ARIC Manuscript Proposal #816

1.a. Full Title: The association between environmental tobacco smoke and pulmonary function measurements of a population-based cohort—from the Atherosclerosis Risk in Communities Study

b. Abbreviated Title (Length 26 characters): ETS and pulmonary function

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

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3. Timeline:

<table>
<thead>
<tr>
<th>Year 1 (August 2001-January 2002)</th>
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<tr>
<td>Event</td>
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<tr>
<td>Establish research data files</td>
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<td>Data analysis</td>
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<td>Submit abstract for national presentation</td>
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4. Rationale:
Environment tobacco smoke (ETS) exposure has been linked to the development of lung cancer, COPD, and childhood asthma and is a significant public health issue. It has been estimated that over a third of Americans are exposed to ETS on a daily basis. It has been suggested that over a third of Americans are exposed to ETS on a daily basis. ETS is a controversial policy topic as well and many state assemblies are currently struggling with proposed legislation addressing public concerns about “second-hand smoke”. It is important that we better describe the health effects of this potentially harmful substance.

Data from past studies examining the effect of ETS exposure on the pulmonary function of adults have yielded disparate results, though associations have been suggested between such exposure and lower than expected FEV1 and FVC. Most studies that have looked at this issue have been cross-sectional in design; only two have been prospective and nearly all have been underpowered to find significant differences between groups. Because of the potentially enormous public health and policy implications of the issue of ETS’s effect on lung function and respiratory symptoms, we have proposed the current research project. We believe that regardless of the cumulative effect—negative or positive—of ETS exposure, these results are important and useful.
The following are important benefits of this research relative to past efforts:

- Prospective data collection
- Largest number of patients yet included in such a study
- Inclusion of non-white patients
- Data on important socioeconomic factors available
- Extensive respiratory symptoms information

A caveat to our research is the fact that others have submitted proposals for similar studies, yet have abandoned the project before completion. We, however, are confident that our study will yield important information that will be of publishable quality. Important benefits of our plan include:

- Examination of small airways airflow measurements (FEF25-75)
- Use of ETS as both a continuous and categorical variable
- Subgroup analysis of persons with obstructive airflow patterns (FEV1<65%)
- Examination of incidence of new respiratory symptoms and use of pulmonary medications among non-smokers exposed to ETS
- Use of modeling to adjust for important differences among groups (by gender and race) such as education, income, possession of insurance

We acknowledge these past efforts and will benefit from our inclusion of a member of a past research team that looked at this data previously (FJN). We believe that such a plan will only increase our likelihood of success by avoiding past problems.

5. **Main Hypothesis/Study Questions:**
In our proposed study of data collected during visits 1 and 2 we aim to:

Test between non-smokers with and without ETS exposure for any differences in:

1. the rate pulmonary function decline over 3 years
2. the prevalence of respiratory symptoms at baseline and incidence over 3 years
3. the need for pulmonary medications at baseline and incidence over 3 years

We expect that there will be significant differences in spirometric indices among groups (black females, black males, white females, white males) by smoking status (current smoker, past smoker/+ ETS exposure, past smoker/- ETS exposure, never smoker/+ETS exposure, never smoker/- ETS exposure). We also expect those non-smokers exposed to ETS to have more respiratory symptoms (cough, sputum, wheeze, breathlessness) and to use more pulmonary medications (albuterol, atrovent, cromolyn, inhaled steroids).

6. **Data (variables, time window, source, inclusions/exclusions):**
We are interested in the following public use data files from Visits 1 and 2 only (visits with spirometric data): PULMPS12/22, PFTAPS12, PFTBPS22, RPAAPS12, RPABPS22, RHXAPS12, HHXPS12, DERPS12/22, PHEAPS12, PHEBPS22, MHXAPS12, and HOMPS12. Variables we hold in particular interest are those for spirometric indices, age, gender, income, education, occupation, and smoking status.

There are also other variables not included with the public use data we are interested in using: variables for center site, pulmonary function test technician ID codes, and medication data (variable numbers in files MSRPS12/22: 410000-451000, 971000, 971010, 971020, 97120, 480000, 480600, 481600, 482400, 520000, 520404). These are the only such variables from the restricted dataset that we would like to use in our analysis. The center site and technician ID codes will be invaluable in assessing validity of
spirometric measurements and for exclusion of outlying values based on past analysis of the pulmonary function test data. Medication data will be important in examining the potential relationship between environmental tobacco smoke exposure and use of pulmonary medications, a relationship never previously reported.

We will include all participants from all sites who completed spirometry at Visits 1 and 2. Exclusions will include spirometry values specific to certain technicians felt by the writing group to be outliers.

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

    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
    (This file ICTDER02 has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8. Will the DNA data be used in this manuscript? 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.

    Yes