

Addendum to Supporting Statement A

0925-0491 Jackson Heart Study

SSN in the JHS are vital for identifying cardiovascular events (deaths/hospitalizations) which occur in the cohort. The SSNs are used to linking to Jackson-area hospital databases and records provided by the Mississippi State Department of Health. Additionally, SSN are enables the study to verify deaths through the National Death Index . Without SSN linkage the collection of events data would not be possible.

As stated in the JHS Supporting Statement under Assurance of Confidentiality Provided to Respondents, the JHS Principal Investigator and co-PIs and their institutions have agreed to comply with the Federal Privacy Act as part of their contractual agreement with the NHLBI. The contract stipulates that research involving human subjects cannot be conducted until 1) protocol has been approved by NHLBI, 2) written notice of such approval is provided by the Contracting Officer, and completed Form SF-310 certifying Institution Review Board (IRB) review and approval of the protocol. In publications, the individual identities of participants and respondents are not be disclosed and data will be reported only in aggregate. Information obtained from the study will be included in the Privacy Act System of Records 09-25-0200, "Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD," as published in the Federal Register, Vol.62, No.66/Monday, April 7, 1997, pp. 16596-16602. Since this is a single study site, the data are entered quickly after collection and will not leave the premises. Data are only made available to persons performing statistical analysis. If outside consultants or investigators with offices outside the study site need access to the data for publications, a data tape is prepared with no personal identifiers included. All investigators maintain data security and confidentiality in accordance with their Institutional Review Board agreement. The Principal Investigator maintains data security and confidentiality in accordance with guidelines of the NIH.