

10/11/18

NCHS Human Subject Research Determination Request Form**Protocol Identifiers**

Protocol Title: National Survey of Hospital-based Victim Services (NSHVS) Frame Development

RD19-01

NCHS Primary Contact

	Name and degrees (First name Last name, Degrees)	User ID	Telephone#	NCHS Division/Branch
Primary Contact	Juliana Huard, M.A.	MTV8	301-458-4409	DHCS/AHCSB
Principal Investigator	Carol DeFrances, Ph.D.	CSD0	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.

☐ 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 purpose of this project is to develop a sampling frame of hospitals providing victim services and programs specifically for victims of crime or abuse. The frame-related data will be collected about hospitals and will include basic characteristics of the hospital, services and programs directed to serving victims of crimes, staffing dedicated to victim services, and any partnerships, taskforces, coalitions directed to victim services. Information to be collected about the provision of victim services will include contact information for the programs and services, staff dedicated and partnerships to include information such as names, addresses, phone numbers, email addresses and job title for the people in charge of overseeing the victim services. Some of the information that will be collected for this project is publicly available through hospitals' websites while some is not. The list would serve as the basis for developing a sampling frame of hospitals offering these programs and services and can be used by the Bureau of Justice Statistics (BJS) to conduct future surveys on hospitals offering victim services or programs.

The data will be collected from hospitals in the National Hospital Care Survey (NHCS) frame through Computer-Assisted Telephone Interviewing (CATI) over a 3 month period. The universe for the NHCS consists of hospitals with six or more beds staffed for inpatient care in the 50 states and the District of Columbia and which are non-federal non-institutional. The NHCS describes national patterns of health care in hospital-based settings including hospital encounters from both Inpatient and Ambulatory departments. Intended respondents include administrative staff of hospitals and designated staff from emergency departments such as directors of emergency rooms, social workers, victim advocates or specialized units and programs serving victims of crimes within hospitals.

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)]?

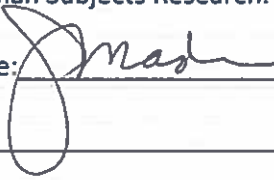
Since the proposed activity consist of a systematic investigation designed to develop a frame with generalizable knowledge of the provision of victim services within the Nation's hospitals, the investigators have concluded that this protocol meets the definition of research as stated by 45 CFR 46.102. However, it is not believed that the research meets the criteria of involving human subjects. All collection information including identifiable (including coded) private data such as contact information will be shared with only BJS.

According to 45 CFR 46.102(f), a human subject is a living individual about whom an investigator conducting research obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information. In turn, the investigative team respectfully submits this human research determination request suggesting that the NSHVS frame development project does not meet the definition of human subject research and therefore would not be subject to IRB (NCHS ERB) review.

Human Subject Contact Office Use Only

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

Date: 1/29/19

Signature: 

Remarks: _____

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

Date: _____

Signature: _____

Remarks: _____