

# NCEH/ATSDR Determination of Applicability of Human Subjects Regulations

Project Title Central America Water and Sanitation Program Sustainability Evaluation

Project Location(s) El Salvador, Guatemala, Honduras, Nicaragua

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Proposed Project Dates Start: 9/1/2011 End: 8/1/2012

## Activity Information

- Activity is not human subjects research. Primary intent is public health practice or a disease control activity.**
- Epidemic or endemic disease control activity; collected data directly relate to disease control needs.
  - Routine disease surveillance activity; data used for disease control program or policy purposes.
  - Program evaluation activity; data are used primarily for that purpose.
  - Post-marketing surveillance of efficacy or adverse effects of a new regimen, drug, vaccine, or device.
  - Laboratory proficiency testing.
- Activity is not human subjects research. Primary intent is public health program activities.**
- Public health program activity (including service delivery, health education, social marketing campaigns, program monitoring and process measures, and risk reduction interventions).
  - Activity is purely administrative (e.g., purchase orders or contracts for services or equipment) and not related to research.
- Activity is research, but does NOT involve identifiable human subjects.**
- Activity is research involving collections or analysis of data about health facilities or other organizations or units which are not individual persons.
  - Activity is research involving data or specimens from deceased persons.
  - Activity is research using unlinked or anonymous data or specimens:  
ALL of the following are required
    - No contact with human subjects is involved for the proposed activity AND
    - Data or specimens are/were collected for another purpose AND
    - No extra data/specimens are/were collected for this purpose AND
    - Identifying information was either:
      - Not obtained
      - Removed prior to this submission so that data cannot be linked or re-linked with identifiable human subjects
      - Protected through an agreement. The investigators and the holder of the key (code linking data to identifiable human subjects) enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased.
- Activity is research involving identifiable human subjects, but CDC involvement does NOT constitute "engagement in the research."**
- This project is conducted under a grant or cooperative agreement award mechanism:  
ALL of the following are required
    - CDC employees or agents do not intervene or interact with living individuals for research purposes.
    - CDC employees or agents do not obtain individually identifiable private information.
    - Project must be reviewed by an IRB with an FWA
      - Supported Institution Name \_\_\_\_\_
      - Supported Institution FWA # \_\_\_\_\_ Expiration Date \_\_\_\_\_
      - Local IRB # \_\_\_\_\_ Expiration Date \_\_\_\_\_
  - CDC staff provide technical support only that does not involve interaction with human subjects or data collection.
  - CDC staff are involved only in manuscript writing for a project that has closed. For this project, CDC staff were not involved with human subjects or with data collection.

  
NCEH/ATSDR Division Associate Director for Science

2/2/11  
Date

NCEH/ATSDR Human Subjects Contact

Date