Attachment 7

NCEH/ATSDR Human Subjects Research Routi : Determination

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

Do NOT use this form for research that falls into one of the Exempt Categories of Huma ubjects Research provided for your information on the last page. Exempt research must be routed to HRPO using CDC Forn 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_____ Telepho __770-488-4332_____

Proposed Project Dates: Start: _01_/15__/_2014____ End: 12/15/2014 Time s itive 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 t : (Circle your response to each question)**

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

Definition: A Systematic investigation:

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

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

Definition: Generalizable knowledge is knowledge that is "expressed in theories, pri ples, and statements of relationships" that can be widely applied to our experiences. Generalizable knowled 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 knowledge.
- The primary beneficiaries of the research are other researchers, scholars and ctitioners in the field of study.
- Publication, presentation or other distribution of the results is intended to inf n the field of study.
- The results are expected to be generalized to a larger population beyond the 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 lers or contracts for services or equipment, emergency response, and program evaluation.

No II. **<u>If the Activity is research but does NOT involve identifiable human subjects</u>. (Ci your response to each question)**

A. Is the activity research involving collection or analysis of data about health fa ies 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? s (No) ..***OR***...

C. Is the activity research using unlinked anonymous data or specimens? (Yes) N

ANSWER **<u>ALL</u>** (1-4) of the following required statements about the proposed acti :

1. For the proposed activity, no contact with human subjects is involvec es (No) ...***and***...
2. Are/were data or specimens collected for another purpose **Yes** (N) ...***and***...
3. Were no extra data/specimens are/were collected for this purpose ((No) ...***and***... MH
4. Was identifying information either *<u>not</u>* obtained or *<u>has been removec</u>* that data cannot be linked or re-linked with identifiable human subjects? (Yes) **No**

(*<u>Note</u>*: under certain conditions, research may qualify as non-human subjects wh identifiers are removed by local staff; contact NCEH/ATSDR ADS office for details.)

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

A. Is this project conducted under a grant or cooperative agreement award echanism? ? (Yes) No

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

C. Do CDC employees or agents obtain individually identifiable private infor tion? 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_____ Expirati 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 deta o 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 subject search 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. D** ctor Date

Additional Comments:

1. This form cannot be used to document human subjects' research that is exemp om human subjects regulations; such research must instead be submitted to the CDC HRPO. (Please contact the NCE ATSDR ADS Office for details).
2. Although CDC HRPO review is not required in this instance, investigators/proje fficers are expected to adhere to ethical principles and standards by respecting and protecting the privacy, confidentiali , 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 y be appropriate. Information disclosed in the consent process should address the basic elements of consent and must submitted with this form for review.

For Official Use Only:

NCEH/ATSDR Center Review **Date received in NCEH/ATSD ISC 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 DC's involvement does not constitute engagement.

Meredith Hully 08/07/2013
for Stephanie I. Davis