

CLINICAL STUDIES CONDUCTED SINCE 2016 BY EPA IN THE HUMAN STUDIES FACILITY, CHAPEL HILL, NC (list updated July 2022)

TITLE: Bronchoscopy (CRU)

IRB STUDY NUMBER: 91-0679

DESCRIPTION: The purpose of this research study is to acquire cells from both blood and lungs for further test tube studies of environmental agents. The effects from pollution are studied using cells collected from the lungs and trachea using the bronchoscope, which is a thin flexible tube inserted through the nose down into the lungs. Volunteer subjects are not exposed to air pollutants in this study.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: No set number

CURRENT STATUS: Active, volunteers recruited as needed

TITLE: Effects of Fish Oil or Olive Oil Supplementation to Healthy Young Subjects Exposed to Ozone (or "PISCES")

IRB STUDY NUMBER: 16-1048

DESCRIPTION: The purpose of the research study is to examine the effects of dietary omega-3 fatty acids in protecting cardiovascular and pulmonary functions from ambient air pollution. Healthy, non-smoking adults ages 25 to 55. Qualified subjects will either have a high intake of fatty acids (EPA/DHA) from dietary sources or supplements (High Group), OR have a low intake of fatty acids from their diets (Low Group). Breathing, blood draw, heart rate tests, retinal imaging and brachial artery ultrasound will be performed.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 60

CURRENT STATUS: Enrollment closed, data analysis only

TITLE: Residential Environment, Allostatic Load and Diseases Study (or "RENALDI")

IRB STUDY NUMBER: 17-1981

DESCRIPTION: The purpose of this research study is to learn how neighborhood characteristics, such as air pollution levels, parks and green spaces, and lifestyle factors, such as physical activity, contacts with living nature and level of stress, affect health. The study involves collecting information on life style, diseases, and neighborhood characteristics, and measuring substances in blood and saliva samples called "biomarkers of health". These biomarkers are naturally produced by the human body in response to stress and disease. Biological changes in the human body can accumulate in time and make people more likely to develop chronic diseases, such as cardiovascular disease, depression and diabetes. We will also measure antibodies to several common disease-causing microbes in your blood and saliva samples. Antibodies are substances that your body produces to fight off infections. We will also analyze your saliva samples to find out what microbes live in your mouth. Finally, we would like to analyze fecal samples from selected healthy volunteers to find out what bacteria live in their intestines.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 300

CURRENT STATUS: Enrollment closed, data analysis only

TITLE: Effects of Fish Oil Or Olive Oil Supplementation to Healthy Young Subjects Exposed to Ozone (or "OMEGOZ")

IRB STUDY NUMBER: 15-2960

DESCRIPTION: The purpose of the research study is to examine the efficacy of fish oil and olive oil in altering cardiovascular and pulmonary functions after exposure to ozone. Healthy, nonsmoking moderately physically active, adults ages 18 to 35 will be exposed to ozone and clean air. They will be given dietary supplementation of fish oil or olive oil or no supplements for 4 weeks. They will perform

moderate exercise on a stationary bicycle or treadmill at 15 minute intervals during exposures.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 60

CURRENT STATUS: Enrollment closed, data analysis only

TITLE: Changes in Heart Rate Variability (HRV) in Healthy Young Adults Exposed to Levels of Particulate Matter (PM2.) (or "RECAP")

IRB STUDY NUMBER: 16-1548

DESCRIPTION: The purpose of the research study is to determine whether exposure to levels of concentrated air particles which are close to the current 24-hour standard cause cardiovascular effects in healthy individuals. Healthy, non-smoking moderately physically active, adults ages 18 to 35 will be exposed to particulate matter and clean air. You will be exposed to a level of concentrated air particles similar to what would be experienced in many urban environments such as Denver, Colorado. Healthy adults will perform moderate exercise on a stationary bicycle at 15 minute intervals during exposures. Lung function tests will be performed and heart and blood pressure will be monitored. Blood will be drawn before and after each exposure and on the follow up day.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 20

CURRENT STATUS: Inactive, study is closed

TITLE: Cardiovascular Effects of Exposure to Wood Smoke in Healthy Human Adults (MASKOFF)

IRB STUDY NUMBER: 19-2078

DESCRIPTION: The purpose of the research study is to investigate cardiovascular effects of young healthy human subjects exposed to wood smoke. Healthy, nonsmoking moderately physically active, adults ages 18 to 35 will be exposed to wood smoke and clean air. Both exposures will be 2 hours long with alternating 15 min of exercise and 15 min rest period.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 80

CURRENT STATUS: Active, recruiting volunteers

TITLE: Health Effects of Repeated Exposure to Low Levels of Concentrated Ambient Particles in Healthy Young Volunteers (RPTCAP)

IRB STUDY NUMBER: 20-1093

DESCRIPTION: The purpose of the research study is to determine whether 3-day consecutive exposures to levels of fine particulate matter (PM2.5) that are close to the current 24-hr national standard will cause changes in inflammatory and cardiopulmonary endpoints which are cumulative in healthy young individuals. Healthy, nonsmoking moderately physically active, adults ages 18 to 35 will be exposed to particulate matter and clean air.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 20

CURRENT STATUS: Active, recruiting volunteers

TITLE: Development of a salivary antibody assay for population surveillance of SARS-CoV-2 infections (COVID-19)

IRB STUDY NUMBER: 20-1206

DESCRIPTION: The purpose of this study is to collect saliva samples from individuals recently infected with SARS-CoV-2 and use these samples as positive controls to develop a non-invasive salivary immunoassay to measure antibody responses to SARS-CoV-2. Individuals who had confirmed SARS-CoV-2 infections virus will be recruited through social media, community centers, physician groups and other medical and testing facilities. Those who agree to participate will be provided a saliva collection kit, instructions and asked to return the kit and a short questionnaire by express mail.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 300

CURRENT STATUS: Active, recruiting volunteers

TITLE: Variation In Facial Morphology As A Determinant Of Face Covering Performance (FACEFIT)

IRB STUDY NUMBER: 20-2612

DESCRIPTION: The purpose of this study is to examine the role of variations in the dimensions of facial features on the fitted filtering efficiency of face coverings available to the public during the COVID-19 pandemic. Healthy, adults ages 18 to 35 will have their 3D facial features measured by facial calipers. Following craniofacial measurements and imaging, participants will enter a chamber where the fitted filtering efficiency (FFE) of 4 types of face coverings will be tested: a N95 respirator, a KN95 respirator (with and without a clip), a surgical mask (with and without a clip), and a KF94 respirator (with and without a clip). The FFE tests will closely follow the Occupational Safety and Health Administration (OSHA) quantitative fit testing protocol for filtering face pieces.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 100

CURRENT STATUS: Active, recruiting volunteers

TITLE: Pulmonary and Inflammatory Responses Following Exposure to a Low Concentration of Ozone or Clean Air for 6.6 Hours with Moderate Exercise in Healthy Young Adults. (LOCONOZ II)

IRB STUDY NUMBER: 21-3193

DESCRIPTION: The primary purpose of this study is to measure pulmonary function, symptoms, and pulmonary inflammatory responses in healthy young adults during and immediately after exposure to a low concentration of ozone (0.070 ppm) or clean air for 6.6 hours while undergoing moderate intermittent exercise. This concentration is the current EPA NAAQS standard for ozone. Healthy, nonsmoking moderately physically active, adults ages 18 to 35 will be exposed to ozone and clean air.

NUMBER OF VOLUNTEERS NEEDED FOR STUDY: 60

CURRENT STATUS: Active, recruiting volunteers

