

Determination of Non-applicability of Human Subjects Regulations National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Project title Surveillance for Invasive Methicillin-Resistant Staphylococcus aureus (MRSA)
Through Active Bacterial Core Surveillance Emerging Infections Program

Primary contact Fernanda Lessa **Division/Branch** DHQP/SB

The purpose of this form is to document NCEZID'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 This project was determined to be non-research in January 2004 by NCID. The purpose of the current determination is to verify that this project remains consistent with routine public health surveillance and to document NCEZID's determination that this activity continues to be non-research.

The ABC Invasive MRSA surveillance is an ongoing public health surveillance activity designed to monitor the frequency and occurrence of invasive MRSA in the catchment areas of the 9 EIP sites. This activity is not designed to contribute to generalizable knowledge.

Additional considerations None.

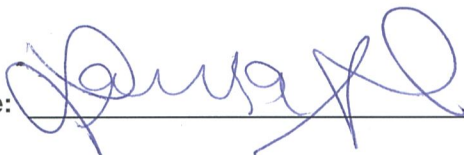
Additional requirements None.

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 Laura Youngblood, MPH, CIP

Title Human Subjects Advisor, NCEZID

Signature:



Date:

7/26/11