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January 4, 2008

Paul Sorlie Division of Prevention and Population Sciences National Heart, Lung, and Blood Institute National Institutes of Health 6701 Rockledge Drive, MSC # 7936 Bethesda, MD 20892

RE: The Framingham Study

Dear Dr. Sorlie:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the National Institutes of Health's (NIH) proposed data collection as part of the Framingham Study.

Since 1924, the American Heart Association has dedicated itself to reducing death and disability from heart disease and stroke – the #1 and #3 leading causes of death in the United States – through research, education, community-based programs, and advocacy. AHA and ASA are committed to achieving a reduction in coronary heart disease, stroke and associated risk by 25% by 2010.

AHA offers the following thoughts and comments on the data collection for the Framingham Study. Our comments focus on two areas: 1) the significance of the Framingham Study and 2) the practical utility of the information collection.

Significance of the Framingham Study

Funded in 1948, the Framingham Study – under the direction of the National Heart Institute (now known as the National Heart, Lung, and Blood Institute, NHLBI) – embarked on an ambitious project in health research. At the time, little was known about the general causes of heart disease and stroke, but the death rates for cardiovascular disease (CVD) had been increasing steadily since the beginning of the century and had become an American epidemic.

Over the past 60 years, careful monitoring of the Framingham Study population has led to a number of milestone discoveries including the identification of the major CVD modifiable risk factors – high blood pressure, high blood cholesterol, cigarette smoking, obesity, diabetes, and physical inactivity – as well as a great deal of valuable information on the effects of related factors such as blood triglycerides and HDL cholesterol, age, gender, and psychosocial measures. Since its inception, the study has produced over 1,200 articles in leading medical journals. The concept of CVD risk factors has become an integral part of the modern medical curriculum and has led to the development of effective treatment and preventive strategies in clinical and public health practice because of the Framingham Study.

Of particular importance are the Risk Assessment Tool for estimating 10-year risk of developing hard coronary heart disease (CHD) and the Stroke Risk Profiles that were developed from the Framingham Study. Both are widely used by cardiologists and general practitioners to predict an individual's likelihood of developing CHD and stroke in the next 10 years. The CHD risk prediction tool has been adopted by the National Cholesterol Education Program, Adult Treatment Panel for detection, evaluation, and treatment of high blood cholesterol in adults.

Because of the Framingham Study and its role in identifying risk factors for CVD, we have observed a marked decline in CHD and stroke mortality over the past few decades.

Practical Utility of the Information Collection

The Framingham Study continues to make important scientific contributions by enhancing research capabilities and capitalizing on its inherent resources. The study investigators are expanding their research into other areas such as the role of genetic factors in CVD and genome-wide association studies for cardiovascular outcomes. The Framingham Study investigators also collaborate with leading researchers from around the country and the world on projects in stroke and dementia, osteoporosis and arthritis, nutrition, diabetes, eye diseases, hearing disorders, lung diseases, and genetics of common disease.

AHA uses a huge amount of information that is generated by the Framingham Study for our research, education, and community-based programs and activities. The above-mentioned CHD risk prediction tool and the Stroke Risk Profiles are disseminated to healthcare providers, patients, and the general public alike through our website and other print materials. Findings from the Framingham Study are repeatedly citied in AHA/American College of Cardiology joint practice guidelines, as well as in a number of AHA scientific statements and evidence-based practice guidelines.

The ongoing research activities and the additional data collection requested by the National Heart, Blood, and Lung Institute will generate new scientific information, which will enhance and improve our capabilities to serve the public who are at risk of developing heart disease and stroke. We believe that it is important and useful to collect the data.

In conclusion, AHA supports the proposed National Institutes of Health data collection in the Framingham Study.

American Heart Association January 4, 2008

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Relations Manager, at 202-785-7908 or via email at susan.k.bishop@heart.org.

Sincerely,

Daniel W. Jonn-mo

Daniel W. Jones, MD President, AHA