

NCEH/ATSDR Human Subjects Research Routing Determination

This form should be used to submit to NCEH/ATSDR Human Subjects Contact materials for projects and activities involving CDC investigations that do not require routing to the CDC Human Research Protection Office. Projects are eligible for this classification either as "non human subjects research" projects (primary intent is not to generate generalizable knowledge), as research projects that do not involve identifiable human subjects, or as research projects in which CDC is not "engaged". Such projects do not require submission to the CDC Human Research Protection Office (HRPO) for human subjects research review.

Do **NOT** use this form for research that falls into one of the Exempt Categories of Human Subjects Research provided for your information on the last page. Exempt research must be routed to HRPO using form 0.1250X.

Project Title: Highway 36 Corridor Exposure Investigation

Project Locations/Sites: Lane County, Oregon

Project Officer(s): Kenneth Orloff, Ph.D. Division: DHAC Telephone: 770-488-0735

Proposed Project Dates: Start: 07/05/2011 End: 07/05/2012 Time sensitive project, check box:

Please answer **Y/N** questions for categories I, II, III:

I. **Activity is research because both of the following are true:**

Y N

A. The activity is a systematic investigation including research development, testing, and evaluation.

Systematic investigation:

- Attempts to answer specific questions (in some research, this would be a hypothesis).
- Is methodologically driven, that is, it collects data or information in an organized & consistent way.
- The data or information is analyzed in some way, be it quantitative or qualitative data.
- Conclusions are drawn from the results.

Y N

B. The activity is intentionally designed to develop OR contribute to generalizable knowledge.

Generalizable knowledge is knowledge that is "expressed in theories, principles, and statements of relationships" that can be widely applied to our experiences. Generalizable knowledge is usually created to share with other people, such as through presentations and publications.

"Generalizable knowledge" would include one or more of the following concepts:

- The knowledge contributes to a theoretical framework of an established body of knowledge.
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study.
- Publication, presentation or other distribution of the results is intended to inform the field of study.
- The results are expected to be generalized to a larger population beyond the site of data collection.
- The results are intended to be replicated in other settings.
- Web based publication for professional purposes

Activities that might not be research are: service delivery, program monitoring, purchase orders or contracts for services or equipment, emergency response, and program evaluation.

II. **Activity is research but does NOT involve identifiable human subjects.**

Y N

A. Activity is research involving collection or analysis of data about health facilities or other organizations or units which are not individual persons...**OR**...

Y N

B. Activity is research involving data or specimens from deceased persons...**OR**...

C. Activity is research using unlinked anonymous data or specimens: **ALL** (1-4) of the following are required:

Y N

1. No contact with human subjects is involved for the proposed activity...**and**...

Y N

2. Data or specimens are/were collected for another purpose...**and**...

Y N

3. No extra data/specimens are/were collected for **this** purpose...**and**...

Y N

4. Identifying information either was not obtained **or** has been removed so that data cannot be linked or re-linked with identifiable human subjects. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCEH/ATSDR ADS office for details.)

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III. **Activity is research involving identifiable human subjects but CDC involvement does not constitute "engagement in the research".** ALL (A-C) of the following are required:

Y N
 Y N
 X N

- A. This project is conducted under a **grant or cooperative agreement** award mechanism.
- B. CDC employees or agents do not intervene or interact with living individuals for research purposes.
- C. CDC employees or agents do not obtain individually identifiable private information. *(only home address)*

Supported Institution/Entity Name: _____

Supported Institution/Entity FWA #: _____ Expiration Date: _____

Local IRB #: _____ IRB Approval Expiration Date: _____

Attach project description (standard format at end of this form) in enough detail to justify the proposed category. Submit through division ADS/Director to: ncehhsc@cdc.gov and sds2@cdc.gov

Check here if this request is an **amendment** of an existing determination of human subjects research review routing.

Approval Initials: Smm 8/9/2011 [Signature] 8/9/11
 Branch or Section Chief Date ADS or Div. Director Date

Additional Comments:

1. This form cannot be used to document human subjects research that is exempt from human subjects regulations; such research must instead be submitted to the CDC HRPO. (Please contact the NCEH/ATSDR ADS Office for details).
2. Although CDC HRPO review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting the privacy, confidentiality, and autonomy of participants. All applicable State and Federal privacy laws must be followed.
3. Although this project does not require routing to CDC HRPO, informed consent may be appropriate. Information disclosed in the consent process should address the basic elements of consent and must be submitted with this form for review.

For Official Use Only

NCEH/ATSDR Center Review Date received in NCEH/ATSDR HSC Office: 8/15/2011

Concur, project does not require human research review beyond NCEH/ATSDR.

or

Project constitutes human subjects research that must be routed to CDC HRPO.

Comments/Rationale:

Signed: Marlena M. Wald 8/15/2011
~~Dolly Sinha, Acting~~ NCEH/ATSDR Human Subjects Contact Date
 MARLENA M. WALD