

NCIPC Determination

General Information

Project Title

Science Officer(s) _____ **Division:** _____ **Telephone:** _____

E-mail _____ **Ethics verification number:** _____

Project Officer(s) _____ **Division:** _____ **Telephone:** _____

E-mail _____ **Ethics verification number:** _____

Proposed Project Dates:

Start: _____ **Ending:** _____

Ex: MM/DD/YYYY

Ex: MM/DD/YYYY

Funding Mechanism

- Cooperative Agreement #: _____
- Grant #: _____
- Contract#: _____
- No funding (Specify): _____

Funding FOA#: _____

Funding FOA#: _____

Describe the purpose, methods, and outcomes of the project (Use space provided - Abstract of purpose, methods and outcomes)

Describe the roles and responsibilities of CDC and any partner organizations (e.g., grantee, contractor).

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Applicability of Human Subjects Regulations

Please check appropriate category:

I. Activity is not research. Primary intent is public health practice: disease/injury control, surveillance, improvement of programs or services. Objectives focused on a specific population.

- A.** Epidemic/endemic **disease/injury control** activity; collected data directly relate to *immediate* disease control needs (e.g., epi-aid).
- B.** Routine **disease/injury surveillance** activity; data used for disease control program or policy purposes for a specific health condition/disease in a specific population and setting. (Includes disease reporting)
- C.** **Program evaluation/monitoring** activity; data are used primarily for assessing, monitoring or improving a program, policy, or a communications activity (e.g., message testing) in a specific population/setting.
- D.** Purchase orders or contracts for services or equipment.

-OR-

II. Activity is research but does NOT involve human subjects. Primary intent is to develop or contribute to generalizable knowledge, but data is obtained solely from non-human sources or not living individuals, or anonymous existing data collected for another purpose are being analyzed:

- A.** Activity is research involving collection/analysis of data about health facilities or other organizations or units, which are not individual persons
- B.** Activity is research using existing unlinked or anonymous data previously collected for another purpose.
- C.** Activity is research involving data and/or specimens from *deceased persons*.

-OR-

III. Activity is research involving human subjects but CDC is not engaged. CDC employees including visiting scientists, fellows, and on-site contractors (but not off-site contractors or other collaborators)
 *Will NOT obtain consent or data by intervening or interacting with participants
 *Will NOT have access to identifiable (including coded) private data or biological specimens

NOTE: Once local IRB approval has been obtained please forward a copy (electronic preferred) to the NCIPC Human Subjects Coordinator for records keeping purposes.

-OR-

IV. Activity is research involving human subjects but exempt according to the categories specified in the regulations 45 CFR 46.101(b). Educational practices, Educational tests, surveys, interviews, or observation of public behavior. Existing data, documents, records (e.g., not identifiable, publicly available). Demonstration projects.

-OR-

V. Activity is research involving human subjects, CDC is engaged, and CDC IRB approval will be sought.

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Applicability of OMB-PRA Regulations

Please check appropriate category:

I. Does the activity involve collecting identical information from 10 or more respondents within a one year period

Including evaluation/monitoring (Examples of collections: Surveys & Interviews (Phone & On-line) - Focus groups – Surveillance – Program evaluation- Program monitoring).

No

Yes - Type of collection:

- | | | | |
|--|--|---|---------------------|
| <input type="checkbox"/> Mail-backquestionnaire | <input type="checkbox"/> On-site questionnaire | <input type="checkbox"/> Personal interview | Telephone survey |
| <input type="checkbox"/> Testing/assessment form | <input type="checkbox"/> Web-based survey | <input type="checkbox"/> Focus groups | Record abstractions |
| <input type="checkbox"/> Evaluation | <input type="checkbox"/> Observation | <input type="checkbox"/> Workshop | Discussion group |
| <input type="checkbox"/> Comment card | | | |
| <input type="checkbox"/> Other (Explain) _____ | | | |

II. Is NCIPC Sponsoring the data collection? Check all that apply.

- A.** NCIPC will initiate or request a data collection.
- B.** NCIPC will develop or design the data collection.
- C.** NCIPC will manage or own the data collection.
- D.** NCIPC will be directing the data collection.
- E.** NCIPC staff will interact/intervene participants.
- F.** NCIPC is requesting specific data reports.
- G.** NCIPC will disseminate the data as an official report or study.
- H.** NCIPC is not conducting any of the above activities and therefore is not sponsoring the data collection.