organizational Unit** (e.g., OSTLTS/DPHPI/ASREB): *OSTLTS/DPHPI/ASREB)*
6. **Data Collection Project Title:** *Assessment of Outcomes Associated with the Preventive Health and Health Services Block Grant*
7. **Funding mechanism (select all that apply):**

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

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

   ☒ Grant; announcement number: *93.991 -- Preventive Health and Health Services Block Grant.*

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

   ☐ Other:

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 select cross-cutting outputs and outcomes of the Block Grant and demonstrating the utility of the grant on a national level.

   ☐ 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:** Data will be collected using a web-based data collection instrument using Qualtrics®. Data will be collected every other year (i.e. fall 2019 and fall 2021). Descriptive statistics will be used to analyze quantitative data. Qualitative analyses will be performed on open-ended questions. Responses will be analyzed using Microsoft Excel®. Data will be used to 1) describe the outcomes and achievements of grantees' public health efforts and identify how the use of PHHS Block Grant funds contributed to those results and 2) help assess how the grant advances work of the public health system and provide evidence to support future budgetary requests. Data will be used to describe the grant as a whole—not individual grantee activities or outcomes.

10. **Estimated number of respondents:** *61*

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 is leading this data collection effort. CDC established the purpose and intended uses of the evaluation, designed the data collection methodology, and developed the instruments. The evaluators will also manage the implementation of the data collection. Through an existing cooperative agreement, CDC has funded the Association of State and Territorial Health Officials to program and disseminate the instrument in Qualtrics.

17. **Anticipated start date of data collection:** October 2019; October 2021

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

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:

Project is non-research; PRA does apply. Program developing ICR that will be submitted for approval.

Corinne Wigington — July 27, 2018

PRA Contact (or designee) — **Date**

Corinne Wigington — July 27, 2018

Human Subjects Contact (or designee) — **Date**