

# **Determination of Applicability of Human Subjects Regulations**For Any Activities/Projects When Human Information/Specimens Will Be Collected



Project Title:			
Date to Begin:	End:	New Project or	Changes to Existing Project
Primary Contact:			Phone:
Division/Branch:		Supervisor's Name:	

Below describe the nature of the activity or project, considering the intended purpose and all aspects that are planned to date. This form should be completed by the CDC scientist, project officer, or other staff responsible for the project. Attach a description of the activity or project (i.e. protocol, concept paper, précis, etc).

# I. PUBLIC HEALTH NON-RESEARCH: Mark all that apply.

The activities/project is not intended to include research, but to:

Identify, control or prevent disease, illness, disability, or death in response to an immediate public health threat

Assess the implementation, performance, coverage, and/or satisfaction with an existing public health program, service, function, intervention or recommendation

Routinely monitor indicators of the public's health and known risk factors

Provide public health services, interventions, education, etc.

#### II. RESEARCH-NO HUMAN SUBJECTS: Mark all that apply.

The activities/project is not intended to involve human subjects. CDC will obtain:

Data in the aggregate only or about groups, organizations, etc. No individual level data will be collected

Data/specimens from or about deceased persons

Data/specimens from animal subjects

Microbiological isolates only without the ability to link to individuals' data/specimens

## Data/specimens:

Not collected specifically for the currently proposed research through interaction or intervention with human subjects;

Never collected with individually identifiable private information about human subjects <u>or</u> the key or linkages to such information was removed or destroyed by the holders of the data/specimen; Individually identifiable private information was collected but the holders of the data/specimens are prohibited from releasing the identifying link due to conditions of IRB approval or non-disclosure agreement.

**III. HUMAN SUBJECTS RESEARCH**: The activities/project is human subjects research. However, the following is being requested with respect to review for human subjects protections:

**CDC IRB Review Requested** – by completing the CDC form 1250 and other required forms along with the study materials (i.e. Protocols, consent forms, data collection forms, recruitment fliers, collaborator IRB approvals)

**Reliance on a Non-CDC IRB** – to have an outside non-CDC IRB review for human subjects protections review in lieu of CDC IRB.

**Exemption from IRB Review at CDC** – as we believe the study meets one of the criteria for exemption.

## **CDC Non-Engagement** - CDC will not be engaged. Mark all that apply.

CDC employees (FTE or contractors) will not have contact with human research subjects;

CDC employees will not obtain nor access any individual level data/specimens (included coded) for this study;

CDC involvement is limited to providing assistance and guidance with technical aspects of the research such as study design, methodology, analytic plan, interpretation of results, and training.

All collaborating institution(s) conducting human research or receiving federal funds for research will have appropriate review for human research protections and hold a valid Federal-wide Assurance (FWA).

Note: Non-engagement requests are considered on a case-by-case basis. If non-engagement status is granted then CDC scientists cannot, at any point, have access to data/specimens or research participants for the purposes of this study.

Results may be of clinical relevance for individuals and/or their family members.				
Involves potentially controversial, sensitive, or high profile issues, populations or testing.				
Informed consent will be sought.				
CDC will fund the study through grant, cooperative agreement, or contract mechanisms.				
Findings will be submitted for publication in the peer	reviewed literature.			
<b>Approvals and Determinations-</b> This section to be completed on the NC, division, and branch specific policies and procedure				
The proposed project has been reviewed by the following:				
Branch Chief	Division ADS			
NC Human Subjects Contact	NC ADS			
Determination of Applicability of Human Subjects Regulations and Review Requirements				
The proposed project was determined to be:				
<b>No further review required at this time.</b> If changes to the project/activities are considered, re-review is required before implementing the changes.				
Further action and review is required. Please complete the forms and submit them division clearance:				
HR Exemption from IRB Review - Include Form(s) 1250X				
HR Review by Non-CDC IRB for Reliance - Include Form(s) 1250, 1370, 1371				
HR Review by CDC IRB - Include Form(s) 1250				
HR Oversight of Activities Not Reviewed by CDC HRPO				
NR Non-Disclosure Requirements				
Public Health Non-Research: Monitoring Human Participation in CDC Public Health Activities				
Comments/Rationale:				
Tracking System ID Number:				
Final Determination Made by (print name): Signature:	Date:			

**Other Considerations:** Mark all that apply.

FDA review is required under IND, IDE, or EUA.

Involves greater than minimal risk to participants.

Data security has been addressed, including security of personally identifiable information.

Clinical, pharmacological, or therapeutic intervention will be involved.