NCEH/ATSDR Human Subjects Research Determination Form

Use this form and the flowcharts for either:

1. CDC projects and activities that do not require CDC IRB review under HHS Human Subjects (45 CFR part 46) or FDA (21 CFR parts 50 and 56) Regulations, which include "non-research", "research not involving identifiable human subjects," or "human subjects research for which CDC is not engaged"; *OR*

2. Human subjects research that will be submitted to the Human Research Protection Office (HRPO) as an Exempt Category of Human Subjects Research.

Project Title: EHS-Net Food Allergen Study

Project Location(s)/Site(s): CA, MN, NY, NYC, RI, TN

Project Officer(s): Laura Brown **Telephone:** (770) 488-4332 **Division or Office:** DEEHS

Proposed Project Dates: Start: 01/05/2014 **End:** 12/31/2014 **Time sensitive:** __

Project Funding and Partners (answer both): HHS: CDC Cooperative Agreement **Non-HHS:** Choose an item

If applicable, name participating external institution(s). California Department of Public Health, Minnesota State Department of Health, New Y

Indicate the holder of the key to decipher the identities of coded data or biological specimens. No key/code/identifiers

Specify CDC role (mark all that apply):

__ CDC is the sole institution conducting activity; OR

If not the sole institution, indicate if:

X CDC is NOT a recipient or provider of private data, specimens, materials or services;

__ CDC is provider of private data/specimens to an institution. __ CDC is recipient of private data/specimens from an institution.

__ CDC is provider of materials/services to an institution. __ CDC is recipient of materials/services from an institution

Questions 1-4 pertain to the HHS Human Subjects Regulations (45 CFR 46):

1. For CDC: Is this activity classified as *research*? **YES** X **NO** __

A. Is the activity a systematic investigation including research development, testing, and evaluation? YES X NO __

B. Is the activity intentionally designed to develop OR contribute to generalizable knowledge? YES X NO __

CDC activity IS research if both 1A and 1B are "YES."
If 1 is "NO," then STOP; otherwise continue.

2. For CDC: Is this research classified as *human subjects research*? **YES** __ **NO** X

A. Does the activity only involve the collection or analysis of non-human data or specimens, including entities, organizations, or environmental materials? YES __ NO X

B. Does the activity only involve the collection or analysis of data or specimens from deceased persons? YES __ NO X

CDC activity IS NOT human subjects research if either 2A or 2B are "YES."
If 2 is "NO," then STOP; otherwise continue.

C. Do CDC employees intervene with, interact with, or obtain informed consent from living persons? YES __ NO X

D. Are/Were the data or specimens collected from living persons *specifically* for this proposed activity? YES X NO __

E. Are/Were extra data or specimens collected from living persons *specifically* for this proposed activity? YES __ NO X

F. Do/Will CDC employees or agents have access to the link between the data or specimens and the identity of these living persons? YES __ NO X

CDC activity IS human subjects research if 2C is "YES."
CDC activity IS NOT human subjects research if 2D, 2E, and 2F are all "NO."
If 2 is "NO," then STOP; otherwise continue.

3. For CDC: Will this activity be submitted to HRPO for approval as *exempt human subjects research*? **YES** X **NO** __

A. Does the research pose more than minimal risk? YES __ NO X

B. Will prisoners be involved? YES __ NO X

C. Will interaction with children occur or will identifiable private information about them be obtained? YES __ NO X

D. Based on the *HRPO Worksheet for Exemption from Human Subjects Regulations*, is there an HHS Exempt Research Category for which this activity will be reviewed? If "YES," specify the Category number: Exempt Category 2a YES X NO __

CDC activity IS exempt human subjects research if 3A, 3B, and 3C are all "NO," and an exempt category (3D) applies.
Exempt research must go to HRPO; use CDC Form 0.1250X.
If 3 is "YES," then STOP; otherwise continue.

4. Is CDC *engaged* in the non-exempt research involving identifiable human subjects? **YES __ NO X**

A. Did CDC receive funding directly from another HHS agency? YES __ NO X

B. Do CDC employees or agents intervene or interact with living individuals for research purposes? YES __ NO X

C. Do CDC employees or agents obtain individually identifiable private information? YES __ NO X

CDC IS engaged if 4A, 4B, or 4C are "YES."
If 4 is "NO," then STOP. Otherwise, research must go to HRPO; use CDC Form 0.1250.

Question 5 pertains to research involving FDA regulated products (21 CFR parts 50 and 56), not including the use of an FDA approved product in the course of medical practice:

5. Based on the *HRPO Worksheet to Determine FDA Regulatory Coverage*, is the research activity subject to FDA human subjects regulations? **YES __ NO __**

Additional Notes:

Although CDC HRPO review is not required, investigators or project officers must adhere to ethical principles and standards to respect and protect the privacy, confidentiality, and autonomy of participants. All applicable State and Federal privacy laws must be followed. Informed consent may be appropriate. Information disclosed in the consent process should address the basic elements of consent. The consent form and all other required supporting documents must be submitted with this form for review. The list of required documents is found in the *NCEH/ATSDR Guided Checklist for Human Subjects and PRA Determinations*.

Division Approval Signatures and Dates:

_____		_____	
Branch Chief	Date Signed	Division ADS/Director	Date Signed

For Office of Science Use Only: Final NCEH/ATSDR Center Determination

Request Received Date: _____

__ **CDC's role does not require HHS human subjects review beyond the center level because:**

__ Activity is not research (Flow chart category NR-1).

__ Activity is not human subjects research (Flow chart category NR-2 through NR-8).

__ Activity is non-exempt human subjects research, but CDC is not engaged (Flow chart category HSR-3).

__ **CDC's role does require HHS human subjects review beyond the center level because:**

__ Activity qualifies as exempt human subjects research (Flow chart category HSR-1).

__ Activity qualifies as non-exempt, engaged human subjects research (Flow chart category HSR-2).

__ **CDC's role does not require FDA human subjects review beyond the center level because:**

__ Activity does not require human subjects review under FDA regulations (Flow chart category NFDA-3 through NFDA-4).

__ **CDC's role does require FDA human subjects review beyond the center level because:**

__ Activity qualifies as human subjects research under FDA regulations (Flow chart category FDA-1 through FDA-2).

NCEH/ATSDR Human Subjects Contact Signature and Date:

_____

Stephanie I. Davis, MSPH Date Signed

Guidance for Completing the NCEH/ATSDR Human Subjects Research Determination Form

For question 1:

- To determine if your project is research for purposes of human subjects protection, consult:
  - The *CDC Policy on Distinguishing Public Health Research and Public Health Nonresearch*
  - Guidance from the Office of Human Research Protections (OHRP)
  - The FDA regulations, if applicable
- See the Research Determination Flowchart 1 for examples of nonresearch activities.

For question 2:

- Research involving living human subjects must adhere to the protection of humans subjects under either the Human Subjects 45 CFR part 46 or FDA 21 CRF part 50 and part 56.
- Guidance on research involving coded private information or biological specimens is available from OHRP.
- More information on human subjects research can be found on the HRPO website.
- See the Research Determination Flowcharts 1–3.

For question 3:

- 45 CFR part 46(b) outlines the Exempt Research Categories.
- The *HRPO Worksheet for Exemption from Human Subjects Regulations* provides more details on Exempt Research Categories.
- The categories most often used for Exempt Research conducted at CDC/ATSDR are 2 and 4.
- See the Research Determination Flowchart 4.

For question 4:

- Guidance on Engagement of institutions in research can be found from OHRP.
- See the Research Determination Flowchart 4.

For question 5:

- Research involving living human subjects that are 21 CFR Part 50 and part 56
- See the Research Determination Flowchart 5 and the *HRPO Worksheet to Determine FDA Regulatory Coverage* for more information on how to make this determination.
- Differences between HHS and FDA human subjects regulations can be found here.

NOTE: If CDC is only providing/receiving materials and services, the Research Determination Flowcharts do not apply.