



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: September 2, 2011

TO: Larissa Avilés-Santa, M.D.
National Heart, Lung, and Blood Institute

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "The Hispanic Community Health Study/Study of Latinos (HCS/SOL)"

I have reviewed the NHLBI submission to OMB to continue to study the prevalence of risk factors for cardiovascular disease among Hispanics/Latinos living in the U.S., and their relationship to cardiovascular morbidity and mortality, compared to non-Hispanic/Latino populations. The randomly selected sample of men and women who identify themselves as being Hispanic or Latin will be contacted annually by phone to update morbidity and mortality information as well as medical/hospitalization documentation and life events since the baseline examination.

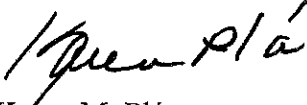
I have determined that the Privacy Act will apply to this data collection. It will involve the collection of personally identifiable information such as name, ID number, Social Security Number, address, phone number, date of death, age at death, place of death, relationship to the decedent, etc. Although providing the SSN is not required for participation, the study will, with permission of the participants, use identifying data to link to the National Death Index and possibly other medical databases (e.g., local hospital and State Department of Health). Information mandated by law (e.g., instances of child abuse or neglect, communicable diseases, etc.) will be reported to outside public health agencies or other explicitly authorized authorities.

Data collected from participants in the study will be de-identified in a manner that complies with NIH security and confidentiality guidelines, stored in encrypted form and maintained in a way that separates personal names and addresses from the clinical information and questionnaires. Each user of the data management system will be required to use a password to access the system. To provide the participants with individual reporting results and referrals, only the investigators at the originating field center and coordinating center will have access to personal information. Output mailed to a field center will identify participants only by an ID number. Paper records will be kept in secure storage and when no longer useful, will be discarded based on center-specific security protocol.

Data will only be made available to persons performing statistical analysis and will adhere to NIH limited access data use policies. If outside consultants or investigators located outside the study site need access to the data for publications, a data release will be prepared with no personal identifiers included. Study results will be published in appropriate scientific journals where the individual identities of participants and respondents will not be disclosed, and data will be reported only in aggregate.

This data collection is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD."

If you have any questions, please contact my office at (301) 402-6201.



Karen M. Plá

Attachment

cc: Kevin Purkiser, NHLBI PRA Liaison