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 subject 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: 2018 Customer Satisfaction Survey for CDC Laboratory Accredited to ISO 17043 (Proficiency Testing)

Project Location(s)/Site(s): CDC/NCEH/DLS 4770 Buford Highway, NE, Atlanta, GA 30341-3724

Project Officer(s): John Bernstein **Telephone:** (770) 488-7950 **Division or Office:** DLS

Proposed Project Dates: Start: 9/24/2018 **End:** 12/31/2018 **Time sensitive:** ___

Project Funding and Partners (answer both): HHS: CDC Funding - Internal Activity **Non-HHS:** NO external funding

If applicable, name participating external institution(s). CDC Funding - Internal Activity

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

Specify CDC role (mark ll that apply):

___ CDC is the sole institution conducting activity; OR

If not the sole institution, indicate if:

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

___ CDC is a provider of private data/specimens to an institution. X CDC is a recipient of private data/specimens from an institution.

___ CDC is a provider of materials/services to an institution. ___ CDC is a 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**	___	**NO**	X
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	___	NO	X

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**	___
A. Does the activity only involve the collection or analysis of non-human data or specimens, including entities, organization, or environmental materials?	YES	___	NO	___
B. Does the activity only involve the collection or analysis of data or specimens from deceased persons?	YES	___	NO	___

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	___
D. Are/Were the data or specimens collected from living persons specifically for this proposed activity?	YES	___	NO	___
E. Are/Were extra data or specimens collected from living persons specifically for this proposed activity?	YES	___	NO	___
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	___

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 or exempt *human subjects research?*	**YES**	___	**NO**	___
A. Does the research pose more than minimal risk?	YES	___	NO	___
B. Will prisoners be involved?	YES	___	NO	___
C. Will interaction with children occur or will identifiable private information about them be obtained?	YES	___	NO	___
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:	YES	___	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** ___

A. Did CDC receive funding directly from another HHS agency? 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 ___

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 papproved 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 standars to respect and protect the privacy, confidentiality, and autonomy of participants. All applicable State and Federal privacy lsws 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:

Carla Cuthbert	9/25/2018 8:19 AM	Jerry Thomas	9/26/2018 2:22 PM
Branch Chief	Date Signed	Division ADS/Director	Date Signed

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

Request Received Date: _____

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

- X Activity is not research (Flow chart category NR-1).
- ___ Activity is not human subjects research (Flow chart coverage 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 category HSR-1).
- ___ Activity qualifies as non-exempt engaged human subjects research (Flow category HSR-2).

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

- X 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 qualfies as human subjects research under FDA regulations (Flow chart category FDA-1 through FDA-2).

NCEH/ATSDR Human Subjects Contact Signature and Date:

Padmaja Vempaty -S Digitally signed by Padmaja Vempaty -S
Date: 2018.09.26 15:34:15 -04'00'

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 regualtions, 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 human subjects under either the Human Subjects 34 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.