



# Biomedical Research Advisory Council

## Strategic Research Goals and Tactics 2014

### Background

Since 2001, the Florida legislature has recognized the need to support vital research conducted in both academic and private institutions throughout the state through the James and Esther King Biomedical Research Program (Section 381.922, Florida Statutes) and the Bankhead-Coley Cancer Research Program (Section 215.5602, Florida Statutes). This funding has improved the health of Florida's families, expanded the research infrastructure of the state, and bolstered efforts to bring external research funding to the state.

The purpose of the James and Esther King Biomedical Research Program is to seek cures in tobacco-related diseases. Heart disease is the second leading cause of death in Florida. Diseases related to tobacco, such as emphysema, chronic obstructive pulmonary disease, and other chronic lower respiratory diseases, were the third leading cause of death in 2012. The King program funds research initiatives that seek new insights and innovative solutions in the prevention, diagnosis, treatment, and cure of Floridians afflicted by cardiovascular disease, stroke, lung disease and tobacco-related cancers.

The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program advances progress toward cures for cancer. Cancer is now the leading cause of death for Floridians, surpassing heart disease. Florida has the second highest cancer burden in the nation. In the three year period from 2009-2011 (the latest time period that national data are available), the total number of cancer deaths was 122,921. On average, 100,000 new cancers are diagnosed in Florida every year. Funding through the Bankhead-Coley program significantly improves cancer research and treatment in the state.

The Biomedical Research Advisory Council (BRAC) (Section 215.5602, Florida Statutes) advises the State Surgeon General as to the direction and scope of the biomedical research program.

### BRAC Membership:

Daniel Armstrong, Ph.D., Chair, Professor and Associate Chair, Pediatrics, Director, Mailman Center for Child Development, University of Miami Miller School of Medicine. Seat: American Cancer Society Representative.

Mark Brantly, M.D., Co-Chair, Chief, Division of Pulmonary and Critical Care Medicine University of Florida, College of Medicine. Seat: American Lung Association Representative.

Charles Wood, Ph.D., Professor and Chair, Department of Physiology and Functional Genomics, University of Florida College of Medicine. Seat: American Heart Association Representative.

Barbara Centeno, M.D., Director of Cytopathology and Anatomic Pathology Quality Assurance/Moffitt Cancer Center, Professor of Oncologic Sciences and Pathology and Cell Biology/University of South Florida. Seat: House of Representatives

Randal H. Henderson, M.D., MBA, Associate Medical Director, Proton Therapy Institute Professor of Radiation Oncology, University of Florida, Jacksonville. Seat: House of Representatives.

Albert Latimer, B.B.A., Senior Vice President, External Affairs & Investor Relations Enterprise Florida, Inc. Seat: Governor.

Edith Perez, M.D., Deputy Director at Large, Mayo Clinic Cancer Center; Director, Breast Cancer Translational Genomics Program, Serene M. and Frances C. Durling Professor of Medicine, Mayo Clinic, Jacksonville. Seat: Senate.

Penny Ralston, Ph.D., Director, Dean Emeritus and Professor, Center on Better Health & Life for Underserved Populations, Institute of Science & Public Affairs, Florida State University. Seat: Senate.

Claes Wahlestedt, M.D., Ph.D., Professor and Vice Chair (Research), Dep. of Psychiatry and Behavioral Sciences, Associate Dean for Therapeutic Innovation, Director, Center for Therapeutic Innovation, Hussman Institute for Human Genomics, University of Miami Miller School of Medicine. Seat: Governor.

## **Introduction**

The purpose of this strategic plan for Florida's biomedical research funding is to specify defined objectives to be accomplished in specific time frames. This will allow the people of Florida to evaluate the health impacts of the research funded through the James and Esther King Program and the Bankhead-Coley Cancer Research Program.

This strategic plan defines the Biomedical Research Advisory Council's substantive areas of focus, and specifies timeframes for evaluating success at one year, three years, five years, and ten years to guide funding opportunities issued by the Department of Health. The strategic plan focuses on the health impact of research and making Florida a destination for cancer care and research. Although this research agenda articulates substantive areas of focus, decisions about fund awards are always made through a competitive, peer-reviewed process. Because cancer and tobacco-related diseases have disparate impacts on Floridians, health equity and opportunity are addressed throughout, including efforts to foster collaborations among institutions, researchers, and community practitioners. This strategic plan demonstrates our commitment to transparency in communicating program priorities. One priority is to increase collaboration by enhancing the ability of Florida researchers to participate in existing alliances and groups, and prevent duplication of studies.

Some substantive goals will take years to realize because the answers we seek require fundamental discoveries in basic science, translation to clinical studies, and then implementation in clinical practice. The time from basic science to implementation in clinical practice can take ten years or more. To achieve the longer-term goals we have identified intermediate goals that can be used to evaluate progress.

During the first year, we recommend issuing a funding opportunity for incidence/prevalence measurement targets so we can improve our ability to measure the health impact of the Strategic Plan. Within three years we recommend issuing a funding opportunity for descriptive studies of barriers, intervention targets, and treatment/intervention trials. Within five years we recommend funding to conduct interim measurement of strategic outcomes, including:

- 20% of Florida-funded investigator studies (between 2008-2016) leading to follow-on extramural (NCI Comprehensive qualifying grants excluding State of Florida funded grants)
- Improvements in health outcomes based on funded projects
- Progress on collaborative research efforts
- Florida's progress on becoming a destination site for cancer care and cancer research

### **Strategic Goals**

- Conduct research with a focus on prevention and improved treatment or care delivery that contributes to decreased deaths in lung cancer by 15%, breast cancer by 15%, prostate cancer by 20%, colon cancer by 25%, and melanoma by 15% within 10 years.
- Develop research that contributes to reductions in deaths due to lung cancer by 30%, breast cancer by 30%, prostate cancer by 30%, colon cancer by 30%, and melanoma by 30% resulting from health disparities due to race, ethnicity, or income within 10 years.
- Improve screening accuracy, detection of high risk subgroups, and/or improved implementation of cancer screening program that result in a 20% increase in early detection of cancer or preventable cancer within 10 years.
- Establish at least five Investigational New Drug(IND)/Investigational Device Exemption (IDE)s based on Florida investigator drug discovery, biologic, or other therapeutics that result in at least two multi-center collaborative clinical trials within 10 years.
- Develop innovative basic and clinical research studies focused on lower incidence of high mortality/high morbidity cancers (e.g., sarcomas, pancreatic tumors, CNS tumors, myeloma, leukemia/myelodysplastic syndrome) that result in significant improvement in survival/quality of survival in adults and children in at least two of these cancers.
- Design research protocols that lead to academic-industry development of five new biotechnology products/companies that subsequently obtain incremental commercial funding (beyond Florida funding) within 10 years.
- Reduce tobacco use in children and adolescents to less than 4% and adults to less than 15% within 10 years.
- Enhanced understanding of the relationship between obesity, healthy weight, and cancer.
- Expand upon research that improves scientific understanding of causes and subsequent impact of cancer/cancer-treatment related morbidities in other systems (e.g, cardiovascular, pulmonary, endocrine, lymphatic, CNS, reproductive, developmental).

## Tactics

- Fund peer-reviewed grants for shared research infrastructure
  - Existing: genetics/genomics, imaging & and imaging bank, radiation oncology, organize existing tissue banks, drug development, pathology cores
  - New: develop statewide genomics bank (full sequencing of cancer patients) with linkages to trial treatment and outcomes- pharmacogenomics and epigenomics (part of clinical trials infrastructure)- also applies to health disparities
  - New: Statewide bioinformatics for cancer
  - Utilize and expand existing clinical trials infrastructure for: Phase I/Phase II, Phase III/IV trials in the state
  - New: develop and expand investigator/community research network infrastructure to support health disparities research with high-risk populations that have multiple barriers to engagement.
  - Integrated planning grants for strategic goals and outcome reporting
  - Common quality indicator data system
  - Improve regulatory process (e.g., State institutional review board or multi-center)
- Fund recruitments in areas that are not existent or inadequate for those goals (shared resource for the state)
  - Program recruitments that target strategic objectives
  - Recruitment/training of research support staff, research for core shared resources: augment currently existing programs, outcome goal for entire program
- Fund investigator initiated projects prioritized by potential impact:
  - Discovery science
  - New drug development
  - Prevention and Cancer Control
  - Screening and Detection
  - Health Services Outcomes and Access To Care
  - Clinical Trials
  - Comparative Effectiveness Research
  - Population Science
  - Health Disparities
  - Obesity
- Funds for different research model
  - New Investigators
  - Bridge funding
  - Investigator-initiated
  - Team Science
  - Technology Transfer
  - Comparative Effectiveness Research
  - Targeted Request for Applications
- Fund research that optimizes public-private partnerships in discovery science and health services research
  - Tech transfer
  - Health system, insurer
- Funding for conferences, cancer strategic plan summit
- Transdisciplinary interactions