CURRENT RESEARCH GRANTS AND CONTRACTS
DEPARTMENT OF EPIDEMIOLOGY
January, 2016

PRINCIPAL INVESTIGATOR: Dr. JENNIFER J. ADIBI
Effects of Phthalates on Trophoblast Differentiation

Funding Agency: NIEHS
R00 ES017780-06 1/27/2014 - 2/28/2016 $291,559.00
3/1/2014 - 2/28/2016 $155,412.00

During this R00 phase, this project will test the theory that placental gene expression responds in a sex-specific manner to phthalate exposure, and that the placental response is correlated with sex-specific fetal development. This will be accomplished using measurements in maternal circulation, in placental tissue, and in the neonates; and a combination of experimental studies using primary placental tissue, cross-sectional and longitudinal studies.

PRINCIPAL INVESTIGATOR: Dr. STEVEN H. BELLE
Continuation of the Longitudinal Assessment of Bariatric Surgery

Funding Agency: NIDDK
U01 DK066557-10 8/1/2009 - 6/30/2016 $7,697,964.00
7/1/2013 - 6/30/2016 $1,679,316.00

This renewal of the Data Coordinating Center (DCC) for the Longitudinal Assessment of Bariatric Surgery (LABS) will continue to support a multi-center consortium that was created to facilitate coordinated clinical, epidemiological and behavioral research in bariatric surgery. The DCC developed the core database and provides logistical and scientific support in all aspects of study design, conduct, analysis, and administration. A supplement funds activities for ending data collection and management, archiving datasets, and completing statistical analyses.

PRINCIPAL INVESTIGATOR: Dr. STEVEN H. BELLE
Cross-Study Analysis of Coordinated Randomized Clinical Trials

Funding Agency: NHLBI
R01 HL122144-02 12/1/2014 - 11/30/2018 $2,420,145.00
12/1/2015 - 11/30/2016 $623,275.00
The long-term objective of this study is to identify the theory-based behavior change techniques that lead to successful weight loss in young adults in the group of interventions at seven participating sites of the Early Adult Reduction of Weight through Lifestyle (EARLY). Another goal of the project is to develop, test and disseminate the process used to identify the most promising techniques across this consortium of studies. The ultimate goals are to identify basic discoveries about intervention components related to weight loss and to disseminate the information to scientists, physicians, and the public.

**PRINCIPAL INVESTIGATOR:** Dr. STEVEN H. BELLE  
**Hepatitis B Research Network - Data Coordination Center**

Funding Agency: NIDDK  
U01 DK082864-08  
9/1/2015 - 5/31/2020  
$7,947,755.00  
9/1/2015 - 5/31/2016  
$1,589,551.00

This is the renewal of the Data Coordinating Center for the Hepatitis B Research Network. The Data Coordinating Center supports all aspects of study design, study conduct, and data analysis for the various studies in the network and coordinates all activities including meetings and conference calls, data sharing and archiving of data, materials, and specimens.

**PRINCIPAL INVESTIGATOR:** Dr. LISA M. BODNAR  
**Informing Maternal Weight Gain Guidelines for Twin Pregnanacies**

Funding Agency: NINR  
R01 NR014245-03  
8/1/2013 - 6/30/2017  
$1,348,890.00  
7/1/2015 - 6/30/2016  
$327,070.00

This study will inform evidence-based gestational weight gain guidelines for twin gestations by evaluating the total amount and pattern of weight gain in twin pregnancies that is associated with optimal health outcomes for mothers and their children.

**PRINCIPAL INVESTIGATOR:** Dr. LISA M. BODNAR  
**Innovative Approaches to Pregnancy Weight Gain Guidelines**

Funding Agency: NICHD  
R01 HD072008-03  
9/17/2013 - 5/31/2017  
$1,808,230.00  
6/01/2015 - 5/31/2016  
$447,501.00

The goal of this project is to address critical research recommendations about total gestational weight gain and pattern of gestational weight gain in two cohorts of singleton births in an effort to inform evidence-based guidelines. The aims are to determine the association between total gestational weight
gain and adverse outcomes for mothers and to examine the relationship between maternal gestational weight gain trajectory and perinatal outcomes.

PRINCIPAL INVESTIGATOR: Dr. MARIA M. BROOKS

Impact of Glycemic Control on Markers in Type 2 Diabetes

Funding: Brigham & Women’s

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This is a subcontract for participation in an ancillary study to BARI 2D for data management and statistical analyses to investigate the effect of elevated levels of cardiac troponin at baseline on risk of adverse cardiovascular events.

PRINCIPAL INVESTIGATOR: Dr. MARIA M. BROOKS

Treatment of Feeding Problems in Children with Autism

Funding: University of Florida

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As a subcontractor, the Epidemiology Data Center coordinates this two-site study of the feasibility and efficacy of a behavioral parent training program for feeding problems in children with autism.

PRINCIPAL INVESTIGATOR: Dr. MARIA M. BROOKS

Diabetes and Coronary Artery Disease Trials Collaboration

Funding: Gilead

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This collaborative study will merge datasets from three landmark clinical trials into a single patient-level dataset which will be analyzed by the Epidemiology Data Center to determine characteristics of diabetic patients who may benefit best from medical therapy instead of revascularization.
This is the Coordinating Center for the Study of Women's Health Across the Nation, a study of aging in women. The aims of the second renewal of the multicenter longitudinal study are to complete the characterization of the natural history of reproductive aging through the late post-menopause, evaluate the impact of reproductive aging on health outcomes, and identify underlying mechanisms linking reproductive aging and health.

This is a subcontract for participation in an substudy to the Study of Women's Health Across the Nation (SWAN), a multi-center, multi-ethnic longitudinal study designed to characterize the biological and psychosocial changes that occur during the menopausal transition. The substudy will obtain Anti-Mullerian Hormone (AMH) measurements to determine if they can be used to predict the final menstrual period.

This is the Coordinating Center for the Study of Women's Health Across the Nation, a study of aging in women. The aims of the second renewal of the multicenter longitudinal study are to complete the characterization of the natural history of reproductive aging through the late post-menopause, evaluate the impact of reproductive aging on health outcomes, and identify underlying mechanisms linking reproductive aging and health.

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This is a subcontract for participation in a planning grant to evaluate the feasibility of a research protocol that will lead to a large-scale clinical trial designed to evaluate the effectiveness of plasma versus no treatment in patients undergoing an invasive procedure.

**PRINCIPAL INVESTIGATOR:** Dr. JANE A. CAULEY  
**Outcomes of Sleep Disorders in Older Men - Pittsburgh Subcontract**

**Funding:** California Pacific Medical Center  
2803209-S107  
5/1/2009 - 4/30/2016 $843,382.00  
5/1/2013 - 4/30/2016 $117,752.00

This subcontract is for continuing participation as a subcontractor in an ancillary study to the Osteoporotic Fractures in Men Study (MROS) investigating the consequences of sleep disorders in older men, including possible effects on risk for cardiovascular disease, mortality, physical and cognitive decline and risk for osteoporosis and fractures.

**PRINCIPAL INVESTIGATOR:** Dr. JANE A. CAULEY  
**Testosterone Trial**

**Funding:** Penn  
563249  
5/15/2009 - 4/30/2016 $1,685,702.00  
6/15/2014 - 4/30/2016 $45,859.00

This is a subcontract for participation in cooperative agreement AG030644 as a site recruiting, screening and conducting a closely coordinated set of five randomized, placebo-controlled clinical trials to test the hypotheses that testosterone treatment for one year of men over 65 years who have low serum testosterone concentrations and both symptoms and objective evidence of mobility disability, age-associated memory impairment, low vitality, diminished sexual function, and anemia will show more favorable changes in these parameters than placebo treatment.

**PRINCIPAL INVESTIGATOR:** Dr. JANE A. CAULEY,  
**Study of Osteoporotic Fractures (SOF) - Pittsburgh Clinic**

**Funding Agency:** NIA  
R01 AG027576-31  
9/1/2011 - 5/31/2016 $1,030,149.00  
6/1/2015 - 5/31/2016 $207,844.00
This project will continue the prospective Study of Osteoporotic Fractures (SOF) and link the comprehensive SOF database with Medicare claims data to determine if age-related trajectories in cognitive function, physical performance, bone mineral density, body weight, and positive affect predict phenotypes of optimal aging defined by longevity, active lifespan, exceptional health span, and rates of inpatient and residential health care utilization.

**PRINCIPAL INVESTIGATOR:** JANE A. CAULEY, DR.P.H.

**Changes in Sleep and Cognition in Older Women**

**Funding:** California Pacific Medical Center

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This is an ancillary study to the Study of Osteoporotic Fractures (SOF) for participation in data analysis for a project focusing on the longitudinal relationships of sleep and cognitive function in older women.

**PRINCIPAL INVESTIGATOR:** Dr. JANE A. CAULEY

**Osteoporotic Fractures in Men (Mr.OS)**

**Funding Agency:** NIA

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This is the second renewal of a study to quantify the determinants of fracture in elderly men. The primary goals of this next phase of MrOS are to identify the determinants and characteristics of musculoskeletal aging trajectories; identify men at increased risk of adverse outcomes; improve understanding of optimal aging; and discover new targets for preventing fractures, declines in activity, disability, increases in health care utilization and placement in long-term care.
Determination of Skeletal Muscle Mass by Creatine Dilution

Funding: California Pacific Medical Center
280201005-S173 9/1/2015 - 8/31/2016  $11,469.00

This is a subcontract for participation in an ancillary study to the Osteoporotic Fractures in Men Study (MROS) using a novel measure of total body skeletal muscle mass to evaluate the relationship to clinical outcomes and identify men at risk of physical decline.

Long-Term Significance of Pre-Radiographic Lesions for Knee OA

Funding: Northwestern University
60036404UP 6/1/2015 - 5/31/2016  $119,593.00

This is a subcontract for participation in grant #R01 AR065473, a long-term, longitudinal study to evaluate the clinical significance of pre-radiographic lesions in persons at higher risk for knee osteoarthritis.

Risk of Incident Knee OA Based on Imaging Biomarkers

Funding: University of Arizona
R01 AR066601-01 9/15/2014 - 7/31/2015  $96,975.00

This subcontract is for participation as a clinical center in a study testing whether structural changes detectable by MRIs predict the onset of radiographic knee osteoarthritis and the development of important clinical outcomes many years later.
PRINCIPAL INVESTIGATOR: Dr. JANE A. CAULEY  
Bone Strength through the Menopausal Transition: Trabecular Bone

Funding Agency: NIA  
R01 AG026463-06  
8/1/2015 - 4/30/2019  $1,485,230.00  
8/1/2015 - 4/30/2016  $461,301.00

This is an ancillary study to the Study of Women's Health Across the Nation (SWAN), a multi-center, multi-ethnic longitudinal study designed to characterize the biological and psychosocial changes that occur during the menopausal transition. Using archived lumbar spine DXA scans and data collected annually from the SWAN cohort, the study will use the trabecular bone score (TBS), a new index of trabecular bone structure to test several novel hypotheses about race/ethnic differences in trabecular microarchitecture and changes across the menopausal transition.

PRINCIPAL INVESTIGATOR: Dr. TINA COSTACOU  
Extreme Phenotypes Relevant to Diabetic Complications in T1D

Funding: University of Dundee  
17-2013-309  
3/1/2013 - 2/29/2016  $56,637.00  
3/1/2015 - 2/29/2016  $18,874.00

This is a subconract for participation in a collaborative research project funded by the Juvenile Diabetes Research Foundation with the aim to identify those at the extremes of liability to diabetic complications in three cohorts and to carry out biomarker discovery studies from these extreme groups.

PRINCIPAL INVESTIGATOR: TINA COSTACOU, PH.D.  
Kidney Iron by Haptoglobin Genotype (KIRHA)

Funding: Georgia Regents  
25732-78  
10/1/2015 - 5/31/2016  $72,037.00  
10/1/2015 - 5/31/2016  $72,037.00

This is a pilot study funded as a subcontract under the DiaComp Pilot and Feasibility Program grant (DK076169) to obtain preliminary data testing the hypothesis that the Haptoglobin genotype is associated with increased kidney iron deposition leading to declining kidney function and progression to end-stage renal disease in type 1 diabetes.
The goal of this study is to characterize the protein composition, subfraction concentrations and sizes, and function of HDL in the postmenopausal stage as compared with the premenopausal stage by conducting state-of-the-art proteomic analysis as an ancillary study to the Study of Women Across the Nation (SWAN) to test the hypothesis that HDL becomes dysfunctional in postmenopausal women.

The Department of Epidemiology Data Center participates as a subcontractor in study design, data management, and data analysis for this research with the long-term goal to establish a pan-Caribbean glaucoma laser program.

This is a subcontract for participation in grant R01 HL119453 to integrate the Group Lifestyle Balance program in a stepped care program for depression using problem-solving therapy as first-line with as-needed intensification in doses and number of antidepressant medications.
This is a subcontract for participation in grant R01 MH104574 to conduct Group Lifestyle Balance training for a healthy lifestyle program in supportive housing for people with serious mental illnesses.

PRINCIPAL INVESTIGATOR: Dr. M. KAYE KRAMER
Research to Promote the Health of People with Disabilities

Funding: University of Texas Health Center
0010409A 9/30/2014 - 9/29/2017 $41,841.00
9/30/2014 - 9/29/2015 $13,581.00

This is a subcontract for participation in cooperative agreement U01 DD001007 to conduct Group Lifestyle Balance training for a healthy lifestyle program for people with mobility impairment.

PRINCIPAL INVESTIGATOR: Dr. ANDREA M. KRISKA
Physical Activity and Sedentary Behavior Change
Funding Agency: NIDDK

R18 DK100933-02 9/1/2014 - 7/31/2018 $1,975,342.00
8/1/2015 - 7/31/2016 $498,503.00

The goal of this study is to understand the impact of movement, specifically physical activity and sitting time, in community lifestyle intervention efforts by examining the impact of a modified version of the Group Lifestyle Balance program focusing on decreasing sedentary behavior which may be as important as participation in moderate intensity activity.

PRINCIPAL INVESTIGATOR: Dr. LEWIS H. KULLER
CHS Events Follow-up Renewal
Funding: University of Washington

R01 HL080295-09 6/1/2009 - 11/30/2016 $682,668.00
12/1/2013 - 11/30/2016 $177,927.00

This is the renewal of a subcontract for participation in cooperative agreement U01 HL080295 designed to continue events follow-up for the Cardiovascular Health Study, an NHBLI-funded cohort study of risk factors for coronary heart disease and stroke in adults 65 years or older.

PRINCIPAL INVESTIGATOR: Dr. IVA MILJKOVIC
Ectopic Adiposity in Black Men with High Type 2 Diabetes Risk

Funding Agency: NIDDK
The main objective of this study is to use archived CT scan image files from over 1,500 black men in the Tobago Health Study to analyze changes in lower leg skeletal muscle adiposity over time and to obtain new CT measures of visceral, liver, pericardial and abdominal muscle adiposity in the entire Tobago Health Study cohort.

PRINCIPAL INVESTIGATOR: Dr. ANNE B. NEWMAN

Aspirin in Reducing Events in the Elderly

Funding: MMRF
U01AG029824
9/15/2009 - 1/31/2017 $230,608.00
2/1/2015 - 1/31/2016 $12,263.00

This project is for participation as a subcontractor in a randomized double-blind placebo-controlled trial of aspirin in primary prevention in healthy people aged 70 years and over to determine whether the potential benefits of low dose aspirin to extend the duration of disability-free life in an aging population will outweigh the risks of severe bleeding in this age group.

Exceptional Survival: Trajectories to Functional Aging (CHS)

Funding Agency: NIA
R01 AG023629-09
9/1/2011 - 5/31/2016 $4,167,390.00
8/15/2015 - 5/31/2016 $733,800.00

This is the renewal of a study investigating functional aging, or disability-free survival by examining long-term survivors of the Cardiovascular Health Study to determine the likelihood of maintaining function, identify the trajectories that distinguish those destined to do well, and define the importance, independence and interactions of physiologic predictors of function.
This is the renewal of an investigation of the exceptional survival of families in the Long Life Family Study (LLFS) cohort. A second examination of the families will be conducted to discover genetic and environmental factors that contribute to healthy aging. These studies could lead to the discovery of new pathways and potential therapeutic/prevention targets affecting healthy aging and longevity.

This third renewal will continue and enhance the Center for Aging and Population Health Prevention Research Center focusing on promoting healthy aging within communities and establishing a new core research program designed to reduce obesity and subsequent chronic disease in old age implementing a weight management intervention in the community setting.

This is the renewal of the long-term follow-up study of the original DCCT intervention trial population. Follow-up testing and evaluation of this diabetic population is conducted in the Diabetes Research Center clinical facility.
PRINCIPAL INVESTIGATOR: Dr. TREVOR J. ORCHARD
Epidemiology of Diabetes Complications (EDC) Phase II: Renewal

Funding Agency: NIDDK
R37 DK034818-31 
6/1/2014 - 5/31/2019 $2,086,225.00  
6/1/2015 - 5/31/2016 $405,275.00

This is an extension of the Epidemiology of Diabetes Complications (EDC) study which has examined risk factors contributing to diabetes complications for 25 years. The extension focuses on further assessment of complication development for a total follow-up period of 30 years with a focus on the roles of glycemic, oxidative and inflammatory stress along with women's health issues and an evaluation of skin advanced glycosylation end products as a complication predictor.

PRINCIPAL INVESTIGATOR: Dr. CATERINA ROSANO
Imaging Biomarkers of Accelerated Brain Aging in Type 1 Diabetes

Funding Agency: NIDDK
R01 DK089028-04 
7/7/2010 - 3/31/2016 $1,521,727.00  
4/1/2013 - 3/31/2016 $336,676.00

This research will quantify the nature, severity and risk factors of brain abnormalities in the ongoing longitudinal Epidemiology of Diabetes Complications (EDC) cohort study as adults with Type 1 Diabetes (T1D) are increasingly more likely to develop brain abnormalities in addition to multiple micro- and macro-vascular complications.

PRINCIPAL INVESTIGATOR: Dr. CATERINA ROSANO
Resilience to Mobility Impairment: Neural Correlates

Funding Agency: NIA
R01 AG037451-05 
5/1/2011 - 4/30/2016 $1,990,138.00  
5/1/2015 - 4/30/2016 $454,100.00

This is a longitudinal neuroepidemiological study to identify the brain characteristics and risk factors of older adults who have maintained good mobility in the face of substantial structural brain abnormalities. A supplement funds reanalysis of extensive longitudinal neuroimaging data using newly developed software.

PRINCIPAL INVESTIGATOR: Dr. CATERINA ROSANO
Ultra High Field Neuroimaging in Elderly after Two Year Exercise

Funding Agency: NIA
R01 AG044474-02 
8/15/2014- 5/31/2017 $613,246.00  
6/15/2015 - 5/31/2016 $211,052.00
This project will quantify the relationship of physical activity with ultra high-field brain markers, quantify the relationship of memory and processing speed with these markers, and explore the role of the markers in explaining brain response to physical activity.

PRINCIPAL INVESTIGATOR: Dr. CATERINA ROSANO

**Retinal Imaging Markers of Cognition in Adults with T1D**

Funding Agency: NIDDK

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This is an exploratory study using existing data to develop a risk score of cognitive impairment and neurovascular abnormalities in middle-aged patients with Type 1 diabetes using existing repeated measures of retinal vascular imaging collected over 30 years and adding new follow-up data on cognitive function by conducting cognitive assessments at participant visits.

PRINCIPAL INVESTIGATOR: Dr. THOMAS J. SONGER

**Targeting Obesity and Blood Pressure in Urban Youth**

Funding: Case Western

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This is a subcontract for participation in grant NIH R01 HL103622 which focuses on the treatment of obesity and elevated blood pressure in urban youth. The subcontract work includes development and analysis of the economic assessment measures applied in the study to assess the costs and cost-effectiveness of three different interventions targeting the child-family environment.

PRINCIPAL INVESTIGATOR: Dr. THOMAS J. SONGER

**Family Management and Glycemic Control in Youth with T1D**

Funding: Indiana University

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This is a subcontract for participation as a health economist in a grant funded by the Helmsley Charitable Trust. The goal of the project is to evaluate the cost effectiveness of interventions to affect the change in glucose levels in youth.
Peripheral Nerve Decline: A Cause of Injurious Falls

The renewal of this ancillary study to the Health Aging Body Composition Study (Health ABC) is designed to determine if poor peripheral sensory and motor nerve function is associated with treated fall injuries, including fractures, and with greater total and fall-related Medicare utilization, Medicare expenditures, and mortality, with the ultimate goal to determine if peripheral nerve testing identifies older adults at higher risk for fall injuries, fractures and death that may benefit from preventive measures for nerve decline.

Sarcoidosis and A1AT Genomics & Informatics Center

This project aims to learn more about the causes and progression of two potentially deadly yet under-studied lung diseases, alpha-1 antitrypsin deficiency and sarcoidosis to help identify new treatments and explore the relationship between the bacteria that live in the lungs, gene activation patterns and disease progression.

Analysis and Characterization of Trauma-Induced Coagulopathy

This is a subcontract for participation in data coordination for the Trans-Agency Research Consortium for Trauma-Induced Coagulopathy (TACTIC). The Epidemiology Data Center will oversee network coordination, data management and analysis, sample collection reimbursement systems, and manuscript preparation.
This is a subconract to serve as the Biostatistics Core for a partnership to examine and integrate data from existing military, civilian, and sports traumatic brain injury databases to identify effective measures of brain injury and recovery, using biomarkers from blood, new imaging equipment and software, and other tools.

**PRINCIPAL INVESTIGATOR:** Dr. STEPHEN R. WISNIEWSKI

**Vitamin D to Prevent Severe Asthma Exacerbations in Children DCC**

**Funding Agency:** NHLBI

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This cooperative agreement funds the Data Coordinating Center for a randomized double-masked placebo-controlled clinical trial designed to determine whether vitamin D supplementation will prevent severe asthma exacerbations in high-risk school-aged children who have vitamin D insufficiency and who are on inhaled corticosteroids for mild to moderate persistent asthma.

**PRINCIPAL INVESTIGATOR:** Dr. STEPHEN R. WISNIEWSKI

**Network Management Core for the Pulmonary Trials Cooperative**

**Funding Agency:** NHLBI

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This project is for the establishment of a Network Management Core (NEMO) which has primary responsibility for organizing and operating the multi-center Pulmonary Trials Cooperative (PTC). The three general areas of responsibility include clinical center supervision, network and trial administration, and biospecimen management.

**PRINCIPAL INVESTIGATOR:** Dr. JOSEPH M. ZMUDA

**Epidemiology of Bone Loss in African Men**

**Funding Agency:** NIAMS

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<td>9/1/2014</td>
<td>8/31/2016</td>
<td>$405,150.00</td>
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This renewal continues a study of the determinants of trabecular and cortical volumetric bone mineral density, bone structural geometry, and the rate of bone loss with aging among men of African descent. The study will continue the Tobago Bone Health Study, a unique-population-based study of bone mineral density in 2,500 men ages 40-92 years who are primarily of African heritage.