Retrieve Data | Reset Form

Determination of Applicability of Human Subjects Regulations

For Any Activities/Projects When Human Information/Specimens Will Be Collected

Project Title: National Disease Surveillance Program - I. Case Reports (OMB No. 0920-0009)

Date to Begin: **End:** ☐ **New Project** **or** ☐ **Changes to Existing Project**

Primary Contact: J. Michael Miller, Ph.D., D(ABMM) **Phone:** 404-639-3029

Division/Branch: NCZVED/OD **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 or 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.

Next Page

Previous Page

Other Considerations: Mark all that apply.

- ☐ FDA review is required under IND, IDE, or EUA.
- ☐ Clinical, pharmacological, or therapeutic intervention will be involved.
- ☐ Involves greater than minimal risk to participants.
- ☐ 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.

Approvals and Determinations- This section to be completed by reviewers only. Clearance requirements will depend on the NC, division, and branch specific policies and procedures. Please indicate all that provided review and comment.

The proposed project has been reviewed by the following:

☐ Branch Chief _____ ☐ Division ADS_____

☑ NC Human Subjects Contact Wendy Carr ☑ NC ADS Mike Miller

Determination of Applicability of Human Subjects Regulations and Review Requirements

The proposed project was determined to be: Public Health Non-Research

☑ **No further review required at this time.** 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:

All projects contained in this package are disease surveillance systems involving the regular, ongoing collection of data to monitor the incidence of disease in the population. Per CDC guidance, these activities do not meet the definition of research under 45CFR46.102(d).

Tracking System ID Number: OMB No. 0920-0009

Final Determination Made by (print name): Wendy Carr

Signature: **Date:**

Save Data Print Email Form