

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: Customer Survey for CDC Laboratory Accredited to ISO 17025

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

Project Officer(s): Mary Halstead

Telephone: (770) 488-7950

Division or Office: DLS

Proposed Project Dates: Start: 9/6/2017

End: 8/31/2020

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 II 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. 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**

A. Is the activity a systematic investigation including research development, testing, and evaluation?

YES **NO** ___

B. Is the activity intentionally designed to develop OR contribute to generalizable knowledge?

YES ___ **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** ___

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 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:

Ben Blount	9/12/2017 1:20 PM	Jerry Thomas	9/20/2017 10:49 AM
Branch Chief	Date Signed	Division ADS/Director	Date Signed

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

Request Received Date: 09/20/2017

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 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).

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:

09/20/2017

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 human subjects under either the [Human Subjects 34 CFR part 46](#) or [FDA 21 CFR 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.