Supporting Statement for
Cardiovascular Health Study (CHS)
OMB 0925-0334, Exp. 09/30/07

Submitted by:

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OMB Submission: Request for Revision of OMB Clearance

Summary and Supporting Statement

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe And Sampling Methods

The respondent universe consists of the surviving men and women of CHS. The collection of information does not employ statistical methods since this is an ongoing study of participants previously enrolled in CHS. All participants have been examined before, and thus, the study deals with a stable and already approached sample. The overall retention rate for the cohort at the end of the final (Year 11) examination was 94.7% (3964/4185), based on individuals who asked not to be contacted again and those whom could not be located. Telephone contact completion rates, which have been done solely since Year 12 through Year 18, are somewhat lower by Year 18 at 85% (1942/2284). The drop in retention rates after clinic exams ended was attributed at least in part to the loss of in-person contacts and to the advancing age of the cohort (average age now 87 years old). The overall retention in Year 18 at the Pittsburgh field site is 90% (545/606). (Note: response rates are calculated here as: examined cohort/surviving members of the cohort.)

B.2 Procedures For Information Collection

The sampling, enumeration, recruitment, home interview and first cohort examination were

completed in May 1990. Follow-up contacts at 6 and 12 months after entry were implemented and have been completed on schedule after the first cohort exam. Annual examinations took place until the last one in Year 11. Only surveillance and ascertainment of events have been done since Year 12 and are proposed to continue through May 31, 2008 under contract support at Pittsburgh's field center.

Semi-annual follow-up of the CHS cohort by telephone is used to maintain contact, to correct address information of participants, and to ascertain medical events. Follow-up contacts are made within 1 month of the 6-month anniversary date of the original examination or previous follow-up contact. These telephone contacts often provide the information that a participant has been hospitalized for a condition of interest to the study (coronary heart disease, heart failure, peripheral vascular disease, or cerebrovascular disease). In these cases, the hospital record is identified and abstracted, and all relevant information becomes part of the participant's study data. The participant has signed a medical release form allowing the study to access medical records. A proxy previously identified by the participant may complete the interview on the participant's behalf if the participant's health or other circumstances prevent him or her from doing so.

In order to classify cardiovascular events during follow-up in the CHS, information has been collected from a variety of sources, including public files (death certificates), medical records from hospitalizations, autopsy reports, and interviews from participants, and in some instances, interviews from their relatives or friends. While the great majority of data are and will continue to be collected from existing documents such as the medical record, information also must be

gathered from personal interviews so that an accurate determination of the cause of death can be made. The data collection tasks that involve contact with the participants or proxies are shown at the end of this section. Forms to be used are in Attachment 8. For those participants who die from cardiovascular disease during follow-up, their relatives or friends are interviewed only if no other information about the circumstances surrounding a participant's death are available. Information on hospitalizations and deaths will be reviewed and a determination of the occurrence of coronary heart disease, heart failure, peripheral vascular disease, and cerebrovascular disease will be made according to defined criteria. Cause of death will also be determined. A system is currently in place to send death certificates to a certified nosologist to provide a standardized classification of cause of death based on information listed on the certificate. Events forms and burden are described below:

Name of Form	Respondent	Qualifying Event	Estimated total number of respondents through May 31, 2008	Duration of interview (minutes)	Total burden (hours)
Semi-annual surveillance call (Participant interview or interview of informant of participant with incident non-fatal coronary heart disease, heart failure, stroke, or peripheral vascular disease who requires a proxy)	Participant, relative or friend	Incident Non-fatal Myocardial infarction, angina, heart failure, stroke, transient ischemic attack, or peripheral vascular disease	346	30	208
Informant interview of relative or friend of	Relative or friend	Participants who died from	121	30	73

decedent with script		CVD			
Total			467		281

Note: In order to obtain the information required for the classification of events, more than one informant of decedents may need to be interviewed; the estimate of the total burden includes these multiple interviews.

B.3 **Methods to Maximize Response Rates and Deal with Nonresponse**

The cohort recruited for CHS is unusually cooperative and enthusiastic about their participation in the study. This is reflected by the high rates of retention and data completeness both during the examination period and throughout the follow-up period. To date, the opportunity to participate in CHS has been a pleasant and rewarding experience for participants. Many have limited social contacts and outside activities and look forward to periodic contact with CHS staff. We have and will continue to encourage our interviewers to demonstrate personal interest in our participants, such as taking extra time to visit with those who seem to enjoy having someone to talk to. By emphasizing our personal concern and making our contacts with participants positive social experiences, we believe our participant retention and data quality will be maximized.

In support of this approach, we have noted that our retention rates have been quite high, as described in B.1 above

B.4 **Tests of Procedures or Methods to be Undertaken**

No pre-testing is requested for this revision, as all interviews and procedures are already in place.

B.5 **Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

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