

Welch Center Research Database

[Lawrence Appel, MD, MPH](#)

Study To Understand Fall Reduction and Vitamin D in You (STURDY)

Welch Center Investigators: Miller ER, Michos E, Coresh J, Mitchell C, Charleston J

Description: STURDY is a completed, Bayesian response-adaptive, randomized dose-finding trial designed to select the best dose of vitamin D supplementation and to potentially confirm the efficacy of that dose for fall prevention and other related outcomes. Vitamin D doses are 200, 1,000, 2,000, and 4,000 IU/day. Participants (n=688) are community-dwelling adults, aged 70+ (~20% black, ~45% women), with a baseline serum 25(OH)D level of 10 to < 30 ng/ml, who are at high risk for falling.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Chronic Renal Insufficiency Cohort Study (CRIC)

Welch Center Investigators: Greer R, Miller ER, Grams M, Rebholtz C, Charleston J

Description: CRIC is an ongoing, NIDDK-sponsored, longitudinal, observational study with a racially and ethnically diverse cohort of over 5,000 participants with chronic kidney disease (CKD), ~ 50% with diabetes. With over 10 years of follow-up, CRIC has the following major goals: (a) identification of novel predictors of CKD progression, and (b) identification of CVD risk factors, among individuals with CKD.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Disparities and Social Determinants of Health, Kidney Disease, Metabolomics and Genetics

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

African-American Study of Kidney Disease and Hypertension (AASK)

Welch Center Investigators: Miller ER, Grams M, Rebholtz C, Ishigami J

Description: AASK is a completed NIDDK-sponsored study with 2 phases: (a) a 2x3 factorial randomized trial that assessed the effect of strict versus usual BP control and 3 anti-hypertensive agents on the progression of CKD and (b) a cohort study with extended follow-up. Trial participants were 1,097 African-Americans with chronic kidney disease attributed to hypertension. Several trainees have conducted secondary analyses of this landmark study that has > 10 years of follow-up.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Health Disparities and Social Determinants of Health, Kidney Disease, Metabolomics and Genetics

Study Design: Clinical Trials, Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Practice-based Opportunities for Weight Reduction (POWER)

Welch Center Investigators: Clark J, Yeh J, Wang NY, Coughlin J, Daumit G, Bennett W, Gudzone K, Charleston J

Description: POWER is a completed, NHLBI-sponsored randomized trial that tested 2 behavioral weight loss interventions in > 400 obese patients with cardiovascular risk factors. The trial documented that a remotely delivered, multi-component intervention sustained weight loss over 2 years. Given the simplicity of the design and the high quality and completeness of data collection, several trainees have conducted secondary analyses.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Weight Loss Maintenance Trial (WLM)

Welch Center Investigators: Coughlin J, Charleston J

Description: WLM is a completed, NHLBI-supported, randomized, controlled trial that tested the effects of 2 lifestyle interventions as a means to sustain weight loss. One intervention involved personal contact and the other used a web-based intervention. With 5 years of follow-up, this trial is one of the longest trials of weight loss interventions.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Disparities and Social Determinants of Health

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Dietary Approaches to Stop Hypertension (DASH)

Welch Center Investigators: Miller E, Charleston J

Description: DASH was a randomized, controlled feeding study that tested the effects of 3 dietary patterns on blood pressure and other outcomes. Trials results have been extremely influential. Given the simplicity of the design (3 arms) and the high quality and completeness of data collection, numerous trainees have conducted secondary analyses.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Dietary Approaches to Stop Hypertension- Sodium Trial (DASH-Na)

Welch Center Investigators: Miller E, Woodward M, Charleston J

Description: DASH-Sodium was a randomized, controlled feeding study that tested the effects of 3 levels of sodium intake in 2 dietary patterns on blood pressure and other outcomes. Trials results have been extremely influential. Several trainees have conducted secondary analyses of this trial.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Optimal Macronutrient Intake for Carbohydrate Trial (OmniCarb)

Welch Center Investigators: Miller E, Charleston J, Mueller N

Description: OmniCarb was a recently completed randomized, controlled feeding study that tested the effects of amount (high vs low %kcal carb) and type (high vs low glycemic index) on blood pressure, lipids, and insulin sensitivity. Trials results have been extremely influential. Trainees have started to conduct secondary analyses of this trial.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Optimal Macronutrient Intake Trial to Prevent Heart Disease (OmniHeart)

Welch Center Investigators: Miller E, Charleston J, Mueller N

Description: OmniHeart was a randomized, controlled feeding study that tested the effects of 3 diets, each with reduced saturated fat, on blood pressure and other outcomes. Trials results have been extremely influential. Several trainees have conducted secondary analyses of this trial.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

PREMIER

Welch Center Investigators: Charleston J

Description: PREMIER was a randomized, controlled behavioral intervention trial that tested the effects of 2 multi-component lifestyle interventions (weight loss, physical activity, sodium reduction, DASH diet) on blood pressure and other outcomes. Given the simplicity of the design (3 arms) and the high quality and completeness of data collection, several trainees have conducted secondary analyses.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Trials of Hypertension Prevention (TOHP)

Welch Center Investigators: Appel L

Description: In Phase 1 of Trials of Hypertension Prevention (TOHP), individuals aged 30-54 years with high normal BP to lifestyle approaches that might prevent hypertension, including weight loss, sodium reduction, stress reduction, and pill supplements (potassium, calcium, magnesium, fish oil) for up to 18 months. In Phase 2 of TOHP, individuals were randomized to weight loss, sodium reduction, both, or neither for 3 to 4 years. Clinical outcomes over extended follow-up period, up to 23 years, were also collected.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Resolve

Welch Center Investigators: Appel L, Matsushita K, Miller ER, Brady T, Neupane D, Henry M

Description: Resolve is a global health initiative funded by the Bloomberg Philanthropies, the Chan Zuckerberg Initiative and the Bill and Melinda Gates Foundation, and implemented by Vital Strategies, a New York-based global health organization that works in more than 60 countries. The head of the overall project is Dr. Tom Frieden, former director of the US Centers for Disease Control and Prevention and former commissioner of the New York City (NYC) Health Department. The initiative aims to save more than 100 million lives by preventing heart attacks and strokes and will help countries close life-threatening gaps in epidemic preparedness and response. JHSPH will support two core programs: hypertension control and sodium reduction. We will provide expert technical support in operational research, expertise in program evaluation and research methodology and support peer-reviewed publications, including systematic reviews, and provide training for professional staff in the target LMICs and build implementation research capacity in the target countries. Our group is a diverse, inter-disciplinary team of investigators from across Johns Hopkins, including faculty

from the Welch Center for Prevention, Epidemiology, and Clinical Research, the Department of International Health, the Department of Epidemiology, and the Division of General Internal Medicine, as well as a faculty from other academic centers.

Study Design: Intervention

Opportunities for secondary analysis: No

Opportunities for participating in study conduct: Yes

DASH for Diabetes Diet Intervention Trial (DASH4D)

Welch Center Investigators: Appel LJ, Maruthur N, Yeh J, Pilla S, Wang NY, Miller ER

Description: DASH4D is a randomized, controlled feeding study that tested the effects of 2 levels of sodium intake in 2 dietary patterns on blood pressure and other outcomes in 100 persons with type 2 diabetes. The trial will commence in the fall of 2019, start feeding in 2020, and end ~ 2 years later. Given the dearth of evidence on the impact of dietary factors on BP in persons with diabetes, we anticipate that results of this trial will potentially be quite influential.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Mary Catherine Beach, MD, MPH

Maximizing Respect and Improving Patient Outcomes in HIV and Substance Abuse (MaRIPHOSA)

Welch Center Investigators: Beach MC

Description: Ongoing data collection to establish a repository of audio-recorded patient-provider encounters in HIV care embedded within the HIV Clinical Cohort such that retrospective case-control analyses examining interpersonal factors associated with patient outcomes (e.g. dropping out of care, substance use relapse, etc.) can be conducted as these outcomes become apparent.

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Improving Patient Outcomes with Respect and Trust (IMPORT)

Welch Center Investigators: Beach MC

Description: Three-year cohort study of 280 adults and adolescents with sickle cell disease, including multiple psychological, behavioral, social and clinical outcomes including measures of pain and pain medication use, as well as patient experience of respect and trust in the healthcare system.

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Enhancing Communication and HIV Outcomes (ECHO)

Welch Center Investigators: Beach MC, Cooper LA

Description: Observational database of 850 audio-recorded routine outpatient patient-provider encounters from 4 sites across the United States, that includes multiple behavioral and clinical measures including detailed substance use history, adherence to therapy, attitudes towards treatment, trust in the healthcare system, and experience of care.

Study Design: Observational Studies, Health Services

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

[Wendy Bennett, MD, MPH](#)

Healthy for 2/Healthy for U: A Pragmatic Randomized Clinical Trial to Limit Gestational Weight Gain and Prevent Obesity in Johns Hopkins Prenatal Care Practices

Welch Center Investigators: Bennett W, Wang NY, Coughlin J

Description: We are conducting a pragmatic RCT to test a remotely delivered health coaching program in pregnant and postpartum women aimed at promoting healthy weight gain.

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

The Impact of Timing of Eating on Weight: A Multi-site Cohort Study Using the Daily24 Mobile Application (Daily24)

Welch Center Investigators: Bennett W, Zhao D, Clark J, Coughlin J

Description: We developed a mobile application for ecologic momentary assessment of timing of eating and sleeping and are implementing it in a large cohort (~1000) of patients enrolled from 3 health systems as part of the PCORNet Clinical Data Research Network.

Health Conditions and Cross Cutting Themes and Other Domains: Cohort Study, mobile technology, obesity prevention

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

[Tammy Brady, MD, PhD](#)

Electronic Media Powering positive health changes in youth: EMPower Study

Welch Center Investigators: Brady, TM, Appel, L, Miller ER

Description: EMPower is a completed randomized clinical trial designed to test the effect of a behavioral intervention delivered by social media on weight, blood pressure and left ventricular mass among children with overweight and obesity. We also aim to compare the effects of the intervention on hormonal regulators of (a) blood pressure, (b) growth, (c) adiposity, and on lipid risk factors.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle, Pediatric health, Obesity

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

ReNEW (Reversing the Negative CV effects of Weight) Clinic Cohort

Welch Center Investigator: Brady, TM

Description: The ReNEW clinic is a multidisciplinary clinic for children, adolescents and young adults with overweight/obesity and elevated blood pressure. Patients are recruited to enroll in this prospective, longitudinal clinic cohort study.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle, Pediatric health, Obesity

Study Design: Observational Study

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Behavioral Risk Factors for Poor Vascular Health in Youth: The BeHealthy Study

Welch Center Investigators: Brady, TM, Appel, L

Description: This is a cross-sectional study investigating the association of diet quality and sodium intake on clinical and

pre-clinical measures of cardiovascular health. Participants are recruited from the ReNEW clinic and undergo detailed dietary analysis, study specific lab work, 24-hour ambulatory blood pressure monitoring, actigraphy and assessments of vascular stiffness and endothelial function.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle, Pediatric health, Obesity

Study Design: Cross-sectional Study

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Association of Mood with Risk for Atherosclerosis (The AuRA Study)

Welch Center Investigator: Brady, TM

Description: This is a cross-sectional study investigating the association of mood disorders and adverse childhood experiences on clinical and pre-clinical measures of cardiovascular health. Participants are enrolled from the BeHealthY study (obese population without mood disorders), the CHAMPION trial (obese population with mood disorders), and the Pediatric Medical Psychiatric clinic (mood disorder patients with normal BMI).

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle, Pediatric health, Obesity, Mental health

Study Design: Cross-sectional Study

Opportunities for secondary analysis: No

Opportunities for participating in study conduct: No

Rest Time before Blood Pressure Measurement Trial: The Best Rest Study

Welch Center Investigators: Brady, TM, Appel, L, Miller, ER, Matsushita, K, Ishigami, J, Charleston, J

Description: This is a RCT with a cross-over design to compare the effects on blood pressure of resting 0 or 2 minutes vs. 5 minutes (reference) before the initial blood pressure measurement. It will also determine the effect of different rest times on blood pressure variability.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension

Study Design: Clinical Trial

Opportunities for secondary analysis: Maybe

Opportunities for participating in study conduct: No

Cuff(SZ): The Cuff Size Blood Pressure Measurement Trial

Welch Center Investigators: Brady, TM, Appel, L, Miller, ER, Matsushita, K, Ishigami, J, Charleston, J

Description: This is a RCT with a cross-over design that will compare the effects of cuff size (too small, too large) on automated blood pressure measurement.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension

Study Design: Clinical Trial

Opportunities for secondary analysis: Maybe

Opportunities for participating in study conduct: No

[Jeanne Clark, MD, MPH](#)

Action for Health in Diabetes (Look AHEAD)

Welch Center Investigators: Clark J, Maruthur N, Pilla S, Yeh, J

Description: The Action for Health in Diabetes (Look AHEAD) is a randomized trial comparing the effects of Intensive Lifestyle Intervention (ILI) focused on weight loss achieved through healthy eating and increased physical activity versus a control condition of Diabetes Support and Education (DSE) in overweight and obese individuals with type 2 diabetes. The Look AHEAD Extension (LA-E) will examine whether ILI, provided for 10 years during mid-life, has enduring benefits that persist beyond the period of the intervention for older individuals with diabetes.

Health Conditions and Cross Cutting Themes and Other: Obesity, Type 2 diabetes, cardiovascular disease, aging, weight

loss

Domains Study Design: Clinical Trials, Observational Studies

Opportunities for secondary analysis: Yes, including analysis of plasma/serum

Opportunities for participating in study conduct: No

Improving Diabetes through Lifestyle and Surgery (IDeaLS)

Welch Center Investigators: Clark J, Maruthur N, Potter J

Description: This pilot randomized trial was designed to compare the effect of 3 weight loss interventions (medical weight loss, Roux-en-Y gastric bypass surgery, and adjustable gastric banding) on glucose homeostasis and diabetes at approximately the same degree of weight loss (10%). Detailed measures of meal-stimulated glucose and gut hormones, as well as visceral fat and the microbiome were collected to help determine the differential mechanisms behind the effects.

Health Conditions and Cross Cutting Themes and Other Domains: Obesity, bariatric surgery

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

The Role of Time-Restricted feeding on obesity and cardio metabolic health (AHA –Obesity Center)

Welch Center Investigators: Clark J, Maruthur N, Bennet W, Appel L, Guallar E

Description: This grant funds an Obesity Center focused on investigating the effect of time-restricted feeding on cardiometabolic health. It will also fund 3 fellows for 2 years of translational research each. The center includes a basic science project (PI Rex Ahima, Endocrinology), a clinical project (PI Nisa Maruthur) and a population project (PI Wendy Bennett).

Health Conditions and Cross Cutting Themes and Other Domains: Obesity, Circadian rhythm, cardiovascular risk

Study Design: Clinical Trials, Population-based observational study

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

[Lisa Cooper, MD, MPH](#)

Achieving Blood Pressure Control Together (ACT Study)

Welch Center Investigators: Ephraim P, Cooper L, Carson K, Wang N-Y, Hill-Briggs F, Gudzone K, Charleston J, Crews D, Greer R, Thornton R

Description: The ACT Study was a 3-arm randomized trial designed to study the effectiveness of interventions that engage patient, family, and community-level resources to facilitate urban African- American hypertensive patients' improved hypertension self-management and subsequent hypertension control. The study enrolled 159 patients with uncontrolled hypertension from an urban primary care clinic and randomly assigned them to receive: 1) an educational intervention lead by a community health worker (CHW) alone, 2) the CHW intervention plus a patient and family communication activation intervention, or 3) the CHW intervention plus a problem-solving intervention. The primary study outcome was blood pressure control at 12 months. Several biomedical, psychological, environmental, social, and demographic correlates and several mediators of hypertension control (e.g., self-monitoring and self-management behaviors, medication adherence) were assessed by patient self-report, and all primary care and CHW encounters were audio recorded.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Health Services Research and Patient Provider Communication, Kidney Disease

Study Design: Clinical Trials, Health Services

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Reducing Disparities and Controlling Hypertension in Primary Care (ReD CHIP)

Welch Center Investigators: Cooper L, Carson K, Miller P, Greer R, Boonyasai T, Charleston J, Purnell T, Dalcin A, Aboumatar H, Thornton, R

Description: ReD CHIP was a large, pragmatic trial that tested the effects of 3 multi-level interventions (blood pressure measurement, patient care management, and provider communication skills training with race-stratified, hypertension dashboard) on racial disparities in blood pressure control at 6 primary care practices in the Baltimore area. The trial included over 40 primary care providers, 60 clinical staff, and 40,000 patients. Several trainees have conducted secondary analyses.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Health Services Research and Patient Provider Communication

Study Design: Quality Improvement

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Reducing Inequities in Care of Hypertension: Lifestyle Improvement for Everyone (The RICH Life Study)

Welch Center Investigators: Cooper L, Appel L, Daumit G, Carson K, Crews D, Greer R, Hill-Briggs F, Miller E, Wang NY, Yeh HC, Boonyasai R, Charleston J, Purnell T, Daumit G, Ndumele C, Thornton R

Description: This is a pragmatic cluster randomized trial in which we will compare the effectiveness of clinic-based standard of care plus audit, feedback and education (SCP) to an intervention that uses a collaborative care team, a community health worker and specialist consultation to deliver contextualized, appropriately stepped care (CC/stepped care) for reducing disparities and improving patient-centered outcomes among patients with hypertension. Thirty primary care clinics, including Federally Qualified Health Centers, across Maryland will recruit 63 patients each (total=1,890). We will use patient and broad stakeholder engagement and apply principles of community-based participatory research to refine and adapt intervention protocols and materials to the needs of participating organizations, clinic sites, and populations. The main study outcomes are blood pressure control at 24 months, change in systolic blood pressure over 24 months, and change in patient activation over 24 months. Pre-specified subgroup analyses will test for differences in intervention effect across race/ethnicity, rural/urban residence, Medicaid/non-Medicaid status, and stepped care status. The project is also conducting an ancillary study assess the impact of the COVID-19 pandemic on households and individuals. Information will be gathered on a range of issues, including food insecurity, household socioeconomic status, and public benefit receipt and utilization prior to and in response to the COVID-19 pandemic.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Health Services Research and Patient Provider Communication: COVID-19 Infection

Study Design: Clinical Trials, Health Services

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

[Josef Coresh, MD](#)

Atherosclerosis Risk in Communities (ARIC)

Welch Center Investigators: Coresh J, Selvin E, Grams M, Matsushita K, Rebholz C, Guallar E, Yeh J, Golden S, Gottesman R, Sharrett R, Szklo M, Platz E, Ballew S, Carson K, Maruthur N, Young H, McAdams M, Michos E, Woodward M

Description: Examines the etiology and natural history of atherosclerosis, cardiovascular disease, and aging related disease in a large community based cohort. Hopkins investigators lead a wide range of ancillary studies on, diabetes, kidney disease, biomarkers and cancer. ARIC recruited nearly 16,000 participants ages 45-65 years in 1986-1988 and

follow-up continues with semi-annual telephone calls about health status and review of all hospitalizations with adjudication of cardiovascular events and dementia. ARIC visit 7 will be conducted during 2017-2018 with multiple ancillary studies, including R01 grants for diabetes (PI:Selvin) and coronary calcium (PI:Matsushita/Blaha). Approximately 8,000 cohort participants are alive and over 4,000 attended visit 6 (2016-2017, ages 75+ years). The ARIC specimen bank includes over 2 Million vials which enable many innovative ancillary studies. Hopkins has a copy of all data facilitating efficient manuscript writing by scores of investigators at Hopkins. ARIC data are used in over 200 papers each year for a total of over 2,000 published papers.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Atherosclerosis Risk in Communities Neurocognitive Study (ARIC-NCS)

Welch Center Investigators: Coresh J, Selvin E, Grams M, Matsushita K, Rebholz C, Guallar E, Yeh J, Golden S, Gottesman R, Sharrett R, Szklo M, Platz E, Ballew S, Carson K, Maruthur N, Deal J, Michos E, Woodward M

Description: Elucidate risk factors underlying ethnic disparities in cognitive decline of dementia. Provide the scientific basis for dementia prevention strategies by identifying vascular therapeutic targets, optimal timing for interventions and useful intermediate outcomes. Ancillary studies focus on brain amyloid deposition, MRI imaging, and hearing loss. ARIC NCS includes all ARIC participants. ARIC recruited nearly 16,000 participants ages 45-65 years in 1986-1988 and follow-up continues with semi-annual telephone calls about health status and review of all hospitalizations with adjudication of cardiovascular events and dementia. ARIC visit 7 will be conducted during 2017-2018. Approximately 8,000 cohort participants are alive. The ARIC specimen bank includes over 2 Million vials which enable many innovative ancillary studies. Hopkins has a copy of all data facilitating efficient manuscript writing. ARIC data are used in over 200 papers each year for a total of over 2,000 published papers.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Health Services Research and Patient Provider Communication, Hearing Dysfunction, Kidney Disease, Metabolomics and Genetics, Women's Health, Cognitive decline in dementia

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Give Us a Clue to Cancer and Heart Disease

Welch Center Investigators: Coresh J, Platz E

Description: Cancer incidence and mortality are related to a specimen bank of over 25,000 people collected in 1975 and 1989 as well as risk factors.

Health Conditions and Cross Cutting Themes and Other Domains: Cancer:

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Aging and Cognitive Health Evaluation in Elders Randomized Trial (ACHIEVE)

Welch Center Investigators: Miller E, Carson K, Appel L, Cooper L, Charleston J, Yeh J

Description: ACHIEVE is an ongoing randomized control trial to determine the effect of a hearing rehabilitative intervention versus a successful aging control intervention on rates of cognitive decline (primary outcome measure) and secondary outcome measures (adjudicated incident dementia, physical and social functioning, health-related quality of life, and physical activity). ACHIEVE is recruiting 850 70-84 year-old cognitively-normal older adults with hearing loss

who will be randomized 1:1 to a hearing intervention (hearing needs assessment, fitting of hearing devices, education/counseling) or successful aging education intervention.

Health Conditions and Cross Cutting Themes and Other Domains: Hearing Dysfunction

Study Design: Clinical Trial

Opportunities for secondary analysis: No

Opportunities for participating in study conduct: No

Chronic Kidney Disease Prognosis Consortium (CKD- PC)

Welch Center Investigators: Coresh J, Matsushita K, Ballew S, Grams M

Description: Use state-of-the-art analysis methods to address pressing questions needed to optimize CKD care and research. The consortium comprises ~200 investigators from 70 cohorts world-wide, new cohorts join each year. With estimated glomerular filtration rate (eGFR) and albuminuria measures in >10 million participants representing general, high cardiovascular risk, and CKD populations, the CKD-PC developed a track record of producing high impact papers and has a plan for advancing knowledge related to CKD progression, risk scores and additional pressing questions.

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Chronic Kidney Disease Biomarkers Consortium (CKD-Biocon)

Welch Center Investigators: Coresh J, Grams M, Rebholz C

Description: Hopkins participates in a consortium to elucidate risk factors for CKD progression. In this phase, the Hopkins investigators are leading use of broad metabolomics assays to discover molecules involved in elevated risk of CKD complications. Metabolite assays are conducted at Metabolon and the BROAD laboratories and the consortium is developing tools to facilitate meta-analysis.

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

[Deidra Crews, MD, ScM](#)

Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS)

Welch Center Investigators: Crews D

Description: Prospective cohort study examining the differential influences of race and socioeconomic status on health outcomes.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Kidney Disease, Mental Illness and Substance Abuse

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Resiliency in Dialysis Initiation (ReDI)

Welch Center Investigators: Crews D, McAdams-Demarco M

Description: Prospective study of older adults with advanced kidney disease who are initiating hemodialysis

Health Conditions and Cross Cutting Themes and Other Domains: Kidney Disease, Older Adults

Study Design: Observational Studies

Opportunities for secondary analysis: Potential

Opportunities for participating in study conduct: Yes

Five, Plus Nuts and Beans for Kidneys

Welch Center Investigators: Miller E, Crews D, Carson K, Appel L, Cooper L, Charleston J, Yeh J, Dalcin A

Description: This study will test whether delivering nutritional advice to adopt a DASH-like diet and \$30/week worth of fruits, vegetables, nuts and beans will reduce kidney damage in socioeconomically disadvantaged African Americans with hypertension and chronic kidney disease. Ancillary qualitative studies will examine participant experiences with the intervention.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Disparities and Social Determinants of Health, Kidney Disease

Study Design: Clinical Trials, Qualitative Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Best Case/Worst Case: A Multisite Randomized Clinical Trial of Scenario Planning for Patients with End-Stage Kidney Disease

Welch Center Site Investigator(s): Crews D

Description: This multi-site study (Schwarze, M., PI, U-Wisconsin) will test the Best Case/ Worst Case intervention, a tool that nephrologists will use for communicating with older adult patients who are deciding whether to initiate dialysis. Outcomes will include initiation of dialysis and palliative care, quality of life, and intensity of treatment at the end of life.

Health Conditions and Cross Cutting Themes and Other Domains: Kidney Disease, Dialysis, Older Adults, Quality of Life, Health Literacy

Study Design: Clinical Trials

Opportunities for secondary analysis: No

Opportunities for participating in study conduct: Yes

Disparities in Chronic Kidney Disease

Welch Center Investigators: Crews D, Purnell T

Description: This study will examine the impact of race/ethnicity, access to specialty care and geographic location on kidney disease progression, associated costs and mortality among the Medicare and Medicaid population.

Health Conditions and Cross Cutting Themes and Other Domains: Kidney Disease, Health Disparities and Social Determinants of Health, Population Health, Specialty Care Access and Utilization

Study Design: Retrospective Chart Review

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Barriers to Arteriovenous Fistula Use in Black Hemodialysis Patients

Welch Center Investigators: Crews D

Description: Despite national guidelines, Black dialysis patients are less likely to use a fistula than are whites. This proposal will examine multi-level factors that may explain racial disparities in fistula use.

Health Conditions and Cross Cutting Themes and Other Domains: Kidney Disease, Health Disparities and Social Determinants of Health, Population Health, Specialty Care Access and Utilization

Study Design: Observational Studies, Qualitative Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Randomized Trial of Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE)

Welch Center Investigators: Daumit G, Appel L, Wang NY, Dalcin A, Young D, Guallar E, Crum R, Charleston J

Description This was a NIMH-funded 18-month behavioral weight loss trial of 291 adults with serious mental illness in 10 sites in Maryland. It was a landmark trial that demonstrated persons with serious mental illness can lose weight with an appropriately tailored intervention.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Mental Illness and Substance Abuse, Health Behaviors and Lifestyles

Study Design: Clinical Trial

Opportunities for Secondary Analysis: Yes

Opportunities for participating in study conduct: No

Comprehensive Cardiovascular Risk Reduction Trial in Persons with Serious Mental Illness (IDEAL)

Welch Center Investigators Daumit G, Appel L, Wang NY, Miller E, Ford D, Dalcin A, Crum R, Young D, Charleston J

Description This was a NHLBI-funded community organization-based randomized clinical trial that tested the hypothesis that an 18-month comprehensive, practical cardiovascular disease (CVD) risk reduction program was superior to control in improving cardiovascular health in persons with serious mental illness. We partnered with a large mental health organization and enrolled 269 adults with serious mental illness. Active intervention participants received individual CVD risk reduction behavioral counseling from a health coach, as well as nurse coordination with primary care providers to promote optimal management of CVD risk factors.

Health Conditions and Cross Cutting Themes and Other Domains Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Mental Illness and Substance Abuse

Study Design Clinical Trial

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: No

Statewide Implementation of Health Homes for Persons with Serious Mental Illness

Welch Center Investigators Daumit G, McGinty EE

Description This NIMH-funded observational study used a combination of analyses of administrative claims data and interviews and surveys with stakeholders to examine the health home program in Maryland. The health home program provides enhanced care coordination services for persons with serious mental illness to better integrate somatic and behavioral health services. This project, along with other studies Dr. Daumit is conducting as part of her clinical trials to implement physical health interventions in mental health settings, and her NIMH P50 ALACRITY Center comprise a developing research program in implementation science.

Health Conditions and Cross Cutting Themes and Other Domains Health Services Research and Patient Provider Communication, Mental Illness and Substance Abuse, Implementation Science

Study Design Observational Studies, Health Services, Qualitative Study

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: No

Randomized Trial of a Healthy Weight Intervention for Youth with Serious Emotional Disturbance (CHAMPION)

Welch Center Investigators Daumit G, Wang NY, Appel L, Dalcin A, Brady T, Young D, Charleston J, Thornton R

Description Youth with mental illness have extremely high prevalence of overweight and obesity, and are therefore at risk for early cardiovascular disease, thus effective weight management interventions are needed urgently for this vulnerable group. This is a NIMH-funded randomized clinical trial of a healthy weight intervention for 120 youth ages 8

to 18 years old with mental illness with a body mass index at or above the 85th percentile. The active intervention group receives a 12-month practical healthy weight program integrating weight management counseling and physical activity.

Health Conditions and Cross Cutting Themes and Other Domains Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Mental Illness and Substance Abuse

Study Design Clinical Trial

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: Yes

Trial of Integrated Smoking Cessation, Exercise and Weight Management in Serious Mental Illness (TRIUMPH)

Welch Center Investigators Daumit G, Wang NY, Appel L, Miller E, Dalcin A, Ford D, Charleston J

Description This is a NIMH-funded community health organization-based, randomized clinical trial that is testing an 18-month comprehensive tobacco smoking cessation program integrating exercise and weight counseling in 192 adults with mental illness.

Health Conditions and Cross Cutting Themes and Other Domains Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle, Mental Illness and Substance Abuse

Study Design Clinical Trial

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: No

The ALACRITY Center for Health and Longevity in Mental Illness (ALACRITY)

Welch Center Investigators Daumit G, McGinty E, Gudzone K, Dalcin A, Wang N, Appel L, Cooper L, Hill-Briggs F, Murphy K

Description This is a NIMH-funded P50 Center uses cutting-edge transdisciplinary methods to advance short- and long-term strategies to reduce cardiovascular risk and premature mortality in persons with serious mental illness. The ALACRITY Center has three core pilot research projects as well as Methods Core projects and opportunities for pilot funding.

The *Core Pilot Research projects* take place in a range of community mental health settings and test innovative implementation strategies to support high-fidelity implementation of evidenced-based practices to reduce cardiovascular risk:

- **R34-1 ACHIEVE-D:** Adapting an evidence-based weight loss intervention and testing strategies to increase implementation in community mental health programs,
- **R34-2 IMPACT:** Promoting evidence-based tobacco smoking cessation treatment in community mental health clinics,
- **R34-3 RHYTHM:** Using an Innovative Quality Improvement Process to Increase Delivery of Evidence-Based Cardiovascular Risk Factor Care in Community Mental Health Organizations.

The *Methods Core projects* include:

- **Quantitative Methods:** Contributing to advanced quantitative methods to support intervention scale-up, including: Informing the design of Sequential, Multiple Assignment, Randomized Trials (SMARTs), Evaluating the heterogeneity of treatment effects, and Assessing the generalizability of trials to target populations,
- **Systems Science:** Building a systems model to characterize health impacts of implementing evidence-based interventions to decrease cardiovascular risk in persons with serious mental illness,
- **Human Factors Engineering:** Development of a Human Factors Engineering Toolkit to Support Implementation of Evidence-Based Somatic Interventions in Community Mental Health Settings
- **Evaluating Avatar-Assisted Training and Assessment of Motivational Interviewing**

Funding for New Research: The ALACRITY Center supports pilot funding for topics related to improving physical

health and addressing premature mortality for persons with serious mental illness. Johns Hopkins-doctoral fellows and faculty at all levels are eligible and can request funding for 1-2 years up to \$50,000 per year.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Mental Illness and Substance Abuse, Health Disparities and Social Determinants of Health, Implementation Science, Health Services Research

Study Design Clinical Trial, Observational Study Health Services, Qualitative Study

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: Yes

Randomized Trial of a Healthy Weight Intervention for Youth with Serious Emotional Disturbance (CHAMPION)

Welch Center Investigators Daumit G, Wang NY, Appel L, Dalcin A, Brady T, Young D, Charleston J, Thornton R

Description Youth with mental illness have extremely high prevalence of overweight and obesity, and are therefore at risk for early cardiovascular disease, thus effective weight management interventions are needed urgently for this vulnerable group. This is a NIMH-funded randomized clinical trial of a healthy weight intervention for 120 youth ages 8 to 18 years old with mental illness with a body mass index at or above the 85th percentile. The active intervention group receives a 12-month practical healthy weight program integrating weight management counseling and physical activity.

Health Conditions and Cross Cutting Themes and Other Domains Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Mental Illness and Substance Abuse

Study Design Clinical Trial

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: Yes

Trial of Integrated Smoking Cessation, Exercise and Weight Management in Serious Mental Illness (TRIUMPH)

Welch Center Investigators Daumit G, Wang NY, Appel L, Miller E, Dalcin A, Ford D, Charleston J

Description This is a NIMH-funded community health organization-based, randomized clinical trial that is testing an 18-month comprehensive tobacco smoking cessation program integrating exercise and weight counseling in 192 adults with mental illness.

Health Conditions and Cross Cutting Themes and Other Domains Cardiovascular Disease and Hypertension, Health Behaviors and Lifestyle, Mental Illness and Substance Abuse

Study Design Clinical Trial

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: Yes

ACRITY Center for Health and Longevity in Mental Illness (ALACRITY)

Welch Center Investigators Daumit G, McGinty E, Gudzone K, Dalcin A, Wang N, Appel L, Cooper L, Hill-Briggs F

Description This is a NIMH-funded P50 Center uses cutting-edge transdisciplinary methods to advance short- and long-term strategies to reduce cardiovascular risk and premature mortality in persons with serious mental illness. The ALACRITY Center has three core pilot research projects as well as Methods Core projects and opportunities for pilot funding.

The *Core Pilot Research projects* take place in a range of community mental health settings and test innovative implementation strategies to support high-fidelity implementation of evidenced-based practices to reduce cardiovascular risk:

- R34-1 ACHIEVE-D: Adapting an evidence-based weight loss intervention and testing strategies to increase implementation in community mental health programs,

- [R34-2 IMPACT](#): Promoting evidence-based tobacco smoking cessation treatment in community mental health clinics,
- [R34-3 Health Homes](#): Using an Innovative Quality Improvement Process to Increase Delivery of Evidence-Based Cardiovascular Risk Factor Care in Community Mental Health Organizations.

The *Methods Core projects* include:

- [Quantitative Methods](#): Contributing to advanced quantitative methods to support intervention scale-up, including: Informing the design of Sequential, Multiple Assignment, Randomized Trials (SMARTs), Evaluating the heterogeneity of treatment effects, and Assessing the generalizability of trials to target populations,
- [Systems Science](#): Building a systems model to characterize health impacts of implementing evidence-based interventions to decrease cardiovascular risk in persons with serious mental illness,
- [Human Factors Engineering](#): Development of a Human Factors Engineering Toolkit to Support Implementation of Evidence-Based Somatic Interventions in Community Mental Health Settings, and
- [Evaluating Avatar-Assisted Training and Assessment of Motivational Interviewing](#)

Funding for New Research: The ALACRITY Center supports pilot funding for topics related to improving physical health and addressing premature mortality for persons with serious mental illness. Johns Hopkins-doctoral fellows and faculty at all levels are eligible and can request funding for 1-2 years up to \$50,000 per year.

Health Conditions and Cross Cutting Themes and Other Domains Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Mental Illness and Substance Abuse, Health Disparities and Social Determinants of Health, Implementation Science, Health Services Research

Study Design Clinical Trial, Observational Study Health Services, Qualitative Study

Opportunities for Secondary Analysis Yes

Opportunities for participating in study conduct: Yes

[Sherita Golden, MD, MHS](#)

Jackson Heart Study (JHS)

Welch Center Investigators: Golden S, Carson K, Echouffo-Tcheugui J

Description: The Jackson Heart Study is a community-based, observational study of 5301 non-institutionalized adult African Americans 35-84 years old, except in the family cohort where those 21 to 34 years of age were eligible, recruited from urban and rural areas of three counties in the Jackson, Mississippi metropolitan area. Participants were enrolled from 4 sources: random, 17%, volunteer, 22%, currently enrolled in the ARIC Study, 30% and secondary family members, 31%. Data include medical history, physical examination, blood/urine analytes, physical activity, stress, coping and spirituality, racism and discrimination, socioeconomic position, and access to health care. At 12-month intervals, participants are contacted by telephone to confirm vital status, document interim medical events, hospitalizations, and functional status, and obtain additional sociocultural information. Following the baseline examination (2000-2004) there were two follow-up exams (2005-2008 and 2009-2013).

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Multi-Ethnic Study of Atherosclerosis (MESA)

Welch Center Investigators: Golden S, Post W

Description: MESA is an ethnically diverse population-based sample of 6,814 men and women from four ethnic groups: non-Hispanic whites (NHW, 38%), African-Americans (AA, 28%), Chinese-Americans (CA, 12%), and Hispanic-Americans (HA, 22%). Participants were aged 45-84 years at baseline. It investigated the prevalence, correlates, and progression of subclinical CVD and risk factors that predict progression to clinically overt CVD, and that predict progression of subclinical disease itself. The cohort was recruited from six Field Centers throughout the United States and characterized with respect to coronary calcification using computed tomography, ventricular mass and function

using magnetic resonance imaging, and other measures at baseline. Several subclinical disease measures were repeated in 4 subsequent examinations.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Endocrinology

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Maybe

[Rebecca Gottesman, MD, PhD](#)

The ARIC-PET Amyloid Imaging Study (ARIC-PET)

Welch Center Investigators: Gottesman R, Sharrett AR, Walker K

Description: In this study, a subset of 346 participants from the ARIC cohort underwent brain amyloid imaging with PET, for evaluation of the association between vascular risk factors and late-life brain amyloid. A subset underwent a repeat brain PET approximately 5 years later. The overall purpose of this study is to evaluate the vascular contributions to cognitive impairment and Alzheimer's dementia. Participants have had one brain MRI and florbetapir PET scan, with a second MRI and PET in almost 200 participants.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

The ARIC Midlife Sleep and Late-Life Brain Amyloid Study (ARIC Sleep-PET)

Welch Center Investigators: Gottesman R

Description: In this study, participants from the ARIC Washington County cohort who were also part of the Sleep Heart Health Study are undergoing brain amyloid imaging with PET, for evaluation of the associations between late-midlife sleep disturbances (using polysomnography from the Sleep Heart Health Study) and late-life brain amyloid. Participants are also undergoing late-life polysomnography and brain MRI to explore these associations in late-life. The overall purpose of this study is to evaluate the relationship between sleep disturbances and sleep-disordered breathing and Alzheimer's dementia. A total of 150 new participants are being recruited for these studies.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research

Study Design: Observational Studies

Opportunities for secondary analysis: Yes, when data collection is complete (ongoing)

Opportunities for participating in study conduct: No

The Johns Hopkins Diuresis Clinic Cognition study (Diuresis cognition)

Welch Center Investigators: Gottesman R

Description: In this study, individuals with congestive heart failure who are being treated in the Johns Hopkins Bayview diuresis clinic with intravenous diuretics are tested with a neurocognitive battery, as well as transcranial dopplers and laboratory testing. These studies are being done to evaluate the association between heart failure, and control of heart failure symptoms, and cognition, and to evaluate possible mechanisms for the impact of heart failure on cognitive impairment. Participants are all tested at two time points.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Determinants of Incident Stroke Cognitive Outcomes and Vascular Effects on RecoverY (DISCOVERY)

Welch Center Investigators: Gottesman R, Walker K

Description: In this new cohort study, individuals with incident stroke (ischemic and hemorrhagic stroke) will be recruited from 30 sites across the U.S., to study cognitive outcomes up to 5 years post-stroke and understand determinants of these outcomes, the goal sample size is 8000 individuals. The study has a particular emphasis on disparities populations. The Cognitive and Statistical Core is led by Dr. Gottesman, with study startup and initial recruitment scheduled to start in December 2020.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension

Study Design: Observational Studies

Opportunities for secondary analysis: Not until data collection is underway and complete

Opportunities for participating in study conduct: Yes

[Morgan Grams, MD, MHS, PhD](#)

Metabolomics and Genomics in African Americans with CKD (AASK)

Welch Center Investigators: Grams M, Appel L, Coresh J, Chen T, Surapaneni A

Description: Investigation of genetic and metabolomics markers of chronic kidney disease in African Americans using participants from a clinical trial of blood pressure management (African American Study of Kidney Disease and Hypertension)

Health Conditions and Cross Cutting Themes and Other Domains: Kidney Disease, Metabolomics and Genetics, Cardiovascular Disease and Hypertension

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Medication Use and Adverse Events in CKD

Welch Center Investigators: Grams M, Shin J-I, Surapaneni A, Coresh J

Description: Effort to promote appropriate, safe, and effective use of medications across the range of kidney function. Uses data from 5 million participants in 5 international cohorts (Geisinger, SCREAM (Sweden), Maccabi, Johns Hopkins, MarketScan) to identify and validate medication-adverse event associations in order to inform safer health care in the ambulatory setting.

Health Conditions and Cross Cutting Themes and Other Domains: Kidney Disease, Pharmacoepidemiology, Cardiovascular Disease and Hypertension, Health Equity, Guideline-directed care,

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Integrative Omics, CKD, and Adverse Outcomes

Welch Center Investigators: Grams M, Surapaneni A, Coresh J

Description: Effort to integrate genetics, epigenetics, proteomics, and metabolomics in the Atherosclerosis Risk in Communities study to identify pathways and genetic variation that are clinically relevant in CKD and its complication. The overarching goal is to inform the risk prediction and potentially treatments of patients with CKD.

Health Conditions and Cross Cutting Themes and Other Domains: Kidney Disease, Genetic Epidemiology, Cardiovascular Disease and Hypertension, Metabolomics, Proteomics, Epigenetics

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

[Kim Gudzone, MD, MPH](#)

Communities CARING

Welch Center Investigators: Gudzone K

Description: Communities CARING is a two-phase study that examines lifestyle behaviors among public housing residents in Baltimore City. Phase I was a cross-sectional survey describing the association between diet, eating, and exercise habits with the perceived lifestyle habits of participants' social networks. Phase II is a pilot social network intervention aiming to reduce intake of added sugars among public housing residents and their social networks.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle

Study Design: Clinical trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

ACHIEVE Dissemination

Welch Center Investigators: Gudzone K

Description: This study aims to adapt the NIMH-funded Achieving Healthy Lifestyles in Psychiatric Rehabilitation (ACHIEVE) behavioral weight-loss intervention and pilot test an implementation strategy designed to translate the curriculum (ACHIEVE-Dissemination) into community mental health settings, which is part of the Johns Hopkins ALACRITY Center for Health and Longevity in Mental Illness.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle

Study Design: Clinical trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

[Nisa Maruthur, MD, MHS](#)

Time-Restricted Intake of Meals Study (TRIM)

Welch Center Investigators: Maruthur N, Clark J, Appel L

Description: In this 12-week randomized feeding study among adults with prediabetes or diabetes not requiring medication treatment, we will evaluate the effect of eating earlier (time-restricted feeding) vs. later (usual feeding pattern) in the day on weight, glucose homeostasis, and blood pressure at 12 weeks.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

[Kunihiro Matsushita, MD, PhD](#)

PAD research in ARIC

Welch Center Investigators: Matsushita K, Coresh J, Selvin E, Jaar B, Ballew S

Description: Peripheral artery disease (PAD) has been understudied despite its growing prevalence and impact on clinical outcomes and physical function. The ARIC study has been collecting data (e.g., ankle-brachial index and hospitalizations related to PAD) for PAD research and gives a unique opportunity to explore major risk factors of incident PAD over three decades of follow-up and the impact of PAD on various aspects of health.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Maybe

ARICAC: CAC in ARIC

Welch Center Investigators: Matsushita K, Blaha M, Coresh J, Ballew S, Mok Y

Description: Coronary artery calcium (CAC) as well as extra-coronary calcium (ECC) were evaluated in ~2,300 ARIC participants at the ARIC visit 7 (2018-2019) when everyone was aged 75+ years. This project aims to determine the value of CAC and ECC for guiding cardiovascular preventive therapies in 75-and-older populations. This study will also provide a unique opportunity to study healthy vascular aging.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Maybe

PASOS: PAD study in the Study of Latino (SOL)

Welch Center Investigators: Matsushita K, Schrack J, Ballew S, Mok Y

Description: PASOS aims to extensively evaluate PAD (i.e., ankle-brachial index, toe-brachial index, and ankle artery waveforms) and objectively assess physical activity (1-week monitoring using Actigraph) in ~6,000 participants in SOL. The overarching goals are to determine the impact of PAD on physical activity and to examine the value of objectively measuring physical activity for diagnosing and classifying PAD.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension

Study Design: Observational Studies

Opportunities for secondary analysis: Maybe

Opportunities for participating in study conduct: Maybe

Washington County Health Initiative (WCHI)

Welch Center Investigators: Matsushita K, Coresh J, Ballew S

Description: The Washington County Health Initiative (WCHI) aims to utilize electronic medical records collected at Meritus Health to better understand the burden and pathophysiological process of important diseases such as heart failure, chronic obstructive pulmonary disease, diabetes mellitus, obesity, and mental health in Washington County. The ultimate goal is to derive targeted preventive strategies that are tailored to the region based on existing local data.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity

Study Design: Observational Studies

Opportunities for secondary analysis: Maybe

Opportunities for participating in study conduct: No

[Edgar Miller III, MD, PhD](#)

Five, Plus Nuts and Beans for Kidneys

Welch Center Investigators: Miller E, Crews D, Carson K, Appel L, Cooper L, Charleston J, Yeh J

Description: This study will test whether delivering nutritional advice to adopt a DASH-like diet and \$30/week worth of fruits, vegetables, nuts and beans will reduce kidney damage in socioeconomically disadvantaged African Americans with hypertension and chronic kidney disease.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Disparities and Social Determinants of Health, Kidney Disease

Study Design: Clinical Trials

Opportunities for secondary analysis: No
Opportunities for participating in study conduct: Yes

The effects of a long-chain polyunsaturated fatty acid supplementation on biomarkers of kidney injury in adults with diabetes (Go Fish)

Welch Center Investigators: Miller E, Appel L, Guallar E

Description: Randomized placebo-controlled 2-period cross-over trial to test the effects of 4 g/d of n-3 PUFA supplementation on markers of glomerular filtration and kidney injury in adults with adult-onset diabetes and > trace amounts of proteinuria.

Health Conditions and Cross Cutting Themes and Other Domains: Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Kidney Disease

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Study Name Diet, exercise, and weight-loss intervention trial (DEW IT)

Welch Center Investigators: Miller E, Appel L, Charleston J

Description: This trial demonstrated that a comprehensive “lifestyle” intervention can substantially lower blood pressure and improve blood pressure control in hypertensive overweight adults taking one antihypertensive agent. Specifically, the lifestyle intervention reduced mean 24 hour systolic blood pressure by 9.5 mm Hg and diastolic blood pressure by 5.3 mm Hg.

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Dietary Approaches to Stop Hypertension (DASH) Diet effects on Serum Uric Acid (SUA) in adults with hyperuricemia and gout (DiGo)

Welch Center Investigators: Miller E, Yeh J, Carson K, Appel L, Gelber A, Charleston J

Description: In this (the Diet-Gout trial), randomized controlled trial (RCT) of 40 adults with gout or with hyperuricemia (SUA level \geq 7mg/dL) who are not yet indicated for urate-lowering drugs (ULDs). This trial has been funded by the Rheumatology Research Foundation. In this trial, we used a crossover design (N=44) to compare a dietitian-directed DASH diet vs. a usual “self-directed” diet on serum uric acid. Each period will last 4 weeks, separated by a 0-1 week wash-out period. The DASH-Plus intervention resulted in: increased self-reported consumption of fruits and vegetables, increased estimated intake of potassium, magnesium and vitamin C, and increased urine potassium excretion. However, there was no significant effect on SBP or DBP.

Health Conditions and Cross Cutting Themes and Other Domains Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Five, Plus Nuts and Beans

Welch Center Investigators: Miller E, Carson K, Appel L, Cooper L, Charleston J, Yeh J

Description: This study will test whether delivering nutritional advice to adopt a DASH-like diet and \$30/week worth of fruits, vegetables, nuts and beans will reduce blood pressure in socioeconomically disadvantaged African Americans with hypertension.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Community Based Participatory Research, Health Disparities and Social Determinants of Health, Kidney Disease

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

[Noel Mueller, PhD](#)

Examining Gut Microbiota-Mediated Pathways in Inflammation and Glycemia: A Randomized Controlled Trial of Metformin and Weight Loss

Welch Center Investigators: Mueller NT, Yeh J, Appel L

Description: The goal of this project is to examine the effects of metformin and behavioral weight loss on gut microbiota, gut permeability, inflammation and glycemia in a randomized controlled clinical trial of overweight and obese cancer survivors. The results generated might elucidate the mechanisms by which these interventions might affect health, and identify novel microbial signatures that can be targeted for the prevention of metabolic disorders.

Health Conditions and Cross Cutting Themes and Other Domains: Cancer, Diabetes Mellitus and Obesity, Metabolomics and Genetics, Microbiome

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Vaginal microbiome seeding and health outcomes in Cesarean-delivered neonates: a randomized controlled trial

Welch Center Investigators: Mueller NT

Description: The incidence of obesity is increasing worldwide at an unprecedented rate, and evidence suggests disruption to the maternal-newborn exchange of bacteria, caused by cesarean delivery, may contribute to this epidemic. We propose a double-blinded, parallel 2-arm RCT in healthy women scheduled to have cesarean delivery. Mothers will inoculate a gauze swab in the vagina before their procedure, after which their cesarean delivered infants will be randomized to receive either: a) gauze covered in their mothers' vaginal microbiota or b) gauze inoculated with sterile saline (control). We will follow children for 3 years.

Health Conditions and Cross Cutting Themes and Other Domains: Diabetes Mellitus and Obesity, Microbiome

Study Design: Clinical Trials

Opportunities for secondary analysis: No

Opportunities for participating in study conduct: Maybe

NURTURE Microbiome Study

Welch Center Investigators: Mueller NT

Description: The incidence of obesity is increasing worldwide at an unprecedented rate, and evidence suggests disruption to the infant microbiome and the short chain fatty acids they produce may contribute to this epidemic. The objective of this observational study of mothers and their infants, followed for 1 year of life, is to examine the determinants of the infant microbiome and short chain fatty acids at 3 and 12 months of life, and how changes in the microbiome relate to changes in measures of infant adiposity.

Health Conditions and Cross Cutting Themes and Other Domains: Diabetes Mellitus and Obesity, Microbiome

Study Design: Longitudinal birth cohort

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Microbiome and Metabolic Health of Mothers and Children in the Gen3g Study (Gen3g)

Welch Center Investigators: Mueller NT

Description: The objective of this observational study of mothers and their children, followed prospectively for 5 years of life, is to examine the determinants of the mother and her child at 5 years after birth. The rich data base allows for the exploration of environmental, genetic and epigenetic determinants of the gut microbiome of mothers and children.

Health Conditions and Cross Cutting Themes and Other Domains: Diabetes Mellitus and Obesity, Microbiome

Study Design: Longitudinal birth cohort

Opportunities for secondary analysis: Yes
Opportunities for participating in study conduct: No

[Craig Pollack, MD, MHS](#)

The Effect of a Housing Mobility Program on Environmental Exposures and asthma morbidity among low-income minority children (MAP)

Welch Center Investigators: Pollack C

Description: Working with a housing mobility program in Baltimore, this study examines whether moving neighborhoods is linked with changes in exposures in one's home environment and asthma outcomes.

Health Conditions and Cross Cutting Themes and Other Domains: Health Disparities and Social Determinants of Health

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Movember TrueNTH Initiative

Welch Center Investigators: Pollack C

Description: Through a series of linked projects, we are attempting to improve the care for prostate cancer survivors. Projects include creating a survivorship care plan and patient navigation services and an online intervention to improve sexual recovery.

Health Conditions and Cross Cutting Themes and Other Domains: Cancer

Study Design: Clinical Trials

Opportunities for secondary analysis: No

Opportunities for participating in study conduct: Yes

The effects of neighborhood poverty on health care utilization and spending for low-income adults and children: Linking the Moving to Opportunity participants to medical claims data Study

Welch Center Investigators: Pollack C

Description: By linking insurance claims and hospital discharge data with a large social experiment, this study attempts to make causal estimates on the association between health care utilization and neighborhood poverty.

Health Conditions and Cross Cutting Themes and Other Domains: Health Disparities and Social Determinants of Health

Study Design: Health Services

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

[Tanjala Purnell, PhD](#)

Patient-Centered Strategies to Reduce Disparities in Access to Kidney Transplantation

Welch Center Investigators: Purnell T, Cooper L, Crews D, Segev D

Description: This is a prospective cohort study of adults evaluated for a kidney transplant (KT) at Johns Hopkins Hospital. The primary goals of the study is to improve transplant education and address social determinants that influence disparities in access to KT using a stakeholder-engaged intervention approach.

Health Conditions and Cross Cutting Themes and Other Domains: Community Based Participatory Research, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Health Services Research and Patient Provider Communication, Kidney Disease

Study Design: Observational Studies, Health Services, Qualitative Study

Opportunities for Secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Novel Biomarkers and their Changes in the Action in Diabetes and Vascular disease: preterax and diamicroN Controlled Evaluation (ADVANCE) trial of adults with type 2 diabetes (ADVANCE Biomarkers)

Welch Center Investigators: Selvin E, Woodward M

Description: To evaluate the relationships of novel diabetes, kidney, and cardiac biomarkers to clinical complications and changes in blood pressure and glycemic control in the setting of a large international randomized clinical trial of persons with type 2 diabetes. The results of this project will inform the use of novel biomarkers in clinical practice.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Kidney Disease

Study Design: Clinical Trials, Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Performance of Novel Cardiac Biomarkers in the General US Population (FNIH Cardiac Biomarkers)

Welch Center Investigators: Selvin E

Description: This study, funded by a grant from the Biomarkers Consortium of the Foundation for the National Institutes of Health, is being undertaken to understanding the distribution, determinants, and mortality implications of novel cardiac biomarkers in the general US population and important population subgroups defined by age, sex, and race.

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Diabetes and Prediabetes in Old Age in the ARIC Study (ARIC Diabetes)

Welch Center Investigators: Selvin E

Description: Diabetes is common in older adults but there is uncertainty regarding how to best identify, treat, and manage diabetes in this population. The overarching goal of the study is to provide evidence to inform best practices for screening and clinical management of older adults with prediabetes or diabetes.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle, Health Disparities and Social Determinants of Health, Kidney Disease

Study Design: Observational Studies

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: Yes

Biomarkers of Healthy Cardiovascular Aging (Hopkins-Baylor ARIC Lab Grant)

Welch Center Investigators: Selvin E, Matsushita K

Description: This project is focused on atherosclerotic cardiovascular disease and heart failure risk prediction tools tailored for older adults using data from the ARIC Study

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Disparities and Social Determinants of Health, Kidney Disease

Study Design: Prospective cohort

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

Study Name HYperglycemic Profiles iN Obstructive Sleep Apnea (HYPNOS)

Welch Center Investigators: Selvin E

Description: Randomized clinical trial to evaluate whether treatment of sleep apnea improves static and dynamic measures of glycemic status and cardiometabolic health in persons with type 2 diabetes.

Health Conditions and Cross Cutting Themes and Other Domains: Cardiovascular Disease and Hypertension, Diabetes Mellitus and Obesity, Health Disparities and Social Determinants of Health, Kidney Disease

Study Design: Clinical Trials

Opportunities for secondary analysis: Yes

Opportunities for participating in study conduct: No

[Maya Venkataramani, MD, MPH](#)

Family-Oriented Diabetes Prevention: Augmenting the Diabetes Prevention Program

Welch Center Investigators: Venkataramani M, Maruthur N

Description: The burden of type 2 diabetes is growing among children, especially in low-income and minority communities, and addressing lifestyle-associated risk factors may be an effective strategy for diabetes prevention. The National Diabetes Prevention Program lifestyle intervention has been proven to be effective in preventing diabetes among high-risk adults, and through this work, we will augment the program with child-related content that would enable caregivers (parents and guardians) to address lifestyle-associated diabetes risk factors in children. We will do this through conducting qualitative in-depth interviews of prior DPP participants to obtain their insights and guidance regarding content and structure of a family-oriented DPP and conducting a pilot randomized controlled trial with a focus on feasibility and acceptability of the intervention. The efforts would result in a family-oriented diabetes prevention program that could benefit both high-risk children and their caregivers, and reduce the burden of type 2 diabetes across generations.

Health Conditions and Cross-Cutting Themes and Other Domains: Diabetes Mellitus and Obesity, Health Behaviors and Lifestyle

Study Design: Qualitative Research, Intervention

Opportunities for secondary analysis: No

Opportunities for participating in study conduct: Yes

[Jessica Yeh, PhD](#)

Metformin and Lifestyle Intervention in Cancer Survivors (SPIRIT)

Welch Center Investigators: Yeh HC, Appel L, Miller ER, Wang NY, Maruthur N, Charleston J, Dalcin A, Tseng E, Mueller N

Description: This RCT examines the effects from metformin or behavioral weight loss to reduce IGF-1 in cancer survivors in Baltimore metro area.

Health Conditions and Cross Cutting Themes and Other Domains: Cancer, Obesity, Health Behaviors and Lifestyle

Study Design: Clinical Trials

Opportunities for Secondary analysis: Yes

Active Opportunities: No

Behavioral Weight Loss for Overweight or Obese Cancer Survivors in Maryland: ASPIRE Study

Welch Center Investigators: Yeh HC, Appel L, Wang NY, Charleston J, Dalcin A

Description: The objective of the ASPIRE study is to design, implement, and evaluate a real-world, lifestyle-based, support for overweight or obese cancer survivors in both urban and rural areas of Maryland. The intervention will provide three options of support to encourage lifestyle change to achieve and maintain a healthy weight for cancer survivors.

Health condition: Obesity, cancer, behavioral and lifestyle

Study design: non-randomized intervention study

Opportunities for secondary analysis: No

Active opportunities: Yes

PaTH-Diabetes: EMR data form 6 major health systems

Welch Center Investigators: Yeh HC, Pilla SJ

Description: The PaTH network contains EMR data from six academic health systems. PaTH-Diabetes is a retrospective cohort study of adults with type 2 diabetes or at risk of type 2 diabetes.

Health Conditions: diabetes, obesity, cardiovascular diseases, health services research

Study Design: Retrospective cohort

Opportunities for secondary analysis: Yes

Active Opportunities: No