

## Health Research Nonformula Grants - State Fiscal Year 2005-06

The Pennsylvania Department of Health selected five collaborative research projects for funding in response to the Request for Application (RFA) # 04-07-15 for Centers of Excellence for Research on Obesity. All research projects addressed the following research priority established by the Department in conjunction with the Health Research Advisory Committee:

Research into the prevention and treatment of obesity and its complications. Research may include, but is not limited to, research in the following areas:

- Prevention-related health services research applicable to community-, school- and employer-based interventions using techniques that promote and sustain changes in behavior, physical activity, and nutrition; practical approaches for the implementation of effective strategies with applications to underserved populations; and community participatory research and studies that test and evaluate the cost effectiveness of interventions conducted in community, neighborhood and nontraditional settings. School-based approaches should be targeted to all students; not only to obese or overweight children. Research to document disparities will not be considered unless it is part of the research effort to understand, develop and evaluate an intervention to eliminate the disparity.
- Obesity-related health services research to evaluate methods to improve management of obesity and its consequences; novel restructuring of health care delivery, including attention to obesity in primary care; and broad population approaches to address the rising prevalence of obesity.
- Clinical research to test novel treatments for obesity including drugs that affect appetite and metabolism. Intervention studies should include novel approaches to weight loss and further understanding of pathophysiology that may improve maintenance of long-term weight loss and decreased morbidity due to obesity. Studies to evaluate the efficacy of bariatric surgery and other existing obesity therapies will not be considered.
- Translational research that would apply knowledge gained from basic research on obesity to the citizens of Pennsylvania, with an emphasis on comparing high- and low-risk populations. Particular emphasis should be placed on biomarkers and other novel research approaches to the mechanisms of obesity and of obesity-related diseases (for example, diabetes, cardiovascular disease, cancer and osteoarthritis).
- Basic research to gain greater insight into the fundamental mechanisms of obesity, appetite, satiety, metabolic control, and other relevant physiological mechanisms; studies related to adipocyte biology and the molecular and genetic factors leading to obesity, including novel hormones, proteins, and genes related to diabetes and metabolic disorders; and studies aimed at understanding the regulation of energy metabolism and the interrelationships between obesity and disease especially type II diabetes and the metabolic syndrome.

Research should emphasize populations that are at high risk for and/or disproportionately affected by obesity. Research may be focused on children, adults or all age groups. Outcomes, i.e., prevention of weight gain or amount of weight loss, must be measured at various intervals, and there must be a clear indication of how they are to be measured and anticipated effects. Applicants must establish a regional Center of Excellence to conduct research in collaboration with other research institutions and organizations. The Center of Excellence must include partners that are from smaller colleges and universities. The Center of Excellence should also include biotechnology and bioengineering companies, or other institutions that are not academic medical centers, in addition to major research institutions. The research may include participation by behavioral scientists, exercise scientists, dietitians and nutritionists with expertise in obesity prevention or treatment. The research should hold the potential for population-based applications that address disparities in obesity among underserved segments of the population, including rural, urban, racial/ethnic minorities, or other high-risk Commonwealth populations. The Center of Excellence must build research

capacity for health disparities research related to obesity through the mentoring and training of students and collaboration with predominantly minority-serving academic institutions in Pennsylvania. At least 50 percent of each grant's funds must be spent on clinical and/or health services research as defined in Act 2001-77; no more than 50 percent of each grant's funds may be spent on biomedical research, as defined in Act 200 1-77.

The following list of grant awards provides the lead and collaborating institutions, title of the research project, amount of the grant award, grant award period, contact person and a description of the project.

- Children's Hospital of Philadelphia, Geisinger Health System, Lincoln University and the University of Pennsylvania - Primary Care Network for the Treatment of Adolescent Obesity, \$4,151,919 for a 48-month project (June 1, 2006 — May 31, 2010)

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The broad objective is to establish a Center of Excellence for Research on Obesity at The Children's Hospital of Philadelphia (CHOP) that will create a statewide, collaborative research network to develop and test effective treatments for reducing adolescent obesity and related medical co-morbidities in underserved populations. Collaborating institutions include Lincoln University (LU), Geisinger Health System (GHS), and the University of Pennsylvania (UPenn). Given the locations of these institutions, we will focus on urban African Americans and Latinos and rural Caucasian adolescents. The novelty of this program will be the use of a family-based, lifestyle modification program within the pediatric primary care setting with interdisciplinary teams trained to treat obese adolescents. Specific aims are to: a) design, implement, and evaluate improved treatments for obese teenagers, b) conduct focus groups and treatment development projects to better understand the needs of these populations and c) train, minority students and faculty to become healthcare research professionals. The primary research project will be a randomized clinical trial occurring at two sites: CHOP and GHS. In a four-year study, 220 adolescents (ages 13-17) will be randomized to either a one-year, 23 session, multi-family, group based Lifestyle Modification Program (LMP), or to a one-year, five-session Enhanced Usual Care (EUC). Both LMP and EUC will be tested as possible treatment protocols for primary care pediatric practice.

The primary aim is to compare the effectiveness of these two treatments in reducing body mass index (BMI) at 6, 12 and 18 months. Secondary aims will compare impact of the treatments on reduction of risk factors related to cardiovascular disease and diabetes, including lipids, glucose and insulin, waist circumference, blood pressure, and measures of appetite. Training aims will be met through collaboration with Lincoln University to set up undergraduate summer internships, graduate assistantships, and faculty development. Other methods for achieving the objectives of the Center include: a) establishing a multidisciplinary advisory board consisting of parents, providers, and researchers; b) providing clinical training in obesity treatment for doctors, nurses, dietitians, and behavioral interventionists at our collaborating institutions (CHOP and GHS); c) making all protocols and materials culturally sensitive to the populations they serve; and d) carrying out treatment development activities to tailor the manuals for Latino youth and their families.

- Temple University, Bloomsburg University, Cheyney University of Pennsylvania, Geisinger Medical Center and Insight Telehealth - Treating Obesity and Its Consequences in Underserved Populations, \$4,151,920 for a 48-month project (June 1, 2006 — May 31, 2010)

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Obesity has reached epidemic proportions with nearly two-thirds of the US population either overweight or obese. Ethnic minorities are disproportionately affected with 37% of African-American adults being obese. In Pennsylvania, the prevalence of obesity increased from 14.7% in 1991 to 24.0% in 2002, and annual medical expenditures attributable to obesity are estimated at \$4.2 billion; making Pennsylvania the 4th highest cost/state in the country.

The goal of this project is to reduce weight and improve insulin sensitivity in overweight adults who live in medically underserved communities. Overweight and obese men and women (n=400) will participate in a 16-week behavioral weight management program that includes a low-fat diet and increased physical activity. To increase accessibility in our underserved population, the program will be given at local churches and community centers. After the 16-week weight loss program, subjects will be randomly assigned to two different weight loss maintenance programs (In-person versus Telemedicine) for an additional one year.

Accordingly our specific aim is to compare, in 400 overweight and obese persons who have completed a 16-week behavioral weight loss program, the effects of "In-Person" contact with a supervised Telemedicine weight maintenance program on weight loss, body composition and insulin sensitivity (assessed by QUICKI). Hypothesis: We predict that those in the telemedicine group will experience greater reductions in body weight, body fat and greater improvements in insulin sensitivity than those in the in-person group. We expect these results will to be due to greater changes in diet and physical activity, which will be mediated through greater participation in and adherence to treatment and telemedicine usage.

- Thomas Jefferson University, Cheyney University of Pennsylvania, Health Promotion Council of Southeastern Pennsylvania, Inc., Pennsylvania Advocates for Nutrition and Activity, Philadelphia Department of Public Health, Beckman Coulter and Thomas Jefferson University Hospital - Adipokines and Genotypes: Injury vs. Protection in Obesity-Related Co-Morbidity, \$4,151,919 for a 48-month project (June 1, 2006 — May 31, 2010)

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The goal of this Center of Excellence (COE) in Obesity Research is to develop knowledge to advance treatments and to reduce racial disparities in obesity and obesity-related

medical conditions, or co morbidities. The COE goal will be accomplished through four objectives. Objective 1 is to conduct research on biomarkers that promote obesity related co-morbidities and also biomarkers that protect against obesity related co-morbidities. The research aims are:

a) Identify a clinical phenotype of obesity that predicts tissue injury and adverse health outcome from obesity; b) Identify intermediate phenotypes or biomarkers (proteins called adipokines produced by fat cells) that mediate injury or protect against injury; c) Identify genes (genetic polymorphisms) that control fat cell secretion of adipokines; d) Determine if weight reduction and/or blood pressure (BP) reduction in obese adults alters the intermediate phenotype. Young adult African Americans will be enrolled and stratified according to body mass (obese or lean) and BP status (high BP or normal BP). Clinical measures, biomarkers, and genetic measures will be obtained before and following weight reduction (for obese) and blood pressure control (for the hypertensive). Objective 2 supports research aim d and applies the Chronic Care Model in primary care clinics to reduce obesity and to treat obesity-related comorbidities in minority young adults. Support for the weight reduction intervention will be augmented by links to existing community based programs. Objective 3 is to establish a Data Resource and Management Center (DRMC) that will function to manage and analyze data for the research project and evaluate the feasibility, effects, and costs of the Clinic-Community Intervention Program (CCIP). Objective 4 is to establish collaborations for education and training between Cheyney University and other COE participants. The Research Project, CCIP and DRMC provide opportunities for Cheyney students and faculty to engage in collaborative research projects with the objectives of enhancing science education at Cheyney and increasing the numbers of Cheyney students who pursue careers or graduate education in science.

- University of Pennsylvania, Albert Einstein Healthcare Network, Cheyney University of Pennsylvania and Independence BlueCross - Modeling Effective Obesity Treatment to Reduce Disparities through Primary Care, \$2,000,000 for a 48-month project (June 1, 2006 — May 31, 2010)

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Research objectives are to:

- 1) Create a sustainable infrastructure for oversight and support of novel research on obesity treatment in primary care.
- 2) Identify a feasible, effective, and sustainable approach to obesity treatment of urban primary care settings, with particular relevance to African American and Latino adults
- 3) Foster student and faculty training and career development in the field of obesity and health disparities research.

The Specific Aim is to demonstrate in a randomized controlled trial (of 240 participants) the effectiveness of a Lifestyle Modification Program for the management of obesity in primary care practice, as compared with a usual care intervention (i.e., an Educational Program).

- University of Pittsburgh, Cheyney University of Pennsylvania, Children's Hospital of Pittsburgh, Cook Myocite, Inc., The Hill House and The Kingsley Center – Preventing

Adverse Effects of Class II and Class III Obesity, \$4,151,919 for a 48-month project  
(June 1, 2006 — May 31, 2010)

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This project from the University of Pittsburgh and its partners will establish a Center of Excellence in Research on Obesity that will focus on severe obesity. The prevalence of severe obesity (i.e., Class 2 and 3 obesity; body mass index > 35 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup>) is increasing more rapidly than is overweight and Class 1 obesity. Treatment guidelines for severe obesity are uncertain. Less than 1% of the severely obese undergo bariatric surgery, which can not be viewed as a public health solution.

Three novel hypotheses regarding the pathogenesis of severe obesity will be tested: a) using non-invasive methods to measure energy expenditure; b) conducting an annotated lipomic search for bio-markers of impaired fat oxidation; and c) examining the role of obesity-induced inflammation as a cause for leptin resistance. Responses will also be measured following intervention with diet and activity.

Health risks of severe obesity, especially those that presage cardiovascular disease will be comprehensively surveyed prior to and in response to intervention. Reasons for heterogeneity in health risks will be sought, examining in this context the role of race and ethnicity. Also, the impact of severe obesity on quality of life will be assessed initially, and in response to treatment. These aspects of the project should lay a groundwork for evidence-based treatment guidelines for the severely obese.