Determination of Non-applicability of Human Subjects Regulations
Office of Sciences (OS)

Project title PERFORMANCE PROGRESS AND MONITORING REPORT (PPMR)

Primary contact Jeffrey M. Zirger, Ph.D. **Division/Branch** OS/OSI/ICRO

The purpose of this form is to document OADS's determination that the above-listed protocol does not require submission to CDC's Human Research Protection Office. Under existing institutional policy, authority to determine whether a project is research involving human subjects or whether CDC is engaged in human subjects research is delegated to the National Centers.

Determination

☒ Project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required.

☐ Project does not involve human subjects under 45 CFR 46.102(f). IRB review is not required.

☐ CDC is not engaged in the conduct of human subjects research per 2008 OHRP engagement guidance. CDC IRB review is not required. *Investigator has provided documentation of appropriate local review.*

Rationale

The CDC distributes funds via contracts, grants, and cooperative agreements, to partners throughout the world to promote health, prevent disease, injury and disability and prepare for new health threats. We are responsible for the stewardship of these funds while providing services to our partners and stakeholders. CDC collects information related to each Awardee's strategies and activities, and the process and outcome performance measures outlined by the cooperative agreement program. Information will be collected as part of the Awardee's progress report, and will be used to monitor progress towards project goals and objectives, for quality improvement, and to respond to inquiries from the Department of Health and Human Services, Congress, and other sources.

Additional considerations

None.

Additional requirements

Awardees are required to provide data as a condition of cooperative agreement funding. Capturing the required information uniformly will allow CDC to formulate ad hoc analyses and reports.

Changes in the nature or scope of this activity may impact the regulatory determination. Please discuss any changes with your NC Human Subjects Advisor before they are implemented.

Reviewed by Jeffrey M. Zirger, Ph.D. **Title** Health Scientist

Date: 4/10/2019