

# **NCIPC Determination of Applicability of Human Subjects Regulations, Request to Classify Project as Not Involving Human Subjects or Research**

Project/FOA Title: \_\_\_\_\_

Science Officer(s): \_\_\_\_\_ Division: \_\_\_\_\_ Telephone: \_\_\_\_\_

Ethics Verification Number: \_\_\_\_\_

Project Officer(s): \_\_\_\_\_ Division: \_\_\_\_\_ Telephone: \_\_\_\_\_

Ethics Verification Number: \_\_\_\_\_

Proposed Project Dates: Starting: \_\_\_\_\_ Ending: \_\_\_\_\_

Award Title: \_\_\_\_\_

Award Institution: \_\_\_\_\_

Funding Mechanism # \_\_\_\_\_

- FOA#: \_\_\_\_\_
- Cooperative Agreement #: \_\_\_\_\_
- Grant #: \_\_\_\_\_
- Contract#: \_\_\_\_\_

Funding Sponsor: \_\_\_\_\_

Number of Participants in Study: \_\_\_\_\_

Intramural or      Extramural

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Categories of data collection that do not constitute human subjects research **OR** do involve human subjects but CDC not engaged are listed below. 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.
  - 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** activity;** data are used primarily for assessing, monitoring or improving a program in a specific population/setting.

**Justification:** Please attach project goals/aims, objectives, design, setting and participants, methods, and data sources.



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**Office Use Only**

**Funding Amount:**