Report of End of Human Research Review

Closure, Withdrawal, Expiration, or Termination

Use this form to bring a formal end to human subjects review of CDC's involvement in IRB-approved or exempt research. See *HRPO Guide: End of Review Cycle* for further details on how to complete this form.

1 Protocol identifiers

CDC protocol ID: 4062 Protocol version number n/a version date exp. 05.2007

Protocol title: National Healthcare Safety Network

2 Key CDC personnel

☒ **No change** in key CDC personnel. Please list the primary contact and principal investigator.

	Name and degrees (FirstName LastName, Degrees)	User ID	SEV #	CDC NC/division
Primary contact (required)	Teresa C. Horan, BS, MPH	tch1	3330	NCPDCID/DHQP
Principal investigator (required)	Teresa C. Horan, BS, MPH	tch1	3330	NCPDCID/DHQP

SEV # is CDC's Scientific Ethics Verification Number. CDC NC/division is the national center or equivalent and division or equivalent, or coordinating center or office if submitted at that level.

3 Closure information

3.1 Mode of closure

Check all that apply.

Study never received IRB/exempt approval.

☐ **Withdrawal before approval**: Submitted protocol never received IRB/exempt approval.

Study received IRB/exempt approval but ended prematurely.

☐ **Withdrawal after approval**: IRB-approved/exempt study never began involvement of human subjects.

☐ **Expiration**: IRB approval expired.

☐ **Termination for risks**: Study stopped for unanticipated problems involving risks to subjects or others.

☐ **Termination for noncompliance**: Study stopped for serious or continuing noncompliance.

☐ **Termination for other reasons**: Study stopped for reasons other than risks or noncompliance.

Study received IRB/exempt approval and ended successfully.

☒ **Closure**: Study completed intervention, interaction, and data/specimen collection per study objectives.

Comments on mode of closure:

This activity was defined as public health practice, was submitted for ethical review and approval by the IRB and has been proceeding without problems. The Office of the General Counsel (OCG) believes that NHSN, as it is currently being utilized by CDC, is NOT a Privacy Act system of records and provides case law to support this determination (Henke v. U.S. Department of Commerce and Fisher v. NIH). Specifically, the OGC stated that "The CDC NHSN system is similar to the computerized information in both the Henke and Fisher cases. While CDC has the capability to retrieve data by personal identifier, CDC does not, as a matter of practice or policy, retrieve data in

this way. Specifically, the primary practice and policy of CDC regarding NHSN data is to retrieve data by the name of the hospital or other non-personal identifier, not an individual patient, for surveillance and public health purposes. Furthermore, patient identifiers are not necessary for NHSN to operate, and CDC does not regularly or even frequently use patient names to obtain information about these individuals." In consultation with Center Senior Staff, the program has been advised that IRB is no longer required and the protocol can be closed.

3.2 Closing report

Citation of published primary report or title of attached final report, if any:

N/A

If study ended prematurely or never received IRB/exempt approval, provide explanation. If study was terminated by the IRB or was terminated because of unanticipated problems involving risks or noncompliance, form 0.1254 is also required.

3.3 Disposition of data

Please observe appropriate policies on preserving federal records. Check all that apply:

☐ **None collected**: No study data have been collected.

☐ **No link**: Link between existing study data and human source of information never existed.

☐ **Destroyed**: Original identifiable data and research materials have been destroyed.

☐ **Link removed**: Link between data and human source of information has been destroyed or will not be disclosed to CDC investigators while subjects are living.

☒ **Link retained**: Link between data and human source of information will be retained and is potentially available to CDC investigators.

Justification: ongoing public health practice activities

Institution(s), location(s), Assurance number(s):

Duration: indefinitely

3.4 Disposition of stored biological specimens

Please observe appropriate policies on preserving federal records. Check all that apply:

☒ **None stored**: No biological specimens have been stored. This includes the case where none were collected.

☐ **No link**: Link between existing biological specimens and human source never existed.

☐ **Destroyed**: Stored, identifiable biological specimens have been destroyed.

☐ **Link removed**: Link between stored biological specimens and human source has been destroyed or will not be disclosed to CDC investigators while subjects are living.

☐ **Link retained**: Link between stored biological specimens and human source will be retained and is potentially available to CDC investigators.

Justification:

Institution(s), location(s), Assurance number(s):

Duration:

Other considerations related to respect for persons. These may include a summary of procedures to protect the privacy of subjects and to maintain the confidentiality of data and considerations of the relevance and communication of potential clinical implications of later specimen analysis.

4 Study participants—cumulative demographic frequencies

Report estimated counts (rather than percentages). Include participants at domestic and foreign sites. See *HRPO Guide: End of Review Cycle* for definitions.

Number of participants	493
Location of participants	
Participating at domestic sites	0
Participating at foreign sites	0
Sex/Gender of participants	
Female	0
Male	0
Sex/gender not available	0
Ethnicity of participants	
Hispanic or Latino	0
Not Hispanic or Latino	0
Ethnicity not available	0
Race of participants	
American Indian or Alaska Native	0
Asian	0
Black or African American	0
Native Hawaiian or Other Pacific Islander	0
White	0
More than one race	0
Race not available	0

Comments on demographics

* counts are facilities, not individuals. All other demographic frequencies n/a.

5 Material submitted with this form

Check all that apply. Describe additional material in the comments section.

- ☐ Final unpublished report(s)
- ☐ Published manuscript(s)

6 Additional comments

The activities this system engages in are defined by the Center as public health practice activities.