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 little:				
Project Location(s)/Site(s):				
Project Officer(s):	•	Telephone: Division or 0 End: Time sens		
Proposed Project Dates: Start:	End:			
Project Funding and Partners (answer	er both): HHS:	Non-HHS:		
If applicable, name participating ext	ernal institution(s).			
Indicate the holder of the key to dec	cipher the identities of coded da	ata or biological specimens.		
Specify CDC role (mark all that apply	<i>(</i>):			
CDC is the sole institution conduc	cting activity; OR			
If not the sole institution, indicate if:				
CDC is NOT a recipient or provide	er of private data, specimens, m	aterials or services;		
CDC is provider of private data/sp		CDC is recipient of private data/specim	ens from an	institution
CDC is provider of materials/servi		CDC is recipient of materials/services fr		
<u> </u>		<u> </u>		
Questions 1-4 pertain to the HHS Hu	ıman Suhiects Regulations (45 C	FR 46).		
1. For CDC: Is this activity classified a			YES	NO
		velopment, testing, and evaluation?	YES	NO
B. Is the activity intentionally de		-	YES	NO
, , , , , , , , , , , , , , , , , , ,	CDC activity IS research if bo	<u> </u>		
	If 1 is "NO," then STOP;	otherwise continue.		
2. For CDC: Is this research classified			YES	NO
A. Does the activity only involve	the collection or analysis of non-	-human data or specimens, including	YES	NO
entities, organizations, or env	vironmental materials?			
B. Does the activity only involve		or specimens from deceased persons?	YES	NO
<u> </u>	CDC activity IS NOT human subjects re			
C. Do CDC employees intervene	If 2 is "NO," then STOP; with interact with or obtain inf	-	YES	NO
C. Do CDC employees intervene with, interact with, or obtain informed consent from living persons?D. Are/Were the data or specimens collected from living persons specifically for this proposed activity?				NO
•	YES YES	NO		
E. Are/Were extra data or specimens collected from living persons specifically for this proposed activity?F. Do/Will CDC employees or agents have access to the link between the data or specimens and the				NO
identity of these living person		veen the data of specimens and the	YES	NO
identity of these living person	CDC activity IS human subjec	ts research if 2C is "YFS."		
	CDC activity IS NOT human subjects res	earch if 2D, 2E, and 2F are all "NO."		
	If 2 is "NO," then STOP;	•	YES	NO
3. For CDC: Will this activity be subm		exempt numan subjects research?		_
A. Does the research pose more	than minimal risk?		YES YES	NO
B. Will prisoners be involved?				NO
C. Will interaction with children occur or will identifiable private information about them be obtained?				NO
		<u>bjects Regulations</u> , is there an HHS Exemp	t YES	NO
	<u> </u>	f "YES," specify the Category number:	. 	
CDC activity IS exempt	t human subjects research if 3A, 3B, and Exempt research must go to HRP	d 3C are all "NO," and an exempt category (3D) appl	ies.	
	If 3 is "YES," then STOP; o			

4. Is CDC <i>engaged</i> in the non-exempt	YES	NO NO NO		
A. Did CDC receive funding directly	YES			
B. Do CDC employees or agents in	YES			
C. Do CDC employees or agents ob	YES			
If 4 is "N		A, 4B, or 4C are "YES." rch must go to HRPO; use CDC Form 0.1250.		
Question 5 pertains to research involvapproved product in the course of me		s (21 CFR parts 50 and 56), not including th	e use of an F	DA
5. Based on the <u>HRPO Worksheet to D</u> to FDA human subjects regulations		Coverage, is the research activity subject	YES	NO
Additional Notes:				
respect and protect the privacy, co be followed. Informed consent m elements of consent. The consent	onfidentiality, and autonom ay be appropriate. Informat form and all other required	roject officers must adhere to ethical princi y of participants. All applicable State and Fe tion disclosed in the consent process should d supporting documents must be submitted ATSDR Guided Checklist for Human Subjects	ederal privacy address the with this for	laws must basic
Division Approval Signatures and Date	- es:			
Branch Chief	 Date Signed	Division ADS/Director	Date Sig	
For Office of Science Use Only: Final N		<u> </u>		<u> </u>
Request Received Date:	,			
CDC's role does not require HHS h	 luman subjects review beyo	ond the center level because:		
Activity is not research (Flow o				
Activity is not human subjects		ory 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 huma	an subjects review beyond	the center level because:		
Activity qualifies as exempt hu	man subjects research (Flov	v chart category HSR-1).		
Activity qualifies as non-exemp	pt, engaged human subjects	research (Flow chart category HSR-2).		
CDC's role does not require FDA h	uman subjects review beyo	and the center level because:		
Activity does not require huma	an subjects review under FC	DA regulations (Flow chart category NFDA-3	through NFD	A-4).
CDC's role does require FDA huma	an subjects review beyond	the center level because:		
Activity qualifies as human sub	ojects research under FDA re	egulations (Flow chart category FDA-1 throu	ıgh FDA-2).	
NCEH/ATSDR Human Subjects Contac	t 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:
 - o The CDC Policy on Distinguishing Public Health Research and Public Health Nonresearch
 - o Guidance from the Office of Human Research Protections (OHRP)
 - o 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 <u>Human</u>
 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 <u>HRPO Worksheet for Exemption from Human Subjects Regulations</u> 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 <u>21 CFR Part 50</u> and <u>part 56</u>
- See the Research Determination Flowchart 5 and the <u>HRPO Worksheet to Determine FDA Regulatory</u> <u>Coverage</u> 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.