

may make searching for a record easier and prevent delay.

#### RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a)(2)).

#### CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7).

#### RECORDS SOURCE CATEGORIES:

Information for this system is collected from the Inpatient Rehabilitation Facilities—Patient Assessment Instrument.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Health Resources and Services Administration (HRSA), with authority to re-delegate, the authority vested in the Secretary of Health and Human Services under Title III, Part B, Section 319F-4, titled "Covered Countermeasure Process," of the Public Health Service Act, as amended, by the Public Readiness and Emergency Preparedness Act of 2006 (Pub. L. 109-148), only insofar as it pertains to the compensation program.

This delegation shall be exercised under the Department's existing delegation of authority and policy on regulations.

This delegation is effective upon signature. In addition, I hereby affirmed and ratified any actions taken by the HRSA Administrator or other HRSA officials which involved the exercise of this authority prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: November 8, 2006.

**Michael O. Leavitt,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute: Circulating Biomarkers of Cardiovascular Risk in the NHLBI's Framingham Heart Study

**AGENCY:** National Heart, Lung, and Blood Institute, NIH, HHS.

**ACTION:** Notice.

**SUMMARY:** National Heart, Lung, and Blood Institute (NHLBI) seeks partners in a biomarker consortium to promote research on novel serum/plasma/urine biomarkers of cardiovascular disease (CVD) and related risk factors including atherosclerosis, obesity, insulin resistance, hypertension, and metabolic syndrome. An immediate consequence of this project will be the development of new diagnostic tests to identify individuals at high risk for CVD and its risk factors at a time when intervention is most feasible. A downstream result of the identification of novel biomarkers of CVD (and its risk factors) will be the discovery of disease promoting pathways, which may serve as new therapeutic targets for treating and preventing our nation's leading cause of death.

**Background:** Despite steady declines in CVD mortality, CVD remains the leading cause of death in the developed world. The NHLBI's Framingham Heart Study (FHS) has been instrumental in the identification and elucidation of key modifiable risk factors for CVD, which in turn have facilitated modern approaches to the prevention and treatment of CVD. Because of its prospective study design, the NHLBI's FHS is ideally positioned to enable identification of novel risk factors for CVD. The availability of frozen serum/plasma/urine samples from over 7000 FHS participants in the Offspring and Third Generation cohorts, in concert with new high-throughput quantitative biomarker technology available from commercial collaborators, provides a unique opportunity to explore the biochemical signatures of key CVD phenotypes. In addition, by the end of 2007 genotyping of 550k SNPs will be completed in nearly all the FHS participants as part of the NHLBI's SHARe project and these data will

permit analysis of the associations of gene variants with biomarker levels.

**Scientific Scope:** The proposed study will measure 150 or more evolving and novel biomarkers from the FHS in 7000 FHS subjects for whom subclinical and clinical CVD and its risk factors have been carefully characterized. Analyses will be conducted for association of biomarkers—individually and collectively—with clinically relevant phenotypes.

The aims of the project are to:

1. Identify the biochemical signature of atherosclerosis as determined by: (a) Aortic and coronary calcification on CT (data available in 3500 people), (b) aortic plaque burden by MRI (n=2000), (c) carotid intimal-medial thickness by ultrasound (n=3500), (d) clinical atherosclerotic CVD (n=500), and (e) the dynamic balance between arterial calcification and bone demineralization (n=3500).

2. Identify the biochemical signature of metabolic syndrome components including (a) systolic and diastolic blood pressure (n=7000), (b) obesity (n=7000) and visceral adiposity by CT (n=3500), (c) dyslipidemia (n=7000), and (d) impaired fasting glucose, diabetes, and insulin resistance.

Biomarkers for this project will be selected by expert consensus on the basis of (a) a careful review of the literature for biomarkers of atherosclerosis and metabolic syndrome, and (b) genes implicated in atherosclerosis and metabolic syndrome (and their constituent components and pathways), or showing evidence of association with the phenotypes of interest.

**Technology:** As part of this project, new quantitative tests will be developed to measure circulating biomarker levels using antibody sandwich assays and/or proteomic approaches that are amenable to high throughput application. Critical to this project is the implementation of methods to measure large numbers of biomarkers with minimal sample volume; proteomic, bead-linked immunoassays, and nanotechnology methods may be necessary to accomplish this aim. Pathways to be studied include but are not limited to: Adhesion/chemoattraction, adipokines, cytokines, growth factors, heat shock proteins, inflammation, lipoproteins, neurohormones, thrombosis/fibrinolysis, and vascular calcification. Demonstrated rigorous assay validation using non-FHS samples will be necessary before FHS biospecimens can be used for this project.

**Study Sample:** The NHLBI's FHS is community-based<sub>[N1]</sub>, which should contribute to the generalizability of