

This form should be used to submit to NCEH/ATSDR Human Subjects Contact materials investigations that do not require routing to the CDC Human Research Protection Office 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: EHS-Net Food Allergen Study

Project Locations/Sites: EHS-Net sites: CA, MN, NY State, NY City, RI, TN

Project Officer(s): Laura Brown Division: EEHS Telephone: 770-488-4332

Proposed Project Dates: Start: 01/15/2014 End: 12/15/2014 Time sensitive project, check box:

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

Yes 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 scope 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 of supplies or contracts for services or equipment, emergency response, and program evaluation.

No 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 factors 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:

- For the proposed activity, no contact with human subjects is involved? No ...and...
- Are/were data or specimens collected for another purpose? Yes No ...and...
- Were no extra data/specimens are/were collected for this purpose? No ...and...
- Was identifying information either not obtained or has been removed 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.)



Yes 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 see table below

Supported Institution/Entity FWA # see table below Expiration Date \_\_\_\_\_

Local IRB # \_\_\_\_\_ IRB Approval \_\_\_\_\_ Expiration Date \_\_\_\_\_

Entity Name	Entity FWA#
California Department of Health (Public Health Foundation Enterprise)	FWA00001790
Minnesota Department of Health	FWA00000072
New York Department of Health	FWA00003700
New York City Department of Health and Mental Hygiene	FWA00009459
Rhode Island Department of Health	FWA00006141
Tennessee Department of Health	FWA00000379

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](mailto:ncehhsc@cdc.gov) or [sgds@cdc.gov](mailto:sgds@cdc.gov)

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

Approval initials: Robert Blake 7/5/2013 [Signature] 7/8/13

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 ADS Office: 7/9/13

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:**  
*This activity is human subjects research, but CDC's involvement does not constitute engagement.*

*Melith Huly 08/07/2013  
 for Stephanie T. Davis*