

Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is “None”, please specify “None” as your response. “Not applicable” is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

1. **Grantee Institution:** University of Pittsburgh – Commonwealth System of Higher Education
2. **Reporting Period (start and end date of grant award period):** 1/1/2010 – 12/31/2013
3. **Grant Contact Person (First Name, M.I., Last Name, Degrees):** Margaret C. McDonald, PhD
4. **Grant Contact Person’s Telephone Number:** 412-383-7474
5. **Grant SAP Number:** 4100050913
6. **Project Number and Title of Research Project:** 08 - Racial Disparities in Associations between Chronic Airflow Obstruction and Cardiovascular Risk
7. **Start and End Date of Research Project:** 8/1/2011 – 12/31/2013
8. **Name of Principal Investigator for the Research Project:** Steven E. Reis, MD
9. **Research Project Expenses.**

9(A) Please provide the total amount of health research grant funds spent on this project for the entire duration of the grant, including indirect costs and any interest earned that was spent:

\$ 410,937.41

9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

| Last Name, First Name | Position Title | % of Effort on Project | Cost |
|-----------------------|--|------------------------------|-----------|
| Reis, Steven | Principal Investigator | 5% Yr1 | \$12,570 |
| Beto, Amy | Research Coordinator | 92% Yr1, 33% Yr2, 20% Yr3 | \$112,468 |
| Bonk, Janet | Recruitment Coordinator | 3.75% Yr1 | \$3,121 |
| Coast, Mary Catherine | Research Coordinator | 14% Yr1 | \$10,431 |
| Dinga, Andrea | Nutrition Specialist / Research Coordinator | 92% Yr1, 8% Yr2 | \$70,342 |
| Gabriel, Margaret | Recruiter | 50% Yr1 | \$19,615 |
| Green, Jowanda | Research Coordinator | 73% Yr1, 33% Yr2 | \$65,572 |
| McDowell, Lee Ann | Data Manager | 69% Yr1, 31% Yr2 | \$59,224 |
| Rebstock, James | Research Associate | 5% Yr1, 5% Yr2 | \$3,215 |
| Thornton, Catherine | Recruiter | 50% Yr1, 25% Yr2 | \$18,004 |

(**Note, Year 01=07/01/11-06/30/12, Year 02=07/01/12-06/30/13 and Year 03=07/01/13-12/31/13).

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

| Last Name, First Name | Position Title | % of Effort on Project |
|-----------------------|------------------------|------------------------|
| Reis, Steven | Principal Investigator | 5% Yr2, 5% Yr3 |
| Beto, Amy | Research Coordinator | 50% Yr2, 50% Yr3 |
| Green, Jowanda | Research Coordinator | 50% Yr2, 50% Yr3 |
| McDowell, Lee Ann | Data Manager | 50% Yr2, 50% Yr3 |
| Gabriel, Margaret | Recruiter | 50% Yr3 |
| Bell, Hilary | Student | Part-time, 50% Yrs1-3 |
| Beto, Rachel | Student | Part-time, 50% Yrs 1-3 |
| Crawford, Allison | Student | Part-time, 50% Yrs1-3 |
| Johnson, Cheryl | Student | Part-time, 50% Yr1 |
| Nolan, Colin | Student | Part-time, 50% Yrs 1-2 |
| Przyuski, Scott | Student | Part-time, 50% Yrs1-3 |
| Steiner, Andrea | Student | Part-time, 50% Yr1 |

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

| Type of Scientific Equipment | Value Derived | Cost |
|------------------------------|---------------|------|
| None | | |

10. Co-funding of Research Project during Health Research Grant Award Period. Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes X No _____

If yes, please indicate the source and amount of other funds:

University of Pittsburgh School of Medicine: \$176,936 of funds were used to support personnel.

11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes X No _____

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert “not funded” in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

| A. Title of research project on grant application | B. Funding agency (check those that apply) | C. Month and Year Submitted | D. Amount of funds requested: | E. Amount of funds to be awarded: |
|---|--|-----------------------------|-------------------------------|-----------------------------------|
| Vulnerable Plaque: Predictive Value for CVD Events, Progression & Pathophysiology | X <input type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify: _____) <input type="checkbox"/> Nonfederal source (specify: _) | 6/2013 | \$3,488,119 | \$ Not Funded* |

*An amended application will be submitted later this year.

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes X No _____

If yes, please describe your plans:

One of our postdoctoral fellows in the Division of Pulmonary, Allergy and Critical Care Medicine, Divay Chandra, MD, will be applying for an NIH K-award. His project stems from preliminary analysis of the data collected in this project and will focus on exploring associations between subclinical and clinical atherosclerosis and chronic obstructive lung disease. In addition, we plan to resubmit the R01 application that is listed above, which will investigate the pathophysiology of vulnerable plaque. We postulate that racial disparities in CVD are due to race-related differences in atherosclerotic plaque biology. Inflammation, which is associated with many diseases such as obstructive lung disease, plays a role in plaque vulnerability.

12. Future of Research Project. What are the future plans for this research project?

We are in the midst of completing additional analyses of the data collected in this project. We will also stratify research participants by GOLD criteria, which is an international classification system for levels of severity of chronic obstructive lung disease, and repeat the analyses. Finally, we are collecting serial spirometry data on some participants, which will enable us to investigate associations between changes in lung function and CVD risk factors.

13. New Investigator Training and Development. Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes X No _____

If yes, how many students? Please specify in the tables below:

| | Undergraduate | Masters | Pre-doc | Post-doc |
|--------------|---------------|---------|---------|----------|
| Male | 2 | | | |
| Female | 5 | | | |
| Unknown | | | | |
| Total | 7 | | | |

| | Undergraduate | Masters | Pre-doc | Post-doc |
|--------------|---------------|---------|---------|----------|
| Hispanic | | | | |
| Non-Hispanic | 7 | | | |
| Unknown | | | | |
| Total | 7 | | | |

| | Undergraduate | Masters | Pre-doc | Post-doc |
|--------------|---------------|---------|---------|----------|
| White | 6 | | | |
| Black | 1 | | | |
| Asian | | | | |
| Other | | | | |
| Unknown | | | | |
| Total | 7 | | | |

14. Recruitment of Out-of-State Researchers. Did you bring researchers into Pennsylvania to carry out this research project?

Yes _____ No X _____

If yes, please list the name and degree of each researcher and his/her previous affiliation:

15. Impact on Research Capacity and Quality. Did the health research project enhance the quality and/or capacity of research at your institution?

Yes X _____ No _____

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

This project enabled the continued follow up of the Heart SCORE cohort and expanded the scope of research to a new avenue—the link between airflow obstruction and CVD. As a result, this project sustained the cohort, which began enrollment in 2003 (as a result of a Commonwealth of Pennsylvania nonformula grant) and provided access to the cohort by new investigators, as well as enabled us to continue to work collaboratively with the general community and local organizations. This project will serve as a resource for junior investigators, as exemplified by a post-doctoral fellow, Dr. Divay Chandra, who is writing an NIH K-grant award application based, in part, on analyses from this project,

16. Collaboration, business and community involvement.

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes X _____ No _____

If yes, please describe the collaborations:

We collaborate with Dr. Kevin Kip from the University of South Florida. Dr. Kip, who is an epidemiologist by training, conducted statistical analyses in this study.

16(B) Did the research project result in commercial development of any research products?

Yes _____ No X _____

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes X _____ No _____

If yes, please describe involvement with community groups that resulted from the research project:

We continue to work collaboratively with organizations such as the Urban League of Greater Pittsburgh. Between this project and other projects led by the PI, these collaborations have resulted in long-term relationships between University of Pittsburgh researchers and local organizations.

17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant agreement). Summarize the progress made in achieving these goals, objectives and aims for the period that the project was funded (i.e., from project start date through end date). Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha (α) and beta (β) should not print as boxes (\square) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.

Racial disparities exist in cardiovascular disease (CVD), with blacks disproportionately affected compared to whites. We have shown that these disparities may be related, in part, to racial differences in inflammation and abnormal arterial vasoreactivity, both of which are more prevalent in blacks. These associations have also been noted in chronic obstructive pulmonary disease (COPD) and may help explain why COPD is associated with high rates of CVD morbidity and mortality. However, the influence of race on COPD may actually be underestimated, as blacks with COPD may be more likely to die from CVD than from end-stage lung disease. This observation is particularly relevant because the presence of CVD risk factors that are more prevalent in blacks (e.g., hypertension) is associated with a nearly three-fold increase in CVD mortality over patients with COPD. This project investigated whether racial disparities exist in associations among lung function, CVD risk factors, and inflammation.

The specific aims of this study were to:

- 1) identify gender and racial disparities in the prevalence of chronic airflow obstruction as measured by spirometry, and
- 2) investigate race-related differences in the interrelationship among airflow obstruction, CVD risk factors, and inflammation, all of which are associated with increased CVD morbidity and mortality.

We proposed to conduct this study in 1,000 participants (approximately 43 percent black) in the ongoing Heart Strategies Concentrating on Risk Evaluation (Heart SCORE) study. Heart SCORE is a community-based participatory research study of 2,000 participants (43 percent black) that began in 2003 to study the epidemiology and mechanisms of racial disparities in CVD. Heart SCORE follows participants annually and has collected a wealth of biological and psychosocial data, markers of subclinical atherosclerosis, and sleep assessment data. The present study: (1) assessed lung function by spirometry and (2) correlated measurements, such as forced vital capacity (FVC), forced expiratory volume in one second (FEV1), FEV1/FVC, and mid-expiratory flow (FEF25-75), CVD risk factors (e.g., blood pressure, lipid levels, glucose) and measured levels of inflammation (high sensitivity C-reactive protein).

Approach: This project capitalized on a wealth of previously collected data along with sustained ongoing subject commitment to the Heart Strategies Concentrating on Risk Evaluation (Heart SCORE) study. Heart SCORE is being used as a foundation to prospectively perform spirometry to measure airflow obstruction and to measure CVD risk factors and inflammation in a racially diverse cohort of western Pennsylvanians.

Research Design: We proposed that 1000 subjects (\approx 43% self-identified blacks) presently

enrolled in Heart SCORE would undergo spirometry and measurement of CVD risk factors and inflammation during their annual study visit. There were no exclusion criteria.

Methods and Measures: During an annual study visit, the following information was collected from Heart SCORE subjects: medical history, list of current medications, physical examination (including measurements of blood pressure and waist/hip circumferences), measurements of fasting glucose, and lipids using standard clinical laboratory techniques. In addition, high-sensitivity C-reactive protein (hsCRP) was measured at a core lab (Harvard Medical School). The concentration of hsCRP was determined using an immunoturbidimetric assay on the Roche P Modular system (Roche Diagnostics - Indianapolis, IN) using reagents and calibrators from DiaSorin (Stillwater, MN). In this assay, an antigen-antibody reaction occurs between CRP in the sample and an anti-CRP antibody that has been sensitized to latex particles, and agglutination results. This antigen-antibody complex causes a decrease in transmitted light, which is detected spectrophotometrically, with the magnitude of the change being proportional to the concentration of CRP in the sample. This high-sensitivity assay has a limit of detection of 0.03 mg/L. The day-to-day variabilities of the assay at concentrations of 0.91, 3.07 and 13.38 mg/L are 2.81, 1.61 and 1.1%, respectively.

Spirometry was performed by a study nurse trained by a registered respiratory therapist. Current smoking was self-reported by the patient and recorded as pack-years. Height, weight, age, and race were similarly recorded. Spirometry results met 1998 American Thoracic Society (ATS) standards if they were acceptable and repeatable. Acceptability includes the following two criteria: the start of test is without hesitation (the volume of back-extrapolation is less than 5 percent of the FVC or 0.15 L, whichever is greater), and expiration lasts at least six seconds or it plateaus. The best test reported is the best FVC and the best FEV₁, even if they are from different trials. The test is considered to be repeatable if the second-best FVC and the second-best FEV₁ are each within 200 mL of the best test, and at least three acceptable trials are performed. Flow-volume loops are also displayed in the final report; these were analyzed during the interpretation and were considered to meet ATS standards if there was no coughing during the first second, no glottic closure, no mouthpiece obstruction by tongue or dentures, and no leaks.¹ For this study, measured FVC and FEV₁ and FEF₂₅₋₇₅ were recorded and the ratio (FEV₁/FVC) calculated from spirometry findings. Reference values for the three variables were calculated using the NHANES III equations specific for gender and race, and using height and age as the predictors. The lower limits of normal from the same source were used to determine whether the FEV₁/FVC was normal or not.²

Results

We enrolled 1,338 participants, which exceeded the proposed cohort of 1,000 participants. Statistical analysis was restricted to Heart SCORE participants of Caucasian or African-

¹ American Thoracic Society. Standardization of spirometry: 1994 update. *Am J Respir Crit Care Med* 1995; 152:1107–1136.

² Hankinson JL, Odencrantz JR, Fedan KB. Spirometric reference values from a sample of the general U.S. population. *Am J Respir Crit Care Med* 1999; 159:179–187.

American race, and those with complete data for measures of both FEV1 and FEF25-75. This resulted in a cohort of 1,299 participants, of whom 529 (40.7 percent) were African American. Demographic data are presented by race and gender in Table 1. These data indicate that black participants were significantly younger than white participants and had significantly lower educational attainment, higher body mass index, higher blood pressure, and higher fasting glucose levels. In contrast, blacks presented with lower triglycerides and, in women, lower cholesterol levels than whites.

Table 1. Baseline Characteristics by Gender and Race (n=1,299)

| Characteristic | Males | | | Females | | |
|--|------------------|------------------|-------------|------------------|------------------|-------------|
| | White (n=287) | Black (n=158) | p- value | White (n=483) | Black (n=371) | p- value |
| Age at date of PFT (mean \pm SD) | 66.9 (7.6) | 65.4 (7.4) | 0.05 | 66.3 (7.2) | 64.6 (7.5) | 0.0008 |
| Education (%) ^b | | | <0.0001 | | | 0.0005 |
| Less than high school | 1.0 | 5.1 | | 0.8 | 1.9 | |
| High school diploma | 7.7 | 16.5 | | 17.4 | 14.9 | |
| Some college | 20.3 | 39.9 | | 28.0 | 42.4 | |
| Bachelors degree | 30.1 | 19.6 | | 21.6 | 22.4 | |
| Advanced degree | 40.9 | 19.0 | | 32.2 | 18.4 | |
| Body mass index (mean \pm SD) ^a | 28.9 (4.7) | 30.4 (5.7) | 0.005 | 28.2 (5.6) | 32.3 (6.9) | <0.0001 |
| Systolic blood pressure (mean \pm SD) | 126 (14) | 129 (15) | 0.02 | 123 (14) | 129 (15) | <0.0001 |
| Diastolic blood pressure (mean \pm SD) | 74 (8) | 77 (8) | 0.0002 | 73 (8) | 76 (9) | <0.0001 |
| Blood pressure classification (%) ^b | | | 0.004 | | | <0.0001 |
| Normal | 32.7 | 17.4 | | 37.6 | 22.6 | |
| Pre-hypertensive | 48.4 | 57.4 | | 45.9 | 51.8 | |
| Hypertensive stage I | 17.4 | 24.5 | | 16.1 | 21.7 | |
| Hypertensive stage II | 1.4 | 0.7 | | 0.4 | 3.9 | |
| Resting pulse per min. (mean \pm SD) | 65 (9) | 68 (12) | 0.007 | 68 (8) | 69 (9) | 0.12 |
| Total cholesterol (mg/dL) (mean \pm SD) | 178 (35) | 173 (35) | 0.15 | 202 (40) | 194 (38) | 0.004 |
| LDL cholesterol (mg/dL) (mean \pm SD) | 110 (29) | 108 (32) | 0.52 | 120 (35) | 114 (36) | 0.04 |
| HDL cholesterol (mg/dL) (mean \pm SD) | 46 (16) | 47 (15) | 0.36 | 59 (18) | 61 (18) | 0.19 |
| Triglycerides (mg/dL) (mean \pm SD) ^a | 115 (70) | 100 (61) | 0.01 | 121 (70) | 102 (54) | <0.0001 |
| Fasting glucose (mg/dL) (mean \pm SD) ^a | 100 (17) | 105 (26) | 0.17 | 94 (17) | 98 (25) | 0.01 |
| Framingham risk strata (%) ^b | | | 0.27 | | | <0.0001 |
| Low risk | 31.8 | 28.4 | | 82.4 | 68.1 | |
| Intermediate risk | 46.4 | 44.7 | | 11.1 | 15.1 | |
| High risk | 21.8 | 26.9 | | 6.5 | 16.8 | |

^aAssessed by Wilcoxon Rank Sum test. ^bAssessed by test of trend.

Aim 1. To identify gender and racial disparities in the prevalence of chronic airflow obstruction as measured by spirometry.

In univariate analyses, our results indicate that black males have more airflow obstruction than white males manifested by significantly lower percent predicted FEV1, and a trend towards lower FEF25-75, both of which are objective measures of airflow obstruction (Figures 1, 2). Similarly, black females had significantly lower predicted FEV1 than white females, yet in a paradoxical manner, higher predicted FEF25-75.

Figure 1. Percent predicted FEV1 (% predicted) by race and gender.

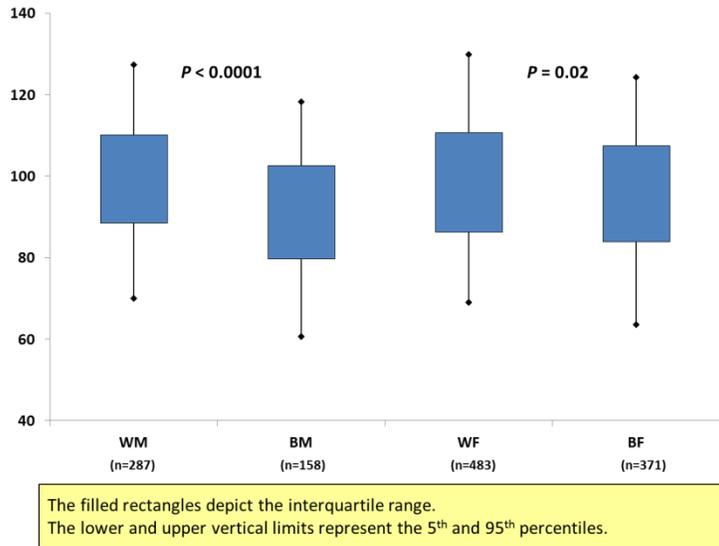
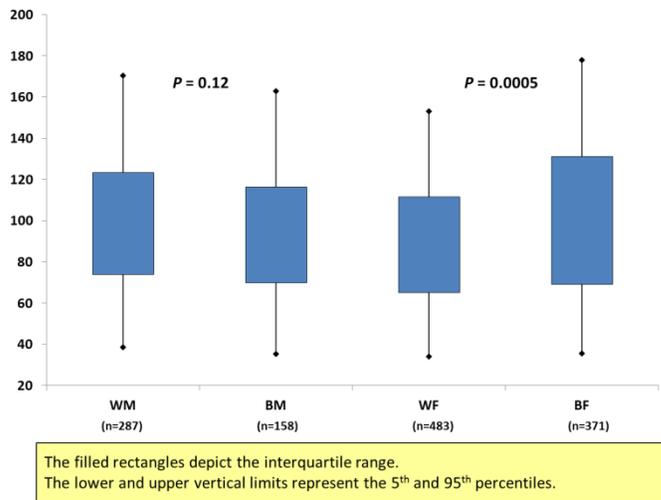


Figure 2. Percent predicted FEF25-75 by race and gender.



Using white males as the comparison (reference) group, Table 2a below demonstrates a lower percent predicted FEV1 among both black males and black females.

Table 2a. Univariate Association Between Race/Gender and Percent Predicted FEV1

| Parameter Estimates | | | | | | |
|----------------------------|-----------|---------------------------|-----------------------|----------------|--------------------|-------------------------------------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t | Squared Partial Corr Type II |
| Intercept | 1 | 99.02230 | 1.09874 | 90.12 | <.0001 | . |
| Black male | 1 | -8.57477 | 1.84394 | -4.65 | <.0001 | 0.01642 |
| White female | 1 | -0.51381 | 1.38729 | -0.37 | 0.7112 | 0.00010592 |
| Black female | 1 | -3.32473 | 1.46326 | -2.27 | 0.0232 | 0.00397 |

Again, using white males as the comparison (reference) group, Table 2b below shows lower percent predicted FEF25-75 among black males and white females in particular.

Table 2b. Univariate Association Between Race/Gender and FEF25-75

| Parameter Estimates | | | | | | |
|----------------------------|-----------|---------------------------|-----------------------|----------------|--------------------|-------------------------------------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t | Squared Partial Corr Type II |
| Intercept | 1 | 4.51367 | 0.02972 | 151.88 | <.0001 | . |
| Black male | 1 | -0.09088 | 0.04988 | -1.82 | 0.0686 | 0.00256 |
| White female | 1 | -0.10223 | 0.03752 | -2.72 | 0.0065 | 0.00570 |
| Black female | 1 | -0.00235 | 0.03958 | -0.06 | 0.9526 | 0.00000273 |

In multivariable analysis adjusting for body mass index and current smoking status, Table 3a indicates that black males have lower adjusted percent predicted FEV1.

Table 3a. Multivariate Association Between Race/Gender and Percent Predicted FEV1

| Variable | DF | Parameter Estimates | | | | Squared Partial Corr Type II |
|----------------|----|-----------------------|-------------------|---------|---------|------------------------------------|
| | | Parameter Estimate | Standard Error | t Value | Pr > t | |
| Intercept | 1 | 113.37406 | 2.79876 | 40.51 | <.0001 | . |
| Current smoker | 1 | -1.11179 | 2.45728 | -0.45 | 0.6510 | 0.00015965 |
| Former smoker | 1 | 0.43697 | 1.05876 | 0.41 | 0.6799 | 0.00013285 |
| BMI | 1 | -0.49001 | 0.08797 | -5.57 | <.0001 | 0.02363 |
| Black male | 1 | -7.96128 | 1.83124 | -4.35 | <.0001 | 0.01453 |
| White female | 1 | -1.27357 | 1.37509 | -0.93 | 0.3545 | 0.00066866 |
| Black female | 1 | -1.91608 | 1.48085 | -1.29 | 0.1959 | 0.00130 |

In contrast to assessment of predicted FEV1, Table 3b indicates that white females have lower adjusted values of FEF25-75.

Table 3b. Multivariate Association Between Race/Gender and FEF25-75

| Variable | DF | Parameter Estimates | | | | Squared Partial Corr Type II |
|----------------|----|-----------------------|-------------------|---------|---------|------------------------------------|
| | | Parameter Estimate | Standard Error | t Value | Pr > t | |
| Intercept | 1 | 4.42862 | 0.07667 | 57.77 | <.0001 | . |
| Current smoker | 1 | -0.08477 | 0.06731 | -1.26 | 0.2081 | 0.00124 |
| Former smoker | 1 | 0.01244 | 0.02900 | 0.43 | 0.6680 | 0.00014354 |
| BMI | 1 | 0.00301 | 0.00241 | 1.25 | 0.2119 | 0.00122 |
| Black male | 1 | -0.09445 | 0.05016 | -1.88 | 0.0599 | 0.00276 |
| White female | 1 | -0.10551 | 0.03767 | -2.80 | 0.0052 | 0.00608 |
| Black female | 1 | -0.01968 | 0.04056 | -0.49 | 0.6276 | 0.00018359 |

The above data indicate that both racial and gender differences exist in objective measurements of airflow obstruction.

Aim 2. To investigate race-related differences in the interrelationship among airflow obstruction, CVD risk factors, and inflammation, all of which are associated with increased CVD morbidity and mortality.

For this analysis, percent predicted FEV1 was used as the primary outcome variable. For the total cohort, high sensitivity C-reactive protein level was not associated (correlated) with predicted FEV1 ($r=-0.02$, $p=0.65$). As seen in Table 4, higher body mass index was associated with significantly lower percent predicted FEV1, whereas higher LDL cholesterol was associated with better function. The category of black male remained a strong independent predictor of lower percent predicted FEV1.

Table 4. Factors Associated with Percent Predicted FEV1.

| Variable | Parameter Estimates | | | | | Squared Partial Corr Type II |
|-------------------------|---------------------|--------------------|----------------|---------|---------|------------------------------|
| | DF | Parameter Estimate | Standard Error | t Value | Pr > t | |
| Intercept | 1 | 118.12810 | 5.82053 | 20.30 | <.0001 | . |
| Current smoker | 1 | 0.19118 | 2.66474 | 0.07 | 0.9428 | 0.00000460 |
| Former smoker | 1 | 0.71147 | 1.12323 | 0.63 | 0.5266 | 0.00035842 |
| Body mass index | 1 | -0.44613 | 0.09868 | -4.52 | <.0001 | 0.01794 |
| Glucose | 1 | -0.04789 | 0.02700 | -1.77 | 0.0764 | 0.00280 |
| Systolic Blood Pressure | 1 | -0.05052 | 0.03863 | -1.31 | 0.1912 | 0.00153 |
| LDL cholesterol | 1 | 0.04421 | 0.01635 | 2.70 | 0.0069 | 0.00650 |
| Black male | 1 | -7.24687 | 1.97178 | -3.68 | 0.0002 | 0.01193 |
| White female | 1 | -1.91496 | 1.46906 | -1.30 | 0.1927 | 0.00152 |
| Black female | 1 | -2.12325 | 1.57644 | -1.35 | 0.1783 | 0.00162 |

Given the predominant finding of black males having significantly lower predicted FEV1, analyses were conducted to examine possible interactions with other risk factors that might explain this association. This analysis was conducted in two ways – comparing black males to white males, and comparing black males to all females and white males together.

There was no evidence of interaction in relation to lower predicted FEV1 between black male and body mass index ($p=0.29$, $p=0.50$), fasting glucose ($p=0.33$, $p=0.24$), systolic blood pressure ($p=0.60$, $p=0.52$), LDL cholesterol ($p=0.72$, $p=0.83$), or C-reactive protein ($p=0.92$, $p=0.51$). Thus, the finding of black males having significantly lower predicted FEV1 could not be explained through differences in conventional CVD risk factors.

18. Extent of Clinical Activities Initiated and Completed. Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be “No.”

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes
 No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes
 No

If “Yes” to either 18(A) or 18(B), items 18(C) – (F) must also be completed. (Do NOT complete 18(C-F) if 18(A) and 18(B) are both “No.”)

18(C) How many hospital and health care professionals were involved in the research project?

4 Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

1000 Number of subjects originally targeted to be included in the study
1299 Number of subjects enrolled in the study

Note: Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached, the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:
445 Males
854 Females
 Unknown

Ethnicity:
 Latinos or Hispanics
 Not Latinos or Hispanics
 Unknown

Race:

American Indian or Alaska Native

Asian

529 Blacks or African American

Native Hawaiian or Other Pacific Islander

770 White

Other, specify: _____

Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

Allegheny County

19. Human Embryonic Stem Cell Research. Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?

Yes

No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

Yes

No

19(C) Please describe how this project involved human embryonic stem cells:

20. Articles Submitted to Peer-Reviewed Publications.

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication or paper submitted for publication, listed in the table, in a PDF version 5.0.5 (or greater) format, 1,200 dpi. Filenames for each publication should include

the number of the research project, the last name of the PI, and an abbreviated title of the publication. For example, if you submit two publications for Smith (PI for Project 01), one publication for Zhang (PI for Project 03), and one publication for Bates (PI for Project 04), the filenames would be:

- Project 01 – Smith – Three cases of isolated
- Project 01 – Smith – Investigation of NEB1 deletions
- Project 03 – Zhang – Molecular profiling of aromatase
- Project 04 – Bates – Neonatal intensive care

If the publication is not available electronically, provide 5 paper copies of the publication.

Note: The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

| Title of Journal Article: | Authors: | Name of Peer-reviewed Publication: | Month and Year Submitted: | Publication Status (check appropriate box below): |
|---------------------------|----------|------------------------------------|---------------------------|---|
| 1. None | | | | <input type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input type="checkbox"/> Published |

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes X No

If yes, please describe your plans:

We are in the process of drafting several manuscripts related to this work. These papers will report our analyses of race-related differences in respiratory flow volumes and associations among airflow, cardiovascular disease risk factors, measures of subclinical atherosclerosis, and race. Additional manuscripts will report the role of inflammation as a modulator for cardiovascular risk associated with airflow obstruction. In addition, we are conducting additional analyses based on classification of participants by the GOLD criteria for COPD. We anticipate manuscripts will be drafted based on these analyses which aim to demonstrate associations between COPD, race, and CVD.

21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project.

Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert “None”; do not use “Not applicable.” Responses must be

single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

Our results indicate that independent predictors of airflow obstruction include being a black male and having a higher BMI. These results suggest that clinicians should have a lower threshold for performing spirometry in black males and obese individuals. Earlier diagnosis of airflow obstruction may lead to early interventions that can decrease morbidity and, potentially, mortality. Our analyses also demonstrated that LDL cholesterol level was the only CVD risk factor that was independently associated with airflow obstruction. Our results do not support our initial hypothesis that systemic inflammation is a potential unifying factor linking airflow obstruction and CVD. Specifically, high sensitivity CRP levels were not associated with measures of airflow obstruction. This finding suggests that routine measurement of CRP levels in clinical practice is not justified for the purpose of screening individuals for airflow obstruction. Furthermore, future studies should identify pathophysiologic mechanisms beyond inflammation for the association between airflow obstruction and CVD. Finally, we plan to promote our findings as part of community outreach initiatives at the University of Pittsburgh that are designed to increase general knowledge about racial disparities in health.

22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment. Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

There were no major discoveries identified by the close of the grant. However, we anticipate that our ongoing data analyses will serve as a foundation for the development of new approaches to CVD risk stratification of patients with airflow obstruction and COPD. Mechanistic insight provided by this study may identify potential therapeutic targets to reduce CVD risk associated with airflow obstruction. These approaches may be personalized based on race and other characteristics identified in our study.

23. Inventions, Patents and Commercial Development Opportunities.

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes _____ No X

If “Yes” to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is “No.”)

a. Title of Invention:

- b. Name of Inventor(s):
- c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):
- d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
 Yes _____ No _____

If yes, indicate date patent was filed:

- e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
 Yes _____ No _____
 If yes, indicate number of patent, title and date issued:
 Patent number:
 Title of patent:
 Date issued:

- f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes _____ No _____

If yes, how many licenses were granted? _____

- g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes _____ No _____

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes _____ No X _____

If yes, please describe your plans:

24. Key Investigator Qualifications. Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| | | | |
|---|---|---------------------|-------------------------|
| NAME Reis, Steven E. | POSITION TITLE Professor of Medicine, Emergency Medicine, and Clinical and Translational Science Associate Vice Chancellor for Clinical Research | | |
| eRA COMMONS USER NAME series | | | |
| EDUCATION/TRAINING (<i>Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.</i>) | | | |
| INSTITUTION AND LOCATION | DEGREE (if applicable) | YEAR(s) | FIELD OF STUDY |
| Massachusetts Institute of Technology, Cambridge, MA | S.B. | 1983 | Biology |
| Harvard Medical School, Boston, MA | M.D. | 1987 | Medicine |
| Brigham and Women's Hospital, Harvard Medical School, Boston, MA | Internship/ Residency | 1987-88/ 1988-90 | Internal Medicine |
| Johns Hopkins Hospital, Baltimore, MD | Fellowship | 1990-94 | Cardiovascular Diseases |

Positions and Employment

- 1987-90 Clinical Fellow in Medicine, Harvard Medical School, Boston, MA
1990-94 Clinical Fellow in Medicine, Johns Hopkins University, Baltimore, MD
1994-00 Assistant Professor of Medicine, University of Pittsburgh, Pittsburgh, PA
1994- Director of Clinical Research, Cardiovascular Institute, University of
Pittsburgh, Pittsburgh, PA
2000-06 Associate Professor of Medicine with Tenure, University of Pittsburgh
2004- Associate Vice Chancellor for Clinical Research, Health Sciences, University of
Pittsburgh
2006- Professor of Medicine and Emergency Medicine with Tenure, University of
Pittsburgh
2006- Founding Director, University of Pittsburgh Clinical and Translational
Science Institute
2008- Professor of Clinical and Translational Science, University of Pittsburgh

Other Experience and Professional Memberships

- 1991- Member, American College of Physicians
1995- Member, American Federation for Clinical Research
1996- Fellow, American College of Cardiology
2005- Member, American Society for Clinical Investigation
2007-8 Member, National Center for Research Resources Clinical and Translational
Science Award (CTSA) Consortium Oversight Operations Group
2008-11 Member, National Center for Research Resources Clinical and Translational
Science Award (CTSA) Consortium Steering Committee
2013 - Member, NIH National Center for Advancing Translational Science Clinical
and Translational Science Award (CTSA) Steering Committee

Selected Peer-reviewed Publications (out of 140 peer-reviewed publications)

1. Reis SE, Gloth ST, Blumenthal RS, Resar JR, Zacur HA, Gerstenblith G, Brinker JA. Ethinyl estradiol acutely attenuates abnormal coronary vasomotor responses to acetylcholine in postmenopausal women. *Circulation* 1994;89:52-60.
2. Johnson BD, Kip K, Marroquin O, Ridker PM, Kelsey SF, Shaw LJ, Pepine CJ, Sharaf BL, Bairey Merz CN, Sopko G, Olson MB, Reis SE. Serum amyloid A as a predictor of coronary artery disease and cardiovascular outcome in women. *The*

- NHLBI-sponsored Women's Ischemia Syndrome Evaluation (WISE) study. *Circulation* 2004;109:726-32.
3. Kip KE, Marroquin OC, Kelley DE, Johnson BD, Kelsey SF, Shaw LJ, Rogers WJ, Reis SE. Clinical importance of obesity versus the metabolic syndrome on cardiovascular risk in women: A report from the Women's Ischemia Syndrome Evaluation (WISE) study. *Circulation* 2004;109:706-13.
 4. Marroquin OC, Kip KE, Kelley DE, Johnson BD, Shaw L, Bairey Merz CN, Sharaf BL, Pepine CJ, Sopko G, Reis SE. The metabolic syndrome modifies the cardiovascular risk associated with angiographic coronary artery disease in women: A report from WISE. *Circulation* 2004;109:714-21.
 5. Reis EC, Kip KE, Marroquin OC, Kiesau M, Hipps Jr. L, Peters RE, Reis SE. Screening children to identify families at increased risk for cardiovascular disease. *Pediatrics* 2006;118:1789-97.
 6. Aiyer AN, Kip KE, Mulukutla SR, Marroquin OC, Hipps Jr. L, Reis SE. Predictors of significant short-term increases in blood pressure in a community-based population. *Am J Med* 2007;120:960-7.
 7. Matthews KA, Kamarck TW, Hall M, Strollo PJ, Owens JF, Buysse DJ, Lee L, Reis SE. Blood pressure dipping and sleep disturbance in African-American and Caucasian men and women. *Am J Hypertens* 2008;21:826-31. (PMC2890257).
 8. Reis SE, Berglund, L, Bernard GR, Califf, RM, FitzGerald GA, Johnson PC. Reengineering the national clinical and translational research enterprise: The strategic plan of the National Clinical and Translational Science Awards Consortium. *Acad Med* 2010;85:463-9. (PMC2829722).
 9. Mulukutla SR, Venkitachalam L, Bambs C, Kip KE, Aiyer A, Marroquin OC, Reis SE. Black race is associated with digital artery endothelial dysfunction: Results from the Heart SCORE study. *Eur Heart J* 2010; doi:10.1093/eurheart/ehq295 (PMID 20736241)
 10. Troxel WM, Buysse DJ, Matthews KA, Kip KE, Strollo PJ, Hall M, Drumheller O, Reis SE. Sleep symptoms predict the development of the metabolic syndrome. *Sleep* 2010;12:1633-40 (PMC2982733).
 11. Bambs CE, Kip KE, Dinga A, Mulukutla SR, Aiyer AN, Reis SE. Low Prevalence of "Ideal Cardiovascular Health" in a Community-Based Population: The Heart Strategies Concentrating on Risk Evaluation (Heart SCORE) Study. *Circulation* 2011;123:850-7 (PMC3061396).
 12. Matthews KA, Strollo PJ, Hall M, Mezick EJ, Kamarck TW, Owens JF, Buysse DJ, Reis SE. Associations of Framingham risk score profile and coronary artery calcification with sleep characteristics in middle-aged men and women: Pittsburgh SleepSCORE Study. *Sleep* 2011;34:711-6 (PMC3099492).
 13. Halder I, Kip KE, Mulukutla SR, Aiyer AN, Marroquin OC, Huggins GS, Reis SE. Biogeographical ancestry, self-identified race and admixture-phenotype associations in the Heart SCORE Study. *Am J Epidemiol* 2012;176:146-55. (PMC3493196).
 14. Bambs CE, Kip KE, Mulukutla SR, Aiyer AN, Johnson C, McDowell LA, Matthews K, **Reis SE**. Sociodemographic, clinical and psychological factors associated with attrition in a prospective study of cardiovascular prevention: The Heart Strategies Concentrating on Risk Evaluation (Heart SCORE) Study. *Ann Epidemiol* 2013;23:328-33 (NIHMSID461237).

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME Patrick J. Strollo, Jr., MD | | POSITION TITLE Professor of Medicine and Clinical Translational Science | |
|--|---------------------------|--|---------------------------|
| eRA COMMONS USER NAME STROLLOPJ | | | |
| EDUCATION/ TRAINING (<i>Begin with baccalaureate or other initial professional education, such as</i>) | | | |
| INSTITUTION AND LOCATION | DEGREE (if applicable) | YEAR(s) | FIELD OF STUDY |
| Washington College, Chestertown, MD | B.S. | 1976 | Chemistry (Cum Laude) |
| Wagner College, Staten Island, NY | M.S. | 1977 | Biomedical Sciences |
| Uniformed Services University of the Health Sciences, Bethesda, MD | MD | 1981 | Medicine |
| Wright Patterson Medical Center, AFB, OH | Internship | 1981-1982 | Internal Medicine |
| Wilford Hall, USAF Medical Center, Lackland AFB, TX | Residency | 1982-1984 | Internal Medicine |
| Wilford Hall, USAF Medical Center, Lackland AFB, TX | Fellowship | 1985-1987 | Pulmonary / Critical Care |

Positions and Honors

Professional Experience: Academic Appointments:

| | |
|--------------|---|
| 2011-present | University of Pittsburgh, Professor of Medicine |
| 2011-present | University of Pittsburgh, Professor, Clinical and Translational Science |
| 2008-present | University of Pittsburgh, Co-Director, CTSI Sleep Medicine Institute |
| 2008-2011 | University of Pittsburgh, Associate Professor, Clinical and Translational Science |
| 2007-2008 | University of Pittsburgh, Director, Office of Clinical Research, Health Sciences |
| 2003-present | University of Pittsburgh, Medical Director, UPMC Sleep Medicine Center |
| 1999-2003 | Co-Director, Sleep Disorders Fellowship |
| 1997-2011 | University of Pittsburgh, Associate Professor of Medicine |
| 1996-2003 | University of Pittsburgh, Associate Chief, Pulmonary Sleep Disorders Program Pittsburgh, PA |
| 1996-2003 | University of Pittsburgh, Medical Director of the Clinical Pulmonary Sleep Evaluation Laboratory, Pittsburgh, PA |
| 1995 - 2000 | University of Pittsburgh, Medical Director, Respiratory Therapy, Pittsburgh, PA |
| 1993 - 1997 | University of Pittsburgh, Assistant Professor of Medicine, Pittsburgh, PA |
| 1993 - 1999 | University of Pittsburgh, Director, Pulmonary Sleep Disorders Training Program |
| 1993 - 1996 | University of Pittsburgh, Associate Director, Pulmonary Sleep Evaluation Center, Pittsburgh, PA |
| 1987 - 1993 | Wilford Hall, USAF Medical Center Staff, Pulmonary/Critical Care Medicine Service, and Medical Director, Sleep Disorders Laboratory, Division of Medicine, Lackland AFB, TX |
| 1988 - 1993 | University of Texas Health, Clinical Assistant Professor Science Center at San Antonio San Antonio, TX |
| 1987 - 1993 | Uniformed Services, University of the Health Sciences, Assistant Professor in Internal Medicine, Bethesda, MD |
| 1984 - 1986 | Uniformed Sciences, University of the Health Sciences, Clinical Assistant Professor, Bethesda, MD |

1982 - 1984 Uniformed Services, University of the Health Sciences, Teaching Fellow
Bethesda, MD

1981 - 1982 Wright State University, School of Medicine, Junior Resident Clinical Instructor

Selected Peer-reviewed Publications (14 of 60)

- 1) **Strollo PJ**, Soose RJ, Maurer JT, de Vries N, Cornelius J, Froymovich O, Hanson RD, Padhya TA, Steward DL, Gillespie MB, Woodson BT, Van de Heyning PH, Goetting MG, Vanderveken OM, Feldman N, Knaack L, and Strohl KP, for the STAR Trial Group. Upper-Airway Stimulation for Obstructive Sleep Apnea. *The New England Journal of Medicine* 2014; 370:139-49.
- 2) Oktay B, Rice TB, Atwood CW, Passero M, Gupta N, Givelber R, Drumheller OJ, Houck P, Gordon N, **Strollo PJ**. Evaluation of a Single-Channel Portable Monitor for the Diagnosis of Obstructive Sleep Apnea. *Journal of Clinical Sleep Medicine*, 2011 7 (4):384-390.
- 3) **Strollo PJ**. Embracing change, responding to challenge, and looking toward the future. *Journal of Clinical Sleep Medicine*. 6(4):312-3, 2010 Aug 15.
- 4) Owens JF, Buysse DJ, Hall M, Kamarck TW, Lee L, **Strollo PJ**, Reis SE, Matthews KA. Napping, nighttime sleep, and cardiovascular risk factors in mid-life adults. *Journal of Clinical Sleep Medicine*. 6(4):330-5, 2010 Aug 15.
- 5) Mezick EJ, Matthews KA, Hall M, Kamarck TW, **Strollo PJ**, Buysse DJ, Owens JF, Reis SE. Low life purpose and high hostility are related to an attenuated decline in nocturnal blood pressure. *Health Psychology* 2010 29(2):196-204.
- 6) Rice TB, Dunn RE, Lincoln AE, Tucker AM, Vogel RA, Heyer RA, Yates AP, Wilson PWF, Pellmen EJ, Allen TW, Newman AB, **Strollo PJ**. Sleep-Disordered Breathing in the National Football League. *SLEEP* 2010 33(6) 819-824.
- 7) Troxel WM, Buysse DJ, Hall M, Kamarck TW, **Strollo PJ**, Owens JF, Reis SE, Matthews KA, *Social integration, social contacts, and blood pressure dipping in African-Americans and whites*. *Journal of Hypertension*, 2010. **28**(2): p. 265-71.
- 8) Tucker AM, Vogel RA, Lincoln AE, Dunn RE, Ahrensfield DC, Allen TW, Castle LW, Heyer RA, Pellman EJ, **Strollo PJ**, Wilson PWF, Yates AP. *Prevalence of cardiovascular disease risk factors among National Football League players*. *JAMA*, 2009. **301**(20): p. 2111-9.
- 9) Epstein LJ, Kristo D, **Strollo PJ**, Friedman N, Malhotra A, Patil SP, Ramar K, Rogers R, Schwab RJ, Weaver EM, M.D., Weinstein MD, *Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults*. *Journal of Clinical Sleep Medicine*, 2009. **5**(3): p. 263-76.
- 10) Wu W, Dave NB, Yu G, **Strollo PJ**, Kovkarova-Naumovski E, Ryter SW, Reeves SR, Dayyat E, Wang Y, Choi AM, Gozal D, Kaminski N., *Network analysis of temporal effects of intermittent and sustained hypoxia on rat lungs*. *Physiological Genomics*, 2008. **36**(1): p. 24-34.
- 11) Matthews KA, Kamarck TW, Hall MH, **Strollo PJ**, Owens JF, Buysse DJ, Laisze L, Reis SE., *Blood pressure dipping and sleep disturbance in African-American and Caucasian men and women*. *American Journal of Hypertension*, 2008. **21**(7): p. 826-31.
- 12) Buysse DJ, Hall ML, **Strollo PJ**, Kamarck TW, Owens J, Lee L, Reis SE, Matthews KA., *Relationships between the Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and clinical/polysomnographic measures in a community sample*. *Journal of Clinical Sleep Medicine*, 2008. **4**(6): p. 563-71.
- 13) Ballard RD, Gay PC, **Strollo PJ**. , *Interventions to improve compliance in sleep apnea patients previously non-compliant with continuous positive airway pressure*. *Journal of Clinical Sleep Medicine*, 2007. **3**(7): p. 706-12.
- 14) **Strollo PJ**, Sanders, MH, Costantino JP, Walsh SK, Stiller, RA, Atwood, CW, *Split-night studies for the diagnosis and treatment of sleep-disordered breathing*. *Sleep*, 1996. **19**(10 Suppl): p. S255-9.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

| NAME Kip, Kevin E. | | POSITION TITLE Professor (tenured) | |
|---|---------------------------|---------------------------------------|----------------|
| eRA COMMONS USER NAME Kevinkip | | Executive Director, Research Center | |
| EDUCATION/TRAINING (<i>Begin with baccalaureate or other initial professional education, such as</i>) | | | |
| INSTITUTION AND LOCATION | DEGREE (if applicable) | YEAR(s) | FIELD OF STUDY |
| University of Central Florida, Orlando, FL | BA | 1984 | Psychology |
| University of Central Florida, Orlando, FL | MS | 1987 | I/O Psychology |
| University of Alabama-Birmingham, Birmingham, AL | MSPH | 1994 | Epidemiology |
| University of Pittsburgh, Pittsburgh, PA | PHD | 1998 | Epidemiology |

Positions and Honors

- 1994 - 1998 *Epidemiologist/Biostatistician*, Univ. of Pittsburgh, Dept. of Epidemiology, Pittsburgh, PA
- 1998 *Adjunct Instructor - Epidemiology*, University of South Florida, Tampa, FL
- 1998 - 1999 *Epidemiologist/Biostatistician*, Jaeb Center for Health Research, Inc. Tampa
- 1999 - 2002 *Assistant Professor - Epidemiology and Mental Health*, University of South Florida, Tampa, FL
- 2002 - 2007 *Assistant/Associate Professor - Epidemiology and Medicine*, University of Pittsburgh Graduate School of Public Health and Division of Cardiology, Pittsburgh, PA
- 2007 – pres *Professor-effective August 2102 (tenured), Executive Director, Research Center*, University of South Florida, College of Nursing, Tampa, FL
- 2007 – pres *Affiliate Professor*, Dept. of Epidemiology and Biostatistics, University of South Florida, College of Public Health, Tampa, FL

Other Experience and Professional Memberships

Referee: American Heart Journal (2004); American Journal of Cardiology (2002–present); American Journal of Medicine (2003); Annals of Epidemiology (2010); Archives of General Psychiatry (2007); Archives of Internal Medicine (2004); Archives of Ophthalmology (2004); Circulation (2004-present); Critical Care Medicine (2006); JAMA (2000,2005); Journal of American College of Cardiology (1998-present); Journal of Behavioral Health Services & Research (2000 – 2002); Journal of Clinical Epidemiology (2011); Metabolism (2006); Nature Clinical Practice Cardiovascular Medicine (2008); Nursing Research (2008-present); Ophthalmology (1999-2004); Obesity Research (2006)

- 1999 – present Member, Society for Epidemiologic Research
- 2003 – present Member, American College of Epidemiology
- 2006 – present Fellow, American Heart Association (FAHA)
- 2001 Invited Grant Reviewer, SAMHSA, Center for Substance Abuse Treatment
- 2003 – present Invited Grant Reviewer, National Inst. Diabetes and Digestive and Kidney Diseases (NIDDK)
- 2009 – present Invited Grant Reviewer, National Heart, Lung, and Blood Institute (NHLBI)
- 2004 – 2009 Member, Data Safety and Monitoring Board, NIDDK, Azathioprine in Crohn's Disease

- 2011 – present Chair, Data Safety and Monitoring Board, NIDDK, Action for Health in Diabetes” (Look AHEAD) Study
- 2012 – present Appointed Special Government Employee and Member of FDA Circulatory System Devices Panel, FDA Office of Device Evaluation, Center for Devices and Radiological Health.

Honors. Delta Omega Omicron Chapter - Doctoral Dissertation Award, Best Dissertation in the Department of Epidemiology, University of Pittsburgh, 1998

Selected peer-reviewed publications (from more than 140).

1. Aiyer AN, **Kip KE**, Marroquin OC, Mulukutla SR, Edmundowicz D, Reis SE. Racial differences in coronary artery calcifications are not attributed to differences in lipoprotein particle sizes: The Heart Strategies Concentrating on Risk Evaluation (Heart SCORE) Study. *American Heart Journal* 2007; 153:328-334.
2. Aiyer AN, **Kip KE**, Mulukutla SR, Marroquin OC, Hipps L Jr, Reis SE. Predictors of significant short-term increases in blood pressure in a community-based population. *American Journal of Medicine* 2007; 120:960-967.
3. Bambs C, **Kip KE**, Dinga A, Mulukutla SR, Aiyer AN, and Reis SE. Low prevalence of "ideal cardiovascular health" in a community-based population: the Heart Strategies Concentrating on Risk Evaluation (Heart SCORE) study. *Circulation* 2011; 123: 850-857.
4. Halder I, **Kip KE**, Mulukutla SR, Aiyer AN, Marroquin OC, Huggins GS, Reis SE. Biogeographic ancestry, self-identified race, and admixture-phenotype associations in the Heart SCORE study. *American Journal of Epidemiology* 2012; doi: 10.1093/aje/kwr518
5. Bambs CE, **Kip KE**, Mulukutla SR, Aiyer AN, Johnson C, McDowell LA, Matthews K, Reis SE. Sociodemographic, clinical, and psychological factors associated with attrition in a prospective study of cardiovascular prevention: the Heart Strategies Concentrating on Risk Evaluation study. *Annals of Epidemiology* 2013 Mar 24. pii: S1047-2797(13)00053-7. doi: 10.1016/j.annepidem.2013.02.007. [Epub ahead of print]
6. Marroquin OC, **Kip KE**, Kelley DE, Johnson BD, Shaw LJ, Bairey Merz CN, Sharaf BL, Pepine CJ, Sopko G, Reis SE, for the Women’s Ischemia Syndrome Evaluation (WISE) Investigators. The metabolic syndrome modifies the cardiovascular risk associated with angiographic coronary artery disease in women: A report from the Women’s Ischemia Syndrome Evaluation. *Circulation* 2004; 109:714-721.
7. **Kip KE**, Marroquin OC, Kelley DE, Johnson BD, Kelsey SF, Shaw LJ, Rogers WJ, Reis SE. Clinical importance of obesity versus the metabolic syndrome in cardiovascular risk in women: A report from the Women’s Ischemia Syndrome Evaluation (WISE) Study. *Circulation* 2004; 109:706-713.
8. **Kip KE**, Marroquin OC, Shaw LJ, Arant CB, Wessel TR, Olson MB, Johnson BD, Mulukutla S, Sopko G, Bairey Merz CN, Reis SE. Global inflammation predicts cardiovascular risk in women: A report from the Women’s Ischemia Syndrome Evaluation (WISE) study. *American Heart Journal* 2005; 150:900-906.
9. Beohar N, Davidson CJ, **Kip KE**, Goodreau L, Vlachos HA, Meyers S, Benzuly K, Flaherty JD, Ricciardi MJ, Bennett CL, Williams DO. Outcomes and complications associated with off-label and untested use of drug eluting stents. *JAMA* 2007; 297:1992-2000.
10. Marroquin OC, Selzer F, Mulukutla SR, Williams DO, Vlachos HA, Wilensky RL, Tanguay TG, Holper EM, Abbott JD, Lee JS, Smith C, Anderson WD, Kelsey SF, and **Kip KE**. A comparison of bare-metal and drug-eluting stents for off-label indications. *New England Journal of Medicine* 2008; 358:342-52.
11. **Kip KE**, Hollabaugh K, Marroquin OC, Williams DO. **The problem with composite end points in cardiovascular studies: The story of major adverse cardiac events and percutaneous coronary intervention.** *Journal of the American College of Cardiology* 2008; 51: 701-707.