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 CDC Form # 0.1250X.

Project Title: National Voluntary Environmental Assessment Information System (NVEAIS)

Project Locations/Sites: Voluntary State Safety Programs and CDC, Atlanta

Project Officer(s): Laura Brown, PhD Division: DEEHE Telephone: 770-488-4332

Proposed Project Dates: Start: __/__/____ End: __/__/____ Time sensitive project, check box: ☐

Please answer all Yes/No questions for categories I, II, III:

NO I. **Is this Activity Research? Activity is research because both of the following are true:** (Circle your response to each question)

A. Is the activity a systematic investigation including research development, testing, and evaluation? (Yes) No

Definition: A 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.

B. Is the activity intentionally designed to develop OR contribute to generalizable knowledge? Yes (No)

Definition: 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.

N/A II. **If the Activity is research but does NOT involve identifiable human subjects**. (Circle your response to each question)

A. Is the activity research involving collection or analysis of data about health facilities or other organizations or units which are not individual persons? Yes No ....***OR***...

B. Is the activity research involving data or specimens from deceased persons? Yes No ...***OR***...

C. Is the activity research using unlinked anonymous data or specimens? Yes No

ANSWER ALL (1-4) of the following required statements about the proposed activity:

1. For the proposed activity, no contact with human subjects is involved Yes No ...***and***...
2. Are/were data or specimens collected for another purpose Yes No ...***and***...
3. Were no extra data/specimens are/were collected for this purpose Yes No ...***and***...

Attachment 6- NVEAIS IRB Determination

4. Was identifying information either *not* obtained or *has been removed* so that data cannot be linked or re-linked with identifiable human subjects? **Yes No**

(*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.)

N/A III. **Is the Proposed Activity research involving identifiable human subjects, but CDC's involvement does not constitute "engagement "? (Circle your response to each question.) All items, A-C are required:**

A. Is this project conducted under a grant or cooperative agreement award mechanism? ? **Yes No**

B. Do CDC employees or agents intervene or interact with living individuals for research purposes? **Yes No**

C. Do CDC employees or agents obtain individually identifiable private information? **Yes No**

If CDC is providing financial support, please provide the following information:

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 or sgd8@cdc.gov**

Is this request is an amendment of an existing determination of human subjects research review routing? **Yes** (No)
(Please circle)

Approval initials: R Blake 2/11/2013 Mildred Mallitt 2/12/13

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:** 01/15/2013

YES **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: The NVEAIS is a non-research program. The data collection is a systematic investigation but the results are not intended to be generalized beyond the individual food safety program jurisdictions. The results are not nationally representative.

Signed: Stephanie Davis 02/07/2013

Stephanie Davis NCEH/ ATSDR Human Subjects Contact Date