ARIC Manuscript Proposal # 1011

PC Reviewed: 05/06/04	**Status: A**	**Priority: 2**
SC Reviewed: 05/07/04	**Status: A**	**Priority: 2**

1.a. Full Title: Long-term Stability of Hemoglobin A1c (HbA1c) Measurements from Frozen Whole Blood Samples Stored for Over a Decade

b. Abbreviated Title (Length 26 characters): Long-term Stability of HbA1c

2. Writing Group (list individual with lead responsibility first):

Lead: Elizabeth Selvin, MPH
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Writing group members: Josef Coresh, MD, PhD; Michael Steffes, MD, PhD; others welcome.

3. Timeline: April 2004-June 2004

4. Rationale: Hemoglobin A1c (HbA1c), a measure of long-term glycemic control, is at the center of the clinical management of diabetes mellitus. However, the accuracy and reliability of HbA1c measurements from whole blood samples which have been in long-term storage at -70°C for over a decade is unknown.

5. Main Hypothesis/Study Questions:
We undertook this study to assess the accuracy and reliability of HbA1c measurements from whole blood samples which have been in long-term storage at -70°C for over a decade. We hypothesize that HbA1c measurements from the frozen samples will be reliable (high correlation with previous HbA1c measurements from ARIC Visit 2) but may have a systematic bias.

6. Data (variables, time window, source, inclusions/exclusions):
The primary data summarized in this manuscript are data from ARIC Ancillary Study # 2003.5, "Glycemic Control (HbA1c) as Visit 2 as a Predictor of Coronary Heart Disease, Kidney Disease, and Incident Diabetes." This manuscript summarizes data on a subset of participants (N=336) included in this Ancillary Study who also had HbA1c measured at Visit 2 as part of a case-control study described in the original ARIC protocol (see ARIC Protocol 7, Blood Collection and Processing, Visit 2, Section 2.3.2).

Variables used: Age (v2agey2); Gender (gender); Center (center); Race(racegrp); HbA1c at Visit 2 (ccaa02); HbA1c values from Ancillary Study #2003.5; Diabetes status (diabts23, diabts03); Glucose (chmb07); Fasting status (fast0823)

We expect to complete the data analysis and writing of this manuscript by June 2004.

7.a. Will the data be used for non-CVD analysis in this manuscript? ____ Yes __X__ No
The data used are from the ARIC Ancillary Study #2003.5 which is directly related to CVD and diabetes.

b. If Yes, is the author aware that the file ICTDER02 must be used to exclude persons with a value RES_OTH = "CVD Research" for non-DNA analysis, and for DNA analysis RES_DNA = "CVD Research" would be used? ____ Yes ____ No
(This file ICTDER02 has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript? ____ Yes __X__ No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER02 must be used to exclude those with value RES_DNA = "No use/storage DNA"? ____ Yes ____ No

9.The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: http://www.cscc.unc.edu/ARIC/search.php

___X___ Yes _____ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?

Vitelli LL, Shahar E, Heiss G, McGovern PG, Brancati FL, Eckfeldt JH, Folsom AR. Glycosylated hemoglobin level and carotid intimal-medial thickening in nondiabetic individuals. The Atherosclerosis Risk in Communities Study. Diabetes Care 1997;20:1454-8.

11. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.