PC Reviewed: <u>05/01/01</u>   **Status:** <u>A</u>   **Priority:** <u>N/A</u>
SC Reviewed: <u>   </u>   **Status:** <u>   </u>   **Priority:** <u>   </u>

1.a. Full Title: Prothrombin G20210A genotype, prothrombin level and venous thromboembolism: LITE

  b. Abbreviated Title (Length 26 characters): Prothrombin and VTE

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

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3. Timeline: Analysis has begun. Draft in a month.

4. Rationale: This is another of the LITE ancillary study nested case-control papers. G20210A has been associated with elevated prothrombin and increased risk of venous thromboembolism (VTE) in many case control studies. There is only one prospective study.

5. Main Hypothesis/Study Questions: VTE is associated positively with G20210A mutation and plasma prothrombin levels. There are interactions with age, factor V Leiden and factor VIII.

6. Data (variables, time window, source, inclusions/exclusions):

Dataset: LITE nested case-control study of VTE.
Dependent var: VTE vs control
Independent: G20210A, plasma prothrombin
Covariates: study, age, sex, race, BMI, factor V Leiden, factor VIII
Analysis: description of mutation prevalence, relation of prothrombin to genotype. Calculate ORs by stratified analysis and logistic regression. Potential interactions assessed by cross-classification

7.a. Will the data be used for non-CVD analysis in this manuscript?   ____ Yes __x__ No

  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?   __x__ 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"?   __x__ 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://bios.unc.edu/units/cscc/ARIC/stdy/studymem.html

__x__ Yes   ____ No