1.a. **Full Title**: Patient Characteristics and Glycemic Control (HbA1c) in Persons with Diagnosed and Undiagnosed Diabetes

b. **Abbreviated Title (Length 26 characters)**: Patient Characteristics and Glycemic Control

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

   **Lead:** Elizabeth Selvin  
   **Address:** Department of Epidemiology  
   Johns Hopkins Bloomberg School of Public Health  
   Welch Center for Prevention, Epidemiology, and Clinical Research  
   2024 E Monument Street, Suite 2-600  
   Baltimore MD 21205-2223  
   **Phone:** 410-614-3752  
   **Fax:** 410-955-0476  
   **E-mail:** lselvin@jhsph.edu

   Writing group members: Josef Coresh, MD, PhD; Sherita H. Golden, MD, MHS; Frederick L. Brancati, MD, MHS; Michael W. Steffes, MD, PhD; others welcome.

   **Acknowledgements:** Joyce Jordahl; Lori Boland, MPH

3. **Timeline:** Manuscript to be completed by December 2004

4. **Rationale:** In patients with diabetes, achieving tight glycemic control is difficult. Predictors of glycemic control in persons with diagnosed and undiagnosed diabetes are not well established. Previous studies of persons with diagnosed diabetes have suggested that measures of adiposity (2-4) and current smoking (4;5) are associated with glycemic control. The associations between glycemic control and age (2;4;6), race (3;7-9), alcohol consumption (4-6;10;11), physical activity (5;12), and depression (1;13-15) have been more mixed. Identifying clinically-relevant patient characteristics associated with glycemic control should help address barriers to glycemic control in individuals with diabetes.

5. **Main Hypotheses/Study Questions:**  
   H1: Individual-level characteristics, such as race, smoking, alcohol consumption, physical activity, depression, and education level, are associated with glycemic control (HbA1c).

   H2: Correlates of glycemic control (HbA1c) may differ in persons with diagnosed vs. undiagnosed diabetes.

6. **Data (variables, time window, source, inclusions/exclusions):**
Study population
The study population will consist of all persons with diagnosed or undiagnosed diabetes by ARIC visit 2. Individuals will be classified as being based on a fasting glucose $\geq 126 \text{ mg/dl}$, a nonfasting glucose $\geq 200 \text{ mg/dl}$, a self-reported physician diagnosis of diabetes, or diabetes medication use. Individuals who self-report a physician diagnosis of diabetes or current diabetes medication use will be classified as having diagnosed diabetes. Persons not meeting this criteria will be considered “undiagnosed.”

Hemoglobin A1c
We measured hemoglobin A1c (HbA1c) from ARIC visit 2 stored whole blood samples as part of ARIC Ancillary Study # 2003.5, “Glycemic Control (HbA1c) at Visit 2 as a Predictor of Coronary Heart Disease, Kidney Disease, and Incident Diabetes.” HbA1c data are available for over 5,400 ARIC participants, including all incident and prevalent diabetes cases.

Other variables of interest
Covariates will include sociodemographic characteristics (age, gender, race, education, marital status, social support, depression), behavioral characteristics (smoking, physical activity, alcohol consumption), anthropometry (body mass index, waist-hip ratio), and medication use.

Data Analysis
For this cross-sectional analysis, we will use logistic regression models to evaluate the relationship between variables of interest and the likelihood of being in “sub-optimal” or “poor” glycemic control (i.e., HbA1c level $> 7\%$ or $> 8\%$).

7.a. Will the data be used for non-CVD analysis in this manuscript?  ____ Yes  ____ 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  ____ 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)?


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.
Reference List


7. Davis TM, Cull CA, Holman RR. Relationship between ethnicity and glycemic control, lipid profiles, and blood pressure during the first 9 years of type 2 diabetes: U.K. Prospective Diabetes Study (UKPDS 55). Diabetes Care 2001;1167-74.


