# Table of Contents

FLORIDA STATUTES ................................................................................................................................. 2  
FLORIDA BIOMEDICAL RESEARCH PROGRAM .................................................................................. 2  
ADVISORY COUNCIL MEMBERSHIP ................................................................................................. 3  
LIST OF RECIPIENTS AND PROJECTS ............................................................................................... 4  
FLORIDA NATIONAL RESEARCH FUNDING DATA ............................................................................ 6  
PUBLICATIONS REPORTED BY GRANTEES ....................................................................................... 7  
FOLLOW-ON FUNDING AWARDS REPORTED BY GRANTEES ............................................................ 18  
PROGRAM PERFORMANCE OUTCOMES ............................................................................................... 21  

Appendix A: Letter to State Surgeon General, Dr. John Armstrong (page 22)
215.5602  JAMES AND ESTHER KING BIOMEDICAL RESEARCH PROGRAM.∗—
(10) The council shall submit a fiscal-year progress report on the programs under its purview to the
Governor, the State Surgeon General, the President of the Senate, and the Speaker of the House of
Representatives by December 15. The report must include:
(a) A list of research projects supported by grants or fellowships awarded under the program.
(b) A list of recipients of program grants or fellowships.
(c) A list of publications in peer reviewed journals involving research supported by grants or fellowships
awarded under the program.
(d) The state ranking and total amount of biomedical research funding currently flowing into the state
from the National Institutes of Health.
(e) New grants for biomedical research which were funded based on research supported by grants or
fellowships awarded under the program.
(f) Progress towards programmatic goals, particularly in the prevention, diagnosis, treatment, and cure
of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary
disease.
(g) Recommendations to further the mission of the programs.
*Report includes Bankhead Coley Florida Cancer Research annual data

FLORIDA BIOMEDICAL RESEARCH PROGRAM (FBRP)
The mission of the Biomedical Research Program is to provide increasingly significant levels of funding to
Florida research institutions for the performance of high-quality and high-impact biomedical research and
technology development to improve prevention, diagnosis, treatment, and cure of cancer and tobacco-
related diseases including cardiovascular disease, stroke, and pulmonary disease.

The Florida Biomedical Research Programs:

- James and Esther King Biomedical Research Program (s. 215.5601, F.S.)
- Bankhead-Coley Cancer Research Program (s. 381.922, F.S.)
- Managed by the Florida Department of Health
- Key partners are American Heart Association, American Lung Association, and American Cancer
  Society
- Website = www.floridabiomed.com
- Email = FBRP@doh.state.fl.us
- The program has awarded 476 grants investing $177.44 million in projects at 22 Florida Institutions

How our grants work:
We offer Florida Researchers merit-based grants, without regard for institutional affiliation, to address the
prevention, diagnosis, treatment, and cure of cancer and tobacco-related diseases.

Grants Award Processes:
- Grants awarded using a competitive process through a “Request for Applications” (RFA)
- All research applications are scientifically peer reviewed (scientific experts) to attain the scientific
  merit of all research applications
- Funding recommendations, based primarily on scientific merit score, provided by the Biomedical
  Research Advisory Council (BRAC) to the State Surgeon General, who makes the final award
decisions
Demonstration of Accountability:

 Grant Monitoring: Grantee progress reports are peer reviewed annually against research milestones and site visits are made to select grantees to evaluate scientific progress. Annual renewals of multi-year grants are dependent on satisfactory performance and availability of funds.

 Online Business Process: Secure web-based system provides user-friendly interface and streamlined processes for grant application, proposal review, grant management transactions, and database report generation.

 Program Evaluation and Performance Measurement: Documented policies and procedures set standards and guide consistent administration, and stakeholder feedback is collected to guide continuous improvement. Progress against metrics tied to program goals informs policy making and strategic planning.

BIOMEDICAL RESEARCH ADVISORY COUNCIL (BRAC)

Richard J. Bookman, Ph.D., Chair, Senior Advisor to the Dean, University of Miami Miller School of Medicine, Special Assistant to the Provost, University of Miami  
Seat: Advisory Council Chair and American Heart Association Representative

Daniel Armstrong, Ph.D., 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., Chief, Division of Pulmonary and Critical Care Medicine, University of Florida, College of Medicine  
Seat: American Lung Association Representative

Randal H. Henderson, M.D., MBA, Associate Medical Director, Proton Therapy Institute, Professor of Radiation Oncology, University of Florida, Jacksonville  
Seat: House – Cancer Program (ACoS)

Myra Hurt, Ph.D., Senior Dean, Research, Graduate, and Undergraduate Programs, Florida State University College of Medicine  
Seat: Research University

Alber Latimer, B.B.A., Senior Vice President, External Affairs & Investor Relations, Enterprise Florida, Inc.  
Seat: General Public

Edith Perez, M.D., Professor of Medicine, Hematology/Oncology, Mayo Clinic, Jacksonville  
Seat: Senate – Cancer Program (ACoS)

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 - Behavioral/Social Research

Mary Lou Sole, R.N., Ph.D., CCNS, FAAN, Professor, College of Nursing, University of Central Florida  
Seat: House – Professional Medical Organization

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: Biomedical Research

Herbert Weissbach, Ph.D., Distinguished Research Professor and Director, Center for Molecular Biology and Biotechnology, Florida Atlantic University  
Seat: Advisory Council Vice-Chair
<table>
<thead>
<tr>
<th>Grantee</th>
<th>Project Title</th>
<th>Institution</th>
<th>Award Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarah McLaughlin</td>
<td>Enhancing the Ability to Predict Lymphedema Development Following Axillary Surgery for Breast Cancer and its Effects on Patient Survivorship</td>
<td>Mayo Clinic</td>
<td>$ 397,473</td>
</tr>
<tr>
<td>Joseph Pidala</td>
<td>Regulatory T Cells for Prevention of Acute Graft-Versus-Host Disease</td>
<td>Moffitt Cancer Center &amp; Research Institute</td>
<td>$ 343,280</td>
</tr>
<tr>
<td>Radka Stoyanova</td>
<td>Metabolic Tumor Volumes in Radiation Treatment of Brain Tumors</td>
<td>University of Miami</td>
<td>$ 400,000</td>
</tr>
<tr>
<td>Yijun Sun (Transferred to Aysegul Gunduz)</td>
<td>Derivation of Molecular Signatures for Accurate Breast Cancer Prognosis</td>
<td>University of Florida</td>
<td>$ 200,862</td>
</tr>
<tr>
<td>Kristen Wells</td>
<td>Developing and Piloting a Patient Navigation Program for Breast Cancer Survivors</td>
<td>University of South Florida</td>
<td>$ 360,000</td>
</tr>
<tr>
<td>Kevin Brown</td>
<td>Epigenetic Basis of Neoplastic Progression in Human Cancers</td>
<td>University of Florida</td>
<td>$1,500,000</td>
</tr>
<tr>
<td>Olveen Carrasquillo</td>
<td>South Florida Center for the Elimination of Colorectal Cancer Health Disparities (SUCCESS-CRC)</td>
<td>University of Miami</td>
<td>$1,500,000</td>
</tr>
<tr>
<td>Lori Hazlehurst</td>
<td>Targeting the Tumor Microenvironment in Multiple Myeloma</td>
<td>Moffitt Cancer Center &amp; Research Institute</td>
<td>$1,500,000</td>
</tr>
<tr>
<td>Jin Cheng</td>
<td>MicroRNA-155 in Breast Cancer</td>
<td>Moffitt Cancer Center &amp; Research Institute</td>
<td>$  180,000</td>
</tr>
<tr>
<td>Christopher Cogle</td>
<td>A Phase I/II Clinical Study of OXi4503 in AML and MDS</td>
<td>University of Florida</td>
<td>$  180,000</td>
</tr>
<tr>
<td>Michael Crary</td>
<td>Sensory Alterations and Swallow Functions in RT Treated Head/Neck Cancer Patients</td>
<td>University of Florida</td>
<td>$  155,250</td>
</tr>
<tr>
<td>David Gilbert</td>
<td>Replication Profiling as a Diagnostic Tool in B-cell Acute Lymphoblastic Leukemia</td>
<td>Florida State University</td>
<td>$  129,171</td>
</tr>
<tr>
<td>Emina Huang</td>
<td>The Role of IL8 in Colitis-Associated Tumor Initiation</td>
<td>University of Florida</td>
<td>$  180,000</td>
</tr>
<tr>
<td>Huabei Jiang</td>
<td>Combined Photoacoustic and Diffuse Optical Tomography</td>
<td>University of Florida</td>
<td>$  155,250</td>
</tr>
<tr>
<td>Michael Kladde</td>
<td>Interplay of Epigenetic Mechanisms in Gene Silencing</td>
<td>University of Florida</td>
<td>$  180,000</td>
</tr>
<tr>
<td>Javier Pinilla-Ibarz</td>
<td>Epigenetic Modifiers to Augment the Immunogenicity of Chronic Lymphocytic Leukemia</td>
<td>Moffitt Cancer Center &amp; Research Institute</td>
<td>$  180,000</td>
</tr>
<tr>
<td>E. Aubrey Thompson</td>
<td>MicroRNAs in Lobular Involution and Breast Cancer</td>
<td>Mayo Clinic</td>
<td>$ 129,375</td>
</tr>
<tr>
<td>Michael Wallace</td>
<td>Confocal Endomicroscopy for Colorectal Neoplasia</td>
<td>Mayo Clinic</td>
<td>$  179,848</td>
</tr>
<tr>
<td>Lizi Wu</td>
<td>Regulation of Notch Pathway Transcription Factor CSL in Normal and Malignant Cells</td>
<td>University of Florida</td>
<td>$  180,000</td>
</tr>
<tr>
<td>Xiangxi Xu</td>
<td>Ovarian Cancer: Nuclear Envelope Defects</td>
<td>University of Miami</td>
<td>$  180,000</td>
</tr>
<tr>
<td>Charles Rosser</td>
<td>Development of a Panel of Monoclonal Antibodies to a Validated Bladder Cancer Diagnoistic Signature</td>
<td>M.D. Anderson Cancer Center</td>
<td>$  100,000</td>
</tr>
<tr>
<td>Yanxia Liu</td>
<td>Development of scale-up synthetic method for Largazole, a novel drug for the treatment of colorectal cancer</td>
<td>University of Florida</td>
<td>$  100,000</td>
</tr>
<tr>
<td>Name</td>
<td>Project Title</td>
<td>Institution</td>
<td>Amount</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Lori Hazlehurst</td>
<td>Targeting CD44 with HM-27 in AML</td>
<td>H. Lee Moffitt Cancer Center and Research Institute</td>
<td>$100,000</td>
</tr>
<tr>
<td>David Reisman</td>
<td>Validate BRM polymorphism as a Biomarker for lung cancer risk</td>
<td>University of Florida</td>
<td>$100,000</td>
</tr>
<tr>
<td>Lei Zhou</td>
<td>A Novel in vivo Assay system for screening epigenetic modulators that de-repress tumor suppressor genes</td>
<td>University of Florida</td>
<td>$100,000</td>
</tr>
<tr>
<td>Johnathan Lancaster</td>
<td>From BAD to Good: Developing an Assay to Predict Ovarian-Cancer-Chemo-Resistance and Survival</td>
<td>Moffitt Cancer Center &amp; Research Institute</td>
<td>$99,999</td>
</tr>
<tr>
<td>Peter Sayeski</td>
<td>Improving the Metabolic Stability of the Jak2 inhibitor, G6</td>
<td>University of Florida</td>
<td>$100,000</td>
</tr>
<tr>
<td>Wei Li</td>
<td>Global Profiling of Colorectal Cancer Biomarkers</td>
<td>University of Miami</td>
<td>$100,000</td>
</tr>
<tr>
<td>John Barrett</td>
<td>Economical device using phosphorescence to measure cellular respiration</td>
<td>University of Miami</td>
<td>$99,987</td>
</tr>
<tr>
<td></td>
<td><strong>James &amp; Esther King Biomedical Research Program Grants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paolo Serafini</td>
<td>A nanobased immunodiagnostic approach for monitoring the immune response in HNSCC</td>
<td>University of Miami</td>
<td>$100,000</td>
</tr>
<tr>
<td>Chuanhui Dong</td>
<td>Gene-Smoking Interactions and Atherosclerosis</td>
<td>University of Miami</td>
<td>$360,000</td>
</tr>
<tr>
<td>Jamie Fernandez</td>
<td>Neuroendocrine Disruption and Nicotine Preference in a Rat Model of Postpartum Depression</td>
<td>University of South Florida</td>
<td>$360,000</td>
</tr>
<tr>
<td>Monica Hooper</td>
<td>Serotonergic Function and Impulsive Responding in Treatment-Seeking Smokers</td>
<td>University of Miami</td>
<td>$359,998</td>
</tr>
<tr>
<td>Jinliang Li</td>
<td>CIP4 Scaffold Protein Regulation of Cardiac Myocyte Hypertrophy and Survival</td>
<td>University of Miami</td>
<td>$360,000</td>
</tr>
<tr>
<td>Dmitriy Minond</td>
<td>Inhibitors of ADAM Proteases for Lung Cancer Therapy and Research</td>
<td>Torrey Pines Institute for Molecular Studies</td>
<td>$360,000</td>
</tr>
<tr>
<td>J Mocco (Transferred to Brian Hoh)</td>
<td>Hematopoietic Stem Cell Function Following Acute Stroke Therapy</td>
<td>University of Florida</td>
<td>$359,262</td>
</tr>
<tr>
<td>Charles Saunders</td>
<td>Improving Surveillance Measures of Tobacco Use in Florida’s Adolescent Population</td>
<td>Florida State University</td>
<td>$360,000</td>
</tr>
<tr>
<td>Gary Wang</td>
<td>Molecular Identification of Subgingival Bacteria Associated with Progression of Periodontitis in Smokers</td>
<td>University of Florida</td>
<td>$360,000</td>
</tr>
<tr>
<td>Dileep Yavagal</td>
<td>Intra-arterial Mesenchymal Stem Cell Delivery in a Canine Model of Acute Ischemic Stroke</td>
<td>University of Miami</td>
<td>$360,000</td>
</tr>
<tr>
<td>Gregory Conner</td>
<td>Regulation of Airway Lactoperoxidase Host Defense</td>
<td>University of Miami</td>
<td>$180,000</td>
</tr>
<tr>
<td>Zhongwei Li</td>
<td>RNA Quality Control Against Oxidative Damage</td>
<td>Florida Atlantic University</td>
<td>$103,500</td>
</tr>
<tr>
<td>Roberto Vazquez-Padron</td>
<td>Leukadherins as Novel Compounds for Treating Restenosis</td>
<td>University of Miami</td>
<td>$180,000</td>
</tr>
<tr>
<td>Jie Wu</td>
<td>Modulation of ErbB Signaling and Lung Cancer by Shp2</td>
<td>Moffitt Cancer Center &amp; Research Institute</td>
<td>$180,000</td>
</tr>
<tr>
<td>Antonis Zervos</td>
<td>A New Signaling Pathway in Myocardial Ischemic Injury</td>
<td>University of Central Florida</td>
<td>$180,000</td>
</tr>
<tr>
<td>Keith Pennypacker</td>
<td>GLG-302 as a Novel Treatment for Stroke</td>
<td>University of South Florida</td>
<td>$100,000</td>
</tr>
<tr>
<td>Name</td>
<td>Project Description</td>
<td>Institution</td>
<td>Funding ($)</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Lori Hazlehurst</td>
<td>Preclinical Testing of HM-27 in Lung Cancer Models</td>
<td>Moffitt Cancer Center &amp; Research Institute</td>
<td>$ 90,000</td>
</tr>
<tr>
<td>Lori Boules</td>
<td>Novel Therapy for Nicotine Addition in Alcholics</td>
<td>Mayo Clinic</td>
<td>$ 99,856</td>
</tr>
<tr>
<td>Yiwen Li</td>
<td>A Method of Producing Recombinant RdCVF Protein</td>
<td>University of Miami</td>
<td>$ 100,000</td>
</tr>
<tr>
<td>Jeffrey Goldberg</td>
<td>Functionalized Magnetic Nanoparticles as a Therapeutic Tool to Improve Axon Regeneration After Stroke</td>
<td>University of Miami</td>
<td>$ 100,000</td>
</tr>
<tr>
<td>Masanobu Komatsu</td>
<td>Development of Novel Lung-Targeted Biologics for Idiopathic Pulmonary Fibrosis</td>
<td>Sanford-Burnham Medical Research Institute</td>
<td>$ 100,000</td>
</tr>
</tbody>
</table>

**FLORIDA NATIONAL RESEARCH FUNDING DATA**  
*Florida’s Rank in Funding, 2011*¹  

<table>
<thead>
<tr>
<th>National Agency</th>
<th>Funding (in millions)</th>
<th>State Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institutes of Health</td>
<td>$493</td>
<td>13</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention</td>
<td>$305</td>
<td>4</td>
</tr>
<tr>
<td>National Science Foundation</td>
<td>$150</td>
<td>13</td>
</tr>
<tr>
<td>Agency for Healthcare Research and Quality</td>
<td>$1</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$949</strong></td>
<td><strong>12</strong></td>
</tr>
</tbody>
</table>

*FL State Population (as of June 1, 2011): 18,801,310  
State rank in population: 4*

**NIH Research Funding and Population of Selected States**  

<table>
<thead>
<tr>
<th>State</th>
<th>2010 Census population (in millions)²</th>
<th>NIH Funding in federal fiscal year 2012 (in millions)³</th>
<th>Funding $ Per capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>37.2</td>
<td>$ 2,400</td>
<td>$64.52</td>
</tr>
<tr>
<td>Texas</td>
<td>25.3</td>
<td>$  783</td>
<td>$30.95</td>
</tr>
<tr>
<td>New York</td>
<td>19.3</td>
<td>$1,536</td>
<td>$79.59</td>
</tr>
<tr>
<td>Florida</td>
<td><strong>18.8</strong></td>
<td><strong>$ 493</strong></td>
<td><strong>$18.40</strong></td>
</tr>
<tr>
<td>Illinois</td>
<td>12.8</td>
<td>$  557</td>
<td>$43.52</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>12.7</td>
<td>$1,101</td>
<td>$86.69</td>
</tr>
<tr>
<td>Ohio</td>
<td>11.5</td>
<td>$  504</td>
<td>$43.83</td>
</tr>
<tr>
<td>Georgia</td>
<td>9.7</td>
<td>$  327</td>
<td>$33.71</td>
</tr>
<tr>
<td>North Carolina</td>
<td>9.5</td>
<td>$  723</td>
<td>$76.11</td>
</tr>
</tbody>
</table>

PUBLICATIONS REPORTED BY GRANTEES
The following list represents new publications in peer-reviewed journals and books reported between July 2011 and June 2012 based on funded research from King and Bankhead Coley Program research. Publication titles are presented in bold print.


E6-AP facilitates efficient transcription at estrogen responsive promoters through recruitment of chromatin modifiers. Catoe HW, and Nawaz Z. Steroids. 2011; 76(9):897-902.


Bone marrow stem cell mobilization in stroke: a 'bonehead' may be good after all! Borlongan CV. Leukemia. 2011; 25(11):1674-86.


Link between insulin resistance and hypertension: What have we learned from our ancestors. Zhou MS, Schulman IH. J Autacoids. 2012; 2012:01:00.


Protein Kinase D signaling in cancer. Storz, P. Cell Signaling and Molecular Targets in Cancer by Springer. 2012.


Clinicogenetic and pathologic characteristics of CADASIL. Roberts K, O'Rourke K, and Ross OA. Neurogenetics of Stroke. 2012; Publisher: J Pub Springer.


Cardiovascular magnetic resonance for the assessment of pulmonary arterial hypertension: toward a comprehensive CMR exam. Ibrahim EH and White RD. Magn Reson Imaging. 2012; [Epub ahead of print].


Myxoma virus lacking the Pyrin-like protein M013 is sensed in human myeloid cells by both NLRP3 and multiple TLRs, which independently activate the inflammasome and NF-KB innate response pathways. Rahman MM, McFadden G. J Virol. 2011; 85(23):12505-17.


The following list represents **$33.89 million** in additional single and multi-year awards reported from July 2011-June 2012 by current and past grantees from projects funded by the James and Esther King and Bankhead-Coley Program. Grants are presented in alphabetical order by last name of the Grantee.

**Bannister, Thomas.** BC, (2010, NIR), "Targeting Slx 16a/Mct Lactate transporters in cancer Therapeutics." National Institutes of Health and National Cancer Institute, $390,000.00.

**Bannister, Thomas.** BC, (2010, NIR), "Identification and optimization of inhibitors of the LAT1 essential amino acid transporter as anti-breast cancer therapeutic agents." Department of Defense, $75,000.00.


**Borlongan, Cesar.** King, (2010-11, RPG), "Battlefield-Related injury Translational Research, Post-Traumatic Disease and Disability - Veterans Re-Integration Strategy." DOD, $1,500,000.00.

**Borlongan, Cesar.** King, (2010-11, RPG), "Blood Brain Barrier Repair in Cell Therapy for Stroke." National Institutes of Health, $2,200,000.00.


**Guldiken, Rasim.** BC, (2010, NIR), "Large Stroke Microscale Actuators Based on Electrowetting." National Science Foundation, $354,121.00.

**Hare, Joshua.** King, (2009, Shared Instrument), "Cell Based Therapy for Non-Ischemic Dilated Cardiomyopathy." National Institutes of Health, $4,284,000.00.


**Hu, Jennifer.** BC, (2006, Shared Instrument), "A Novel Assay to Detect Multiple Viral Gene Expression in Cancer." Women's Cancer Association at University of Miami, $50,000.00.

**Hu, Jennifer.** BC, (2006, Shared Instrument), "Regulation of Melanoma Heterogeneity and Metastasis by Stromal Fibroblasts in Tumor Microenvironment." Women's Cancer Association at University of Miami, $50,000.00.


Li, Wei. King, (2010-11, TTF), "Anti-retinal autoantibodies as AMD biomarkers." American Health Assistance Foundation, $100,000.00.


Ning, Shunbin. BC, (2010, NIR), "Targeting an oncogenic miRNA by IRFs promotes survival of tumor virus-transformed cells." American Society of Hematology, $150,000.00.


Salihu, Hamisu. King, (2010-11, RPG), "Delineating the genetic pathway for folate-induced fetal brain growth among smoking mothers participating in a randomized clinical trial." University of South Florida, Office of Research & Innovation, $25,000.00.


Wang, Liyong. King, (2010-11, NIR), "Vitamin D Concentration, Genetic Modifiers, and Parkinson Disease." National Institutes of Health, $983,365.00

Yu, Hong-Guo. BC, (2008, NIR), "Mechanism of spindle pole body duplication and separation in yeast meiosis." National Science Foundation, $675,000.00.
PROGRAM PERFORMANCE OUTCOMES

Florida Statistics:

- In 2011, cancer surpassed heart disease as the leading cause of death in the state of Florida accounting for almost 23.8 percent of all deaths
- Cancer was the leading cause of death for individuals aged 45-84 accounting for 30.8 percent of the total deaths in this age group

James & Esther King:

- $196.8m received in follow-on funding
- 2,376 new jobs created, for every research job in Florida
- 66% of Florida investigators completing King grants have earned additional, non-state funds based on their finding, averaging $700,000 each
- More than 250 scientists at 22 different institutions throughout the state have led King Program projects, aided by hundreds more graduate and post-doctoral students
- 860 peer-reviewed journals
- 1,331 scientific presentations on grant findings
- 18 early partnership’s created between academic researchers and small businesses
- Among 8 early partnership projects, 5 have formed new Florida companies and brought $13.8M in additional external funding
- $16.62M awarded for Collaboration Grants
- National recognition for State Science and Technology Institute (SSTI) as the winner of its 2009 Excellence in Tech-Based Economic Development

Florida Statistics:

- In 2011, cancer surpassed heart disease as the leading cause of death in the state of Florida accounting for almost 23.8 percent of all deaths
- Cancer was the leading cause of death for individuals aged 45-84 accounting for 30.8 percent of the total deaths in this age group

William “Bill” Bankhead, Jr., & David Coley:

- $140.5M in follow-on funding has been awarded directly related to Coley grants
- 1,600 new jobs created (for every research job in Florida, 2.12 new jobs are created)
- 755 people working on cancer projects
- 410 peer-reviewed journal articles on the findings of their sponsored projects
- 272 researchers invited to give presentation at scientific meetings on their research
- 48 new investigators have launched independent cancer research careers in Florida
- Provided funds to 154 senior researchers who, in addition to their own work, employ and train lab professionals and students
- Provided Collaboration Research grants resulting in more than 70 researchers meeting monthly as a team to concentrate on an aggressive form of breast cancer
- 37 Health Disparities projects in two years
- 62% of grants in 2010 classified as translating laboratory discoveries
Appendix A

Richard J. Bookman, Ph.D.
Senior Advisor for Program Development and Science Policy

State Surgeon General John Armstrong, M.D.
Florida Department of Health
2585 Merchants Row Blvd.
Tallahassee, FL 32399

Dear Dr. Armstrong,

Thank you for participating in the September 26th meeting of the Department’s Biomedical Research Advisory Council (BRAC). Your leadership was welcomed and energizing. We fully concur that the time is ripe to move forcefully to improve health through biomedical research and to lessen the impact of disease, particularly cancer.

As a result, a subcommittee meeting to respond to your charge was organized, noticed, and held on October 12th. This letter reflects that dialogue as well as full BRAC review, revisions and approval of the work performed by the subcommittee.

WHAT WE HEARD
We heard loud and clear that you want to take bold action to create a “Florida System of Cancer Care”, designed and built to serve all Floridians, a system founded upon the best available science and protocols for treatment, and one which will continuously improve through outcomes-based measures and feedback.

We agree that it is appropriate to align the Bankhead-Coley Cancer Research Program (covering all cancers regardless of cause) and the King Biomedical Research Program (all tobacco-related illnesses including cancer caused by tobacco) to the new, broader vision of cancer care and treatment you have articulated. In a number of important scientific and healthcare delivery respects, cancer can provide a model by which we can work to address other preventable disease, including cardiovascular disease, lung disease, and stroke.

The members of the BRAC see both real value as well as the economic necessity to focus and to coordinate our efforts both within the Department of Health and across the state. Our work to date has been influenced by our proactive collaborations with DoH’s Office of Minority Affairs, the university-based technology transfer directors, FLCURED, and BioFlorida. To extend this, we have reached out to CCRAB and will work together with them and other stakeholders going forward.

We also heard your request that the BRAC develop a research agenda to support the Florida System of Cancer Care. This agenda is to ask specific research questions relevant to Florida, to establish goals

October 26, 2012
and dates, and to seek proposals that address those questions. Incorporated into the agenda will be incentives for inter-institutional and interdisciplinary collaboration. We want to assure you, we can create focused Requests for Applications (RFAs) designed around this vision and these goals.

**WHAT WE DID**
The attached document, “BRAC’s Research Agenda in Support of Florida’s System of Cancer Care”, puts forward a range of research activities. We have consulted broadly with colleagues both in Florida and around the country from patient advocacy groups, big pharma, academia, venture capital, non-profits, health policy think tanks and others to take advantage of their expertise and diverse perspectives. It reflects BRAC’s best effort in the time since we met. The agenda provides background, suggested principles for research grants, and a three-pronged approach – Infrastructure, Talent, and Problem-Focused RFAs.

As you know, healthcare and the world of biomedical research are changing rapidly. As we prepared our recommendations to support the Florida System of Cancer Care, we felt it was important to try a) “to skate to where the puck will be”, to **seize emerging opportunities** in cancer care and research, and b) to factor in Florida’s specific needs and opportunities. Florida is what the US will look like in the next 20 years. Our diversity gives us the opportunity to **provide national research and clinical care leadership** to understand how such diversity may impact cancer etiology and disease outcomes. Florida can be ahead of the curve, **addressing transformative research questions** in a way that only Florida can.

The options described in the Research Agenda may have value either individually or taken together; however, the 13 ideas, if only seen as pieces, fail to be responsive to your call for a clear, simple, bold, and ambitious goal. Aligned, each can complement what we think is a unifying theme: personalization of medicine is the future and a patient’s genome is the key.

**WHAT WE PROPOSE:**
The overarching goal is, by 2025, to offer the genome sequencing option to all Floridians who present with a cancer diagnosis.

It’s a way of saying “If you’re a Floridian and you’re diagnosed with cancer, you can have your cancer genome sequenced.”

It’s a way of saying to the people of Florida “Cancer in Florida just got personal.”

It’s a way of saying to the world that “Florida is a cancer care destination” – or even more strongly, “Florida is the cancer care destination.”

Such individualized analysis not only personalizes cancer diagnosis and treatment, but also increasingly makes it **more effective – both for outcomes and cost – in all of Florida’s diverse communities.** This sequencing effort will need to be carefully ramped up, likely starting in selected clinical trials to ensure consistent approaches, and should include the malignant genome, epigenomics, as well as the patient’s normal genome.

Much collaborative effort is needed on protocols, data infrastructure, training, ethics, privacy, patient/community education and engagement, and getting all healthcare professionals ready to handle the data. A project like this **brings the Cancer Centers together with community oncologists** and primary care networks. The project will **spur economic development** through building the first industrial scale clinical genomics platform in the US. It may take us 10 years of planning, infrastructure
construction, and resource development to stand this effort up. But, **setting the goal now and getting to work immediately** on planning and implementation is something that we can do. The sooner we commit to this goal, the sooner Florida’s cancer patients and their families will start to benefit.

**NEXT STEPS**

As you stated, the BRAC is uniquely positioned to help make Florida a more attractive environment for biomedical researchers and those who fund them (public and private) and, in so doing, to make Florida a better place for patients to receive the most advanced and effective care.

Thank you for including us in your vision and on your team. With a signal from you, and in consultation with CCRAB and other stakeholders, we will start to craft the RFAs to take the first important steps to make this ambitious goal a reality.

Sincerely,

Richard J. Bookman, Ph.D.
Chair, and on behalf of
Florida Biomedical Research Advisory Council

cc: CCRAB – Dr. Thomas George, Chair
BRAC’s Research Agenda
in support of
The Florida System of Cancer Care

BRAC BACKGROUND: For more than a decade, the BRAC, supported by outstanding Department of Health staff and a dedicated contractor, has accumulated substantial experience in the design and running of research grant programs. Our efforts have won awards and national recognition. Our grant programs have been approved by the NCI as a funding source that counts towards NCI standards for research intensity. Also, our procedures pay scrupulous attention to any potential conflicts of interest, issues which now are bedeviling the cancer efforts in Texas. Finally, we have a proven return on investment of more than $2.5-to-$1 for getting federal research dollars as follow-on funding.

We therefore feel confident that we can contribute a proven system and operating procedures to produce calls for applications, create peer review criteria, run an unconflicted peer review process, make award recommendations in a blinded fashion based on merit, rigorously track progress of awardees, and utilize various outcome measures for continuous program improvement.

From our history, certain principles have evolved and we would like to share those before detailing our suggestions.

PRINCIPLES FOR FLORIDA BIOMEDICAL RESEARCH GRANT PROGRAMS:
1. **Competition** - Funds should be awarded through merit-based competition with proposal review carried out by out-of-state, unconflicted peer reviewers.
2. **Alignment and leverage** - Florida’s cancer research programs need to be agile and responsive to the environment (e.g., NIH funding, partnership opportunities, evolving FDA regulations, etc.).
3. **Collaboration** – Discovery is accelerated by rewarding people for working together, whether within or across institutions, disciplines or borders.
4. **Accountability** - Florida’s grant programs should use clear outcome measures such as follow on funding, translation of research, IP, startups, workforce development, reductions in morbidity and mortality, etc. as outcome measures.
5. **Openness and transparency** - Grant competitions should be open to all Florida-based investigators, institutions, and companies. And, importantly, results of publicly funded research should be made available to the public. Data sharing serves the patient’s interest.

This last principle is worth some extra attention. Clinical data, collected as part of the Florida System of Cancer Care, represent an important source of information for further knowledge creation. Re-use of such data for research purposes should be encouraged, open to all, including through partnerships with the private sector – both large and small. Similarly, translational and clinical research data need to be made broadly available, consistent with and mindful of intellectual property considerations. The mantra: “re-useful is the new useful” should inform our policy in this area, as it is increasingly doing with federal agencies, big pharma, the Institute of Medicine, and various patient advocacy groups. Transparency to avoid real or perceived conflicts of interest is an important required element.

We believe a three-pronged approach to competitive grant funding -- general infrastructure, talent, and problem-focused research projects -- will be highly effective as a means of driving a focused cancer research program to enhance cancer care in Florida, to support the big goal, and to improve cancer outcomes significantly.
I. INFRASTRUCTURE COMPONENT

1. Clinical Research Data Platforms:
   Platforms are enablers and data are the fuel for innovation. Our ability to capture detailed patient data, from the behavioral to the molecular, is increasing. Advances in genomics and related data-intensive sciences are emerging as keys to the challenge of personalized cancer diagnostics and therapeutics. The state is in a unique position to forge and to force a shared, standards-based cancer research data platform across the state. Such a platform may be developed based on phased requirements for interoperability, for example. It might build upon the base of DoH’s existing Florida Cancer Data System. With necessary privacy protections, aggregated patient-level data can accelerate evaluation and refinement of new treatment protocols. This type of initiative can attract outside partners including federal (e.g., NIH, PCORI, AHRQ, CMS), public/private partnerships (e.g., Project DataShare, DataLiquidityCoalition.Org), NGOs (e.g., Sage Bionetworks, Cancer Commons), or private (e.g., GSK’s new open data initiative.) Importantly, these clinical research data platforms, enhanced with ‘omics’ data, can ignite the virtuous cycle of bed-to-bench-to-bed information flow.

2. Shared Core Facilities:
   Certain assays, whether in support of laboratory research or as part of hi-tech clinical tests, require expensive cutting edge equipment, trained experts to operate, and adherence to strict QA/QC standards. Core facilities often require partial subsidy in order to operate at research scale and provide general access to a diverse set of users. Any state support for core facilities should avoid duplication, promote sharing, and require high standards for data reproducibility. The robust core facilities and integrated research programs of the CTSA Programs at UF and UM and the cancer research cores at Florida’s cancer centers can serve as seeds for state investment and statewide expansion. Further, earlier state investments in infrastructure, such as those for expression profiling and genomics, should be leveraged.

3. Clinical Trial Cooperation and Recruitment:
   A number of steps can be taken to increase cancer clinical trials participation in Florida. Master affiliation agreements between collaborative research and clinical trial sites, centralized data safety monitoring oversight resources, and reciprocity agreements among the various IRBs would all help to expedite the initiation of new clinical trials at many sites. These agreements should be part of a framework among cancer research organizations that make it possible to test new therapeutic ideas rapidly in a conflict-free manner. Lastly, the availability of community-informed clinical trial navigators for cancer patients as part of a statewide trials matching program will increase patient understanding and trial enrollment from all of Florida’s diverse communities.

II. TALENT COMPONENT

4. As our cancer efforts become better defined, it is certain that additional talent will accelerate our efforts. The Florida cancer effort could provide a portion of the resources needed for research institutions to accomplish cluster hires of teams of experts. Such institutional grants should require matching funds and utilize the 5 year funding window that FBRP statutes now permit. An open question is whether the cluster can have or should be required to have a multi-institutional base.

5. The BRAC strongly supports a continued focus on support for young investigators. While some of these may be hired in the context of a cluster hire program, many will not. Such support helps to level the playing field by making all of Florida’s institutions more competitive with wealthier ones with respect to start-up funds. These future stars of
cancer care and research, representing diverse backgrounds and training, need our support - particularly at a time of declining federal dollars for cancer research.

6. Cancer clinical trials need to be conducted throughout the state and we need to expand the clinical research workforce. There are numerous specialist roles beyond the MDs, RNs, and PhDs. Job training programs, recognition of all healthcare professionals as key cancer team members, consistent standards for credentialing, and curriculum development for health professional schools are needed. This training effort is a win/win for both patients and for economic development through job creation. Cancer centers and medical schools should provide leadership for this and content can be deployed through community colleges and online methods. Collaboration with FLASCO can help to achieve this goal.

7. The molecular evidence seems increasingly clear: if you’ve seen one patient’s cancer, you’ve seen one patient’s cancer. Our comprehensive system of cancer care needs to take the diversity of Florida’s population and communities into account. An approach to cancer screening and prevention in one neighborhood might be ineffective in another. We therefore need to train and deploy community engagement specialists as part of the system approach.

8. An increasing number of clinical practice areas are discovering the benefits of interprofessional education (IPE), forging strong teams of healthcare professionals. A curriculum development grant to support IPE training programs in next-gen cancer care will positively impact patients, cancer care, and the clinical research effort.

III. PROBLEM-FOCUSED COMPONENT

9. The data we have on hand today are clear: we have significant disparities in cancer outcomes based on various factors such as socioeconomic status, race, ethnicity, place of residence, etc. Some of the largest and earliest improvements in statewide cancer outcomes can be achieved through focused projects to reduce cancer disparities. The state is in a unique position to drive this effort and to demonstrate improvement towards health equity, setting an example for other states to follow.

10. Given the diversity of Florida’s population, we know that one size doesn’t fit all. We need to understand more about the specific needs of different communities and how best to engage people in those communities with respect to cancer prevention, screening and care. A focused RFA to develop models for community engagement can provide needed examples for emulation in other parts of Florida.

11. As our lives, and particularly our health, become increasingly digitized, issues of privacy and confidentiality may appear threatened. Since more and better data are so key to the evolution of Florida’s system of cancer care, we need to address the intersection of ethics, privacy and electronic health records. A modest, focused RFA can generate ideas to guide policy and practice.

12. As Florida’s biomedical researchers create new knowledge, some of it may be appropriate for commercialization and therefore require patent protection. But the complexity of biology has proven repeatedly that single patents rarely generate new drugs. Rather, it is bundles of IP that are more likely to be attractive for venture funding. We should consider funding a project to explore different models of IP pooling and continue our innovative ‘feasibility’ grants in partnership with the technology transfer directors.

13. Investigator-initiated research is an important element of a balanced research portfolio. Basic and translational research projects should focus on key molecular mechanisms, pathway elucidation, therapeutic obstacles or potential targets. We would suggest that this might be focused on a subset of cancers of high prevalence or cancer disparities in Florida such as lung, breast, prostate, and colorectal.