STARS Tracking Number: 0900f3eb820531e1 **NCEZID Tracking Number:** 121322MD

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

Project title National Healthcare Safety Network Surveillance System

Primary contact Margaret Dudeck **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. This authority is delegated to the CDC Centers, Institutes, and Offices under CDC Policies SSA-2010-01 and SSA-2010-02.

Determination

☐ Project is neither conducted nor supported by a Common Rule agency. IRB review is not required. [45 CFR 46.101(a)]

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

☑ Project is deemed not to be research under the following provision. IRB review is not required.

Public health surveillance activities, 45 CFR 46.102(l)(2)

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

☐ CDC's role in the project does not meet the threshold requiring submission to HRPO. *Investigator has provided documentation of appropriate local review.*

Rationale

NHSN data are used to monitor progress toward infection prevention goals, to support guideline development, and measure healthcare performance, quality, and resiliency. Data pertaining to healthcare worker vaccinations, healthcare-associated infections, patient-centered outcomes and healthcare capacity are reported to the system by over 38,000 healthcare facilities. Data will be regularly analyzed by members of the Surveillance Branch to develop various reports, summaries, dynamic dashboards, and manuscripts. As such, the use of NHSN data to monitor prevention, support guidelines, and measure performance to inform public health activities is consistent with non-research public health surveillance.

Additional considerations

Additional requirements

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 James Peterson, PhD **Title** Human Subjects Advisor

Signature James M. Peterson -S Digitally signed by James M. Peterson -S Date: 2022.12.13 13:56:08 -05'00' **Date** 12/13/2022