

## **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 #: \_\_\_\_\_ Funding FOA#: \_\_\_\_\_
- Grant #: \_\_\_\_\_ Funding FOA#: \_\_\_\_\_
- Contract#: \_\_\_\_\_
- No funding (Specify): \_\_\_\_\_

**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.**

**Required Signatures**

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**Branch/Team Official (e.g., Branch chief or TeamLead)** **Date**

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**Division Official (e.g., ADS, Director)** **Date**

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**Human Subjects Coordinator** **Date**

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**Office Use Only**

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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.