



REQUEST FOR DETERMINATION OF RESEARCH STATUS

To be completed by the staff member with lead responsibility for the project and approved by branch chief (if applicable) and Division ADS. A separate PGO funding memo is required if project is research and involves human subjects regardless of the CDC staff role.

- Instructions:**
- (1) Use this form to declare: (a) the research status of any project, (b) role or roles of CDC staff
 - (2) A short summary should be attached offering specific details about the project and the role of staff.
 - (3) Be sure to complete all applicable items, obtain appropriate signatures and submit this form for approval.

Tracking Number: To Be Determined

(Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 01/27/2020

Title of Project: DP 18-1810 State Actions to Improve Oral Health Outcomes

Dates for project period:

Dates for funding (if applicable):

Beginning: 09/01/2018

Beginning: 09/01/2018

Ending: 08/31/2023

Ending: 08/31/2019

Project is (choose one):

NOTE: Revision, as used below, refers to any substantive change made to the project including scope of project, funding restrictions, personnel, role of CDC staff member, determination of research status, etc.

New

Revision

Continuation, without revision(s)

Continuation, with revision(s)

Lead staff member:

Contact information:

Please indicate your role(s) in this project:

Name: Marcia Parker

Division: DOH

Project officer **Technical monitor**

User ID: KUV7

Telephone: 770-488-6075

Principal investigator **Investigator**

Scientific Ethics number: _____

Mailstop: F-80

Consultant **Other (please explain)**

1. Are any or all of the activities within this project DESIGNED to contribute to generalizable knowledge (i.e., research)?

YES **NO**

If YES, list those activities which are research:

2. Is this CDC project research or public health practice (check all that apply)?

Research

Public health practice

Check one:

Check all that apply:

Human subjects involved

Emergency Response **Surveillance**

Human subjects not involved

Program evaluation **Other (please explain)**

3. If RESEARCH involving human subjects, has the project or research activities been reviewed by the CDC IRB for human subjects protection?

a. **NO, New project, not yet reviewed**

d. **YES, Reviewed and approved by CDC**

b. **NO, Existing project, not ready to submit**

If YES, please list protocol number and

c. **NO, Submitted for approval**

expiration date _____

e. **NO, RESEARCH, no CDC investigators (CDC IRB not required)**

f. **N/A (Not Applicable)**

If RESEARCH, list any other CDC staff involved in this project, please include the name, role, and scientific ethics number

Tracking NO. To Be Determined

| Name | Role (project officer, investigator, consultant, etc.) | Scientific ethics number Prin |
|---------------|--|-------------------------------|
| Marcia Parker | | |

IF YOU THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 45CFR46.101), PLEASE ANSWER questions 4-6, OTHERWISE SKIP TO question 7.

4. Does the proposed research involve prisoners?
 YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).
 NO
5. Does the proposed research involve fetuses, pregnant women, or human in vitro fertilization as targets (such that Subpart B would apply)?
 YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).
 NO

Educational Research

- 6.1 Is this research conducted in established or commonly accepted educational settings, AND does the research involve normal educational practices (e.g., research on regular and special education strategies or research on the effectiveness of, or comparison among instructional techniques, curricula or classroom management methods)?
 YES NO

Research Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational Tests

- 6.2 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?
 YES NO If NO skip 6.3

Will children (<18 years of age) be research subjects?

- YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7)
 NO

- 6.2.1 Is the information obtained recorded in such a manner that human subjects can be identified directly or indirectly through identifiers (such as a code) linked to the subjects;
 YES NO

- 6.2.2 Will any disclosure of the human subjects' responses outside of the research setting have the potential to place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation? (Examples here may include: the collection of sensitive data regarding the subjects' (or relatives' or associates') possible substance abuse, sexuality, criminal history or intent, medical or psychological condition, financial status, or similarly compromising information).
 YES NO

- 6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior but the research is not exempt under paragraph 6.2 of this section:

YES NO If NO skip to 6.4

- 6.3.1 Will this research involve human subjects that are elected or appointed public officials or candidates for public office?
 YES NO

- 6.3.2 Does federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? (Note: CDC can use this exemption criterion only in the case where a 308(d) Assurance of Confidentiality has been obtained to cover the research).
 YES NO

Existing Data Which Is Publicly Available or Unidentifiable

- 6.4 Does this research involve only the collection or study of existing* data, documents, records, pathological or diagnostic specimens? (* 'existing' means existing before the study begins)?

YES NO If NO skip to 7

- 6.4.1 Is this material or information publicly available?
 YES NO

Tracking NO. To Be Determined

6.4.2 Is this material or information recorded in such a manner by the investigator that the subjects cannot be identified directly or indirectly through identifiers linked to the subjects?

(Note: If a link is created by an investigator even temporarily, for research purposes, this criterion is not met. If a temporary link is created by clinical staff who already have access to the data, this criterion is met).

YES (there are no identifying information and no unique identifiers or codes)YES

NO (there are identifiers (including codes))

7. Please prepare and attach a short summary paragraph (<1 page); if this is new:

a. Be sure to include the purpose of the project, specific details about the project and the role of the CDC staff member (s) in the project. In explaining one's role as a consultant be particularly careful to identify involvement in things like: study design decisions, oversight of protocol development, participation in review of data collection procedures, and participation in data analysis and/or manuscript preparation, as well as whether there will be access to identifiable or personal data.

b. Explain your project status selection (research--non-exempt, exempt, no CDC investigator or not involving human subjects; public health practice). If you selected research not involving human subjects be sure to indicate if the data includes any personal information (e.g., name, SSN), linkable study identification numbers or codes, or geographical information.

The DP18-1810 State Actions to Improve Oral Health Outcomes program is a five-year cooperative agreement competitive renewal to continue CDC investment in and support for state oral health programs. This program is not research. Purpose is to assist States to decrease dental caries, oral health disparities, and other co-morbid chronic diseases associated with poor oral health outcomes. Recipients will accomplish these outcomes through implementing priority strategies to support school sealant programs (including promoting adherence to infection prevention guidelines), supporting and increasing community water fluoridation, conducting state oral health surveillance, and optionally integrating oral health with other chronic disease programs (i.e., medical/dental integration). The proposed program replaces FOA 13-1307 [FY 2013-FY 2017] and incorporates programmatic strategies from FOA 16-1609 [FY 2016-FY 2017] Models of Collaboration among Chronic Diseases and Oral Health Programs, to support enhanced medical/dental integration and provide improved quality of care. The public health impact of priority strategies includes decreases in dental caries, oral health disparities and other co-morbid chronic diseases.

CDC's role is to provide programmatic, evaluation, epidemiologic, and technical assistance for recipients and their stakeholders and partners through programmatic and one-on-one technical consultation, national training, workshops, Web Conferences, SEALS, and Water Fluoridation Reporting System (WFRS) training, and other forms of guidance. CDC will facilitate technical assistance between national partners and recipients as needed. Four electronic data systems address the collection of information to support states receiving 18-1810 funds. The Water Fluoridation Reporting System (WFRS) is an online tool that helps states manage the quality of their water fluoridation programs. WFRS information is the basis for national surveillance reports that describe the percentage of the U.S. population on community water systems who receive optimally fluoridated drinking water. Sealant Efficiency Assessment for Locals and States (SEALS) is designed to capture, store, and analyze school sealant program data. Programs use this information to evaluate the effectiveness of individual school sealant programs by comparing the benefits (e.g., averted treatment) with the associated costs (e.g., resources used, labor hours). The Basic Screening Survey collects data on percent of students with caries experience, untreated tooth decay and sealants. These systems are tools useful to states in collecting and reporting their performance measure information. States will use CDMIS, a password protected web-based system that allows funded state programs to submit their progress reports annually by entering information into the system, eliminating the need for additional written reports.

8. Please list the primary project site and all collaborating site(s).

Explanation of project components:

9. If project involves research that is funded extramurally, list amount of award that should be restricted pending IRB approval and describe which project components will be affected, if known:

| Approvals (signature and position title) | Date | Research Determination / Remarks |
|--|-------------------|--|
| <p>Marcia Parker - Team Leader</p> <p>staff member completing this form</p> | <p>01/27/2020</p> | <p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p> |
| <p>Lorena Espinoza - Associate Director for Science</p> <p>Team Lead</p> | <p>01/27/2020</p> | <p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p> |
| <p>Lorena Espinoza - Associate Director for Science</p> <p>Division ADS</p> | <p>01/27/2020</p> | <p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p> |
| <p>Joan Redmond Leonard - PUBLIC HEALTH ANALYST</p> <p>CUC ADS, Deputy ADS, or Human Subjects Contact</p> | <p>02/05/2020</p> | <p><input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p> |