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: National Toxic Substance Incidents (NTSIP) Program

Project Location(s)/Site(s): ATSDR

Project Officer(s): Maureen Orr **Telephone:** 770-488-3806 **Division or Office:** DTHHS

Proposed Project Dates: **Start:** 1/1/2013 **End:** n/a **Time sensitive:** ☐

Project Funding and Partners (answer both): **HHS:** CDC funding - internal program **Non-HHS:** No external funding

If applicable, name participating external institution(s). Click here to enter text.

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:

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

☐ 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 ☒ NO ☒

research

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, including entities, organizations, or environmental materials? YES ☒ NO ☐ collects information on chemical events not human subjects

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 as *exempt human subjects research*? YES ☐ NO ☐

A. Research poses no more than minimal risk. YES ☐ NO ☐

B. No prisoners are involved. YES ☐ NO ☐

C. No interaction with children will occur; no identifiable private information about them will 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 "YES," 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 Guide to Project Development*.

Division Approval Signatures:

11/6/13
Date: Click here to enter a date.
Branch Chief D. Kevin Horton

John Wheeler 11/12/2013
Date: Click here to enter a date.
Division ADS/Director

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

Request Received Date: Click here to enter a 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).

Center Human Subjects Contact Signature:

Stephanie I. Davis, MSPH
NCEH/ATSDR Human Subjects Contact

11/24/2013
Date: Click here to enter a date.

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) guidance.
  - The FDA regulations, if FDA funds are used.
- 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.