

Date received by Human Subject Contact Office:

NCHS Human Subject Research Determination Request Form

Protocol Identifiers

Protocol Title: **The National Survey of Prison Health Care**

NCHS Primary Contact

	Name and degrees (First name Last name, Degrees)	User ID	Telephone#	NCHS Division/Branch
Primary Contact	Carol DeFrances, PhD	CSDO	301.458.4440	DHCS/AHCSB

NCHS' Role in the Project

Yes No NCHS Employees or agents will obtain data by intervening or interacting with participants.

(Note: NCHS staff will be calling the identified respondent at each state department of corrections or Federal Bureau of Prisons.)

Yes No NCHS Employees or agents will obtain or use identifiable (including coded) private data or biological specimens.

Protocol Description (Please attach copies of any relevant protocol materials.)

The National Survey for Prison Health Care (NSPHC) is an administrative data collection in which each state's department of corrections and the Federal Bureau of Prisons will provide aggregate-level data on measures of health care within their prison system. Data collected in NSPHC will provide an overall picture of the global structure of health care services in prisons in the United States; close the gap on information about availability, location, capacity, and utilization of health care services provided to inmates; and identify the extent to which electronic medical records are utilized within correctional health care system.

For more information, please see the enclosed project summary that includes a copy of the survey questionnaire and revised induction letters. Thank you for your consideration of this matter.

Assessment of Requirements for IRB Review

Please provide details as to how the protocol relates to Title 45 Code of Federal Regulations (CFR), Part 46 requirements for IRB review. (Go to <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> to access 45 CFR part 46.) Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)]? Does the research involve a living individual about whom the investigator conducting the research obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information [45 CFR 46.102(f)]?

The NSPHC meets the definition of research [45 CFR 46.102(d)] as the study involves systematic investigation, including research development, testing and evaluation and is designed to develop or contribute to generalizable knowledge. However, the NSPHCS does not meet the criteria for human subjects research [45 CFR 46.102(f)] since the data collection will not include obtaining data from inmates directly nor will the data collected be individually identifiable.

Data collected through the NSPHC include the availability and utilization of health care services as well as health care staffing of the state and federal prison systems. Due to the fact that the state DOCs and the BOP are publicly funded, the data collected by the NSPHC are publicly available or justifiably obtainable by any member of the public. Although the names of facilities are not directly collected, the identity of a facility may be revealed through certain data inferences. However, neither the names of the facilities nor the health care services offered constitute sensitive or confidential data; this is public information. Therefore, NCHS will not offer protection to names or identities of facilities or establishments in this survey. Further, prisoners are not the respondents of this survey and NSPHC will not collect any health information about individual prisoners in these facilities.

Human Subject Contact Office Use Only

Does not meet the definition of Human Subjects Research: Does not require IRB (NCHS ERB) Review

Date: 7/14/11 Signature: [Signature]

Remarks: _____

Does meet the definition of Human Subjects Research: Requires IRB (NCHS ERB) Review

Date: _____ Signature: _____

Remarks: _____
