Biomedical Research Advisory Council

Bankhead-Coley Cancer Research Program

James and Esther King Biomedical Research Program

Annual Report 2015-2016

Rick Scott
Governor

Celeste Philip, MD, MPH
Surgeon General and Secretary of Health

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Florida Biomedical Research Program Overview

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 Bankhead-Coley Cancer Research (Bankhead-Coley) Program (Section 215.5602, Florida Statutes) and the James and Esther King Biomedical Research (King) Program (Section 381.922, Florida Statutes). In 2015-2016, this funding continued to improve the health of Florida's families, expanded the research infrastructure of the state, and advanced efforts to bring external research funding to the state. Research grants are issued based on a competitive peer-review process. Awards from the King and Bankhead-Coley Programs are based on scientific merit, as determined by independent peer review involving experts located outside Florida who are free from conflicts of interest. Researchers at any university or established research institute in the state are eligible to apply for state funding. In 2015-2016, the Legislature appropriated $17,139,397, which funded a total of 17 grants.

Per statute requirements, a 2015-2016 fiscal-year progress report is to be submitted that includes the following information:

- A list of recipients of program grants or fellowships
- A list of publications in peer reviewed journals involving research supported by grants or fellowships awarded under the program
- The state ranking and total amount of biomedical research funding currently flowing into the state from the National Institutes of Health
- New grants for biomedical research which were funded based on research supported by grants or fellowships awarded under the program
- Progress toward programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease
- Recommendations to further the mission of the programs

William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program

The Bankhead-Coley Cancer Research Program advances progress toward cures for cancer. Cancer is the second leading cause of death for Floridians, second to heart disease. Florida continues to have the second highest cancer burden in the nation. Funding through the Bankhead-Coley program significantly improves cancer research and treatment in the state by:

- Attracting new research talent and grant-producing researchers;
- Funding proposals that demonstrate the greatest ability to attract federal research grants;
- Encouraging the development of bioinformatics to allow researchers to exchange information;
- Facilitating technical collaboration, business development, and support for intellectual property related to research; and
- Aiding multi-disciplinary research through greater participation in clinical trials networks and reducing the disparate impact of cancer on certain groups.

The James and Esther King Biomedical Research Program

The purpose of the James and Esther King Biomedical Research Program is to advance cures in tobacco-related diseases. The King program funds research initiatives that seek new insights and

innovative solutions in the prevention, diagnosis, treatment, and cure of Floridians afflicted by tobacco-related diseases including cardiovascular disease, stroke, lung disease, and tobacco-related cancers, the leading causes of death in Florida and nationally.

Biomedical Research Advisory Council Membership as of June 2016

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

Richard Nowakowski, Ph.D. (Vice-Chair), Professor and Department Chair of Biomedical Sciences at Florida State University College of Medicine; Seat: Governor

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

Stephen J. Gardell, Ph.D., Senior Director, Scientific Resources & Associate Professor, Sanford-Burnham Medical Research Institute; Seat: House of Representatives

Paul B. Jacobsen, Ph.D., Professor, Division of Population Science, Moffitt Cancer Center and Research Institute; Seat: Governor

Abubakr A. Bajwa M.D., FCCP, Division Chief, Associate Professor of Medicine, Medical Director Pulmonary Hypertension and Interstitial Lung Disease Clinic, Division of Pulmonary, Critical Care and Sleep Medicine, University of Florida College of Medicine; Seat: American Lung Association

John R. Wingard, M.D., Price Eminent Scholar and Professor of Medicine, Deputy Director for Research, University of Florida Health Cancer Center; Director, Bone Marrow Transplant Program, Division of Hematology/Oncology, University of Florida College of Medicine; Seat: Senate – Cancer Program (ACoS)

Allison Eng-Perez, Principal, Deloitte & Touche, LLP; Seat: Governor

Barbara A. Centeno, M.D., Senior Member and Director of Cytopathology and Anatomic Pathology Quality Assurance, Moffitt Cancer Center; Seat: House of Representatives

David A. Decker, M.D., Attending Physician, Orlando Veterans Administration Medical Center; Seat: Governor

New Member Appointed After July 1, 2016

Susan Vadaparampil, Ph.D., M.P.H., Senior Member, Department of Health Outcomes and Behavior, Moffitt Cancer Center and Research Institute; Seat: Governor (Replaced Dr. Jacobsen's seat)

Strategic Goals

In 2014, the Biomedical Research Advisory Council (BRAC) created a strategic plan for Florida's biomedical research funding to specify defined objectives to be accomplished in specific timeframes. The strategic plan focuses on the health impact of research and making Florida a destination for cancer care and research. This strategic plan also demonstrates the Department's commitment to transparency in communicating program priorities, defines the BRAC's substantive areas of focus, specifies timeframes for evaluating success, and guides funding opportunities issued by the Department. The BRAC recommended that the following strategic goals be included in the funding opportunity announcement.

- Prevention & Treatment
    - Conduct research with a focus on prevention and improved treatment or care delivery that contributes to decreased deaths due to lung cancer by 15%, breast cancer by 15%, prostate cancer by 20%, colon cancer by 25%, and melanoma by 15% 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.
    - Enhanced understanding of the relationship between obesity, healthy weight, and cancer.
    - Improve screening accuracy, detection of high risk subgroups, and/or improved implementation of cancer screening programs that result in a 20% increase in early detection of cancer or preventable cancer within 10 years.
- Technology Transfer Feasibility
    - 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.
    - 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.
- Health Disparities
    - 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.
- Tobacco Use
    - Reduce tobacco use in children and adolescents to less than 4% and adults to less than 15% within 10 years.
- Treatment Related Morbidities
    - 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).

Fiscal Year 15/16 funding cycle awards were made to support the following research priorities:

9 Awards – Prevention and Treatment
4 Awards – Technology Transfer Feasibility (TTF)
1 Awards – Health Disparities
2 Awards – Tobacco Use
1 Award – Treatment-Related Morbidities

Biomedical Research Advisory Council

The Biomedical Research Advisory Council (Section 215.5602, Florida Statutes) advises the State Surgeon General regarding the direction and scope of the biomedical research program. The responsibilities of the council include, but are not limited to:

- Providing advice on program priorities and emphases
- Providing advice on the overall program budget
- Participating in periodic program evaluation
- Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program
- Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials
- Developing criteria and standards for the award of research grants
- Developing guidelines relating to solicitation, review, and award of research grants and fellowships to ensure an impartial, high-quality peer review system
- Reviewing reports of peer review panels and making recommendations for research grants and fellowships

Bankhead-Coley Cancer Research Program Fiscal Year 2015-2016			
Grant Recipients	**Research Projects**	**Institution**	**Award Amount**
Michael Antoni, Ph.D.	Stress Management Effects on Affective Status and Influenza Vaccine Response in Older Breast Cancer Patients	University of Miami	$1,618,155
David D. Tran, M.D., Ph.D.	Novel Strategies to Target Disseminated Tumor Cells in Triple Negative Breast Cancer	University of Florida	$1,617,981
Walter O'Dell, Ph.D.	Early Markers of Subclinical Pulmonary Vascular Radiation Toxicity in Breast Cancer	University of Florida	$1,310,643
Anthony Capobianco, Ph.D.	Lead Optimization and Preclinical Evaluation of Small Molecule Inhibitors of Notch Transcriptional Activation	University of Miami	$1,218,170
Nupam Mahajan, Ph.D.	Epigenetic Regulation of Androgen Receptor in Castration Resistant Prostate Cancer	H. Lee Moffitt Cancer Center & Research Institute	$1,205,595
Aubrey Thompson, Ph.D.	Predictive Markers of HER2-Targeted Therapy	Mayo Clinic Florida	$965,143
Michael P. Kladde, Ph.D.	Temporal Epigenetic Mechanisms in Breast Cancer Oncogenesis	University of Florida	$618,170
Alexander M. Ishov, PH.D.	Functions of Histone Variants in Castration-Resistance Prostate Cancer	University of Florida	$100,000
Daiqing Liao, Ph.D.	Target HDAC2 for Treating ER-Positive and Drug-Resistant Breast Cancer	University of Florida	$100,000

James and Esther King Biomedical Research Program Fiscal Year 2015-2016			
Grant Recipients	**Research Projects**	**Institution**	**Award Amount**
Maria Jose Miguez, M.D., Ph.D.	Biobehavioral Intervention For Smokers Living With HIV	Florida International University	$1,628,449
Julie Y. Djeu, Ph.D.	Nanoparticle-based targeting of miR183 for immunotherapy of lung cancer	H. Lee Moffitt Cancer Center & Research Institute	$1,231,336
Jong Park, Ph.D., M.P.H., M.S.	Biobank for African American Prostate Cancer Research in Florida	H. Lee Moffitt Cancer Center & Research Institute	$1,231,336
Jang-Yen Wu, Ph.D.	Granulocyte colony-stimulating factor (G-CFS) gene therapy for stroke	Florida Atlantic University	$1,231,336
David J. Drobes, Ph.D.	Facilitating Smoking Cessation with Reduced Nicotine Cigarettes	H. Lee Moffitt Cancer Center & Research Institute	$1,186,164
Daiqing Liao, Ph.D.	Pharmacologic inhibition of acetyltransferase CBP/p300 as a new therapeutic approach for breast cancer	University of Florida	$795,236
Shyam S. Mohapatra, Ph.D.	Microfluidic-Acoustic Biosensing-Multicell Tumoroid (MABMCT) Platform Targeting TME	University of South Florida	$100,000
Fraydoon Rastinejad, Ph.D.	Molecular Characterization of Nrf2 as a Drug Target in Cancer Therapeutic Resistance	Sanford Burnham Prebys Medical Discovery Institute	$100,000

Federal Research Funding 2015

State	NIH Funding	Rank	Total (NIH, CDC, NSF, AHRQ)*	Rank
California	$3,581,764,094	1	$3,891,905,345	1
Massachusetts	$2,519,342,334	2	$2,579,487,932	3
New York	$2,149,771,633	3	$2,734,502,129	2
Pennsylvania	$1,538,118,189	4	$1,633,737,641	4
North Carolina	$1,067,284,633	5	$1,176,758,751	7
Texas	$1,040,799,728	6	$1,197,032,537	6
Maryland	$984,919,207	7	$1,548,145,413	5
Washington	$862,176,970	8	$1,010,349,539	8
Illinois	$794,979,202	9	$906,014,462	9
Ohio	$694,751,046	10	$774,600,329	10
Michigan	$654,349,171	11	$739,694,569	11
Florida	**$527,733,701**	**12**	**$685,727,275**	**13**
Minnesota	$513,335,268	13	$577,721,320	14
Connecticut	$506,188,803	14	$516,097,284	17
Georgia	$497,568,909	15	$695,114,170	12
Tennessee	$483,022,887	16	$528,240,269	16
Missouri	$482,818,909	17	$529,841,700	15
Wisconsin	$415,365,292	18	$467,334,387	18
Colorado	$343,161,117	19	$409,329,864	21
Virginia	$296,219,739	20	$416,191,484	20

*www.report.nih.gov
*https://taggs.hhs.gov/2015AnnualReport/Portfolios
*http://dellweb.bfa.nsf.gov/AwdLst2/default.asp

Total Follow-on Funding Awards Reported by Grantees: $2,088,548.99

1. Shenkman, James and Esther King (2016) OneFlorida Clinical Data Network. Patient-Centered Outcomes Research Institute $1,599,999.99
2. Shenkman, James and Esther King (2016) Maximizing HPV Vaccination: Real-time Reminders, Guidance, and Recommendations. NCI $407,050
3. Meckes, Bankhead-Coley (2016) Blood Exomes and Neurodegenerative Disease. FDOH Moore Alzheimer's Disease Research Program $81,499

Publications in peer reviewed journals

Researchers reported 22 new publications in peer-reviewed journals between July 1, 2015 and June 30, 2016 based on Florida's research funding from the King and Bankhead Coley research programs.

1. Cohen, I., Kayode, O., Hockla, A., Sankaran, B., Radisky, D.C., Radisky, E.S., Papo, N. Combinatorial protein engineering of proteolytically resistant mesotrypsin inhibitors as candidates for cancer therapy. Biochem J. 2016 Mar 8. Pii: BJ20151410. [Epub ahead of print] PMID: 26957636
2. Liu, y., Zhao, Y., Skerry, B., Wang, X., Colin-Cassin, C., Radisky, D.C., Kaestner, K.H., Li, Z. Foxa1 is essential for mammary duct formation. Genesis. 2016 Feb 26 doi: 10.1002/dvg.22929. [Epub ahead of print] PMID: 26919034
3. Radisky, D.C., Visscher, D.W., Frank, R.D., Vierkant, R.A., Winham, S., Stallings-Mann, M., T.L., Nassar, A., Vachon, C.M., Denison, L.A., Hartmann, L.C., Frost, M.H., Degnim, A.C. Natural History of Age-Related Lobular Involution and Impact on Breast Cancer Risk. Breast Cancer Res. Treat. 2016, 155:423-430. PMID: 26846985
4. Mazar, J., Qi, F., Lee, B., Marchica, J., Govindarajan, S., Shelley, J., Li, J.L., Ray, A., Perera, R.J. MicroRNA 211 Functions as a Metabolic Switch in Human Melanoma Cells. Mol Cell Biol. 2016;36(7):1090-108.
5. Zhao W, Mazar J, Lee B, Sawada J, Li JL, Shelley J, Govindarajan S, Towler D, Mattick JS, Komatsu M, Dinger ME, Perera RJ. The Long Noncoding RNA SPRIGHTLY Regulates Cell Proliferation in Primary Human Melanocytes. J Invest Dermatol. 2016;136(4):819-28.
6. Sung, H, Kanachi, K.L., Wang, X., Hill, K.S., Messina, J., Lee, J.-H., Kinm, Y., Dees, N., Ding, L., Teer, J., Yang, S., Sarnik, A., Sondak, V.K., Mule, J.J., Wilson, P.K., Weber, J.S., Kim, M. Inactivation of RASA1 promotes melanoma tumorigenesis via R-Ras activation. Oncotarget In Press.
7. Degnim, A.C., Dupont, W.D., Radisky, D.C., Vierkant, R.A., Frank, R.D., Frost, M.H., Winham, S.J., Sanders, M.E., Smith, J.R., Page, D.L., Hoskin, T.L., Vachon, C.M., Ghosh, K., Hieken, T.J., Denison, L.A., Carter, J.M., Hartmann, L.C., Visscher, D.W. Extent of atypical hyperplasia stratifies breast cancer risk in 2 independent cohorts of women. Cancer. 2016 Jun 28. Doi: 10.1002/cncr.30153. [Epub ahead of print] PMID: 27352219
8. Degnim, A.C., Visscher, D.W., Radisky, D.C., Frost, M.H., Vierkant, R.A., Frank, R.D., Winham, S.J., Vachon, C.M., Dupont, W.D., Hartmann, L.C. Breast cancer risk by the extent and type of atypical hyperplasia. Cancer. 2016 Jun 28. Doi: 10.1002/cncr.30151. [Epub ahead of print]. PMID: 27352099
9. Cichon, M.A., Moruzzi, M.E., Shqau, T.A., Miller, E., Mehner., C., Ethier, S.P., Copland, J.A., Radisky, E.S., Radisky, D.C. MYC IS a Crucial Mediator of TGFB-Induced Invasion in Basal Breast Cancer. Cancer Res. 2016 Jun 15;76(12):3520-30. PMID: 27197167

10. Pretence H, Modi J, Menzie J, Chou H, Marshal M, Weiss A and Wu J --Y: Nueroprotective mechanisms of action of G-CSF, DETC-MeSO, Sulindac, Taurine and AEURA. SciTz Neurology and Neurosciences. (in press).
11. Garcia-Arcos I., Geraghty P., Baumlin N., Campos M., Dabo A.J., Jundi B., Cummins N., Eden E, Salathe M. and Foronjy R. The nicotine in e-cigarette vapor triggers inflammation, airway hyperreactivity and lung tissue distruction. Thorax in revision.
12. Grosche A, Baumlin-Schmid N, Krick S, Dennis JS and Salathe M. Effects of Nicotine-Containing E-cigarette Vapor on Mucociliary Clearance in NHBE Cells. Accepted to ATS International Conference in San Francisco May 2016.
13. Lu Chen, Courtney A. Kurtyka, Eric A. Welsh, Jason I Rivera, Brienne E. Engel, Teresita Munoz-Antonia, Sean J Yoder, Steven A Eschrich, Ben C. Creelan, Alberto A. Chiappori, Jhanelle E. Gray, Jose Luis Ramirez, Rafael Rosell, Matthew B. Schabath, Eric B. Haura, Dung-Tsa Chen, and W. Douglas Cress. EnF score predicts benefit of adjuvant chemotherapy in lung adenocarcinoma. Lancet Oncology. (Feb 10, 2016)
14. Mehta HJ, Begnaud A, Penley AM, Wynne J, Malhotra P, Fernandez-Bussy S, Cope JM, Shuster JJ, Jantz MA. Treatment of isolated mediastinal and hilar recurrence of lung cancer with bronchoscopic endobronchial ultrasound guided intratumoral injection of chemotherapy with cisplatin. Lung Cancer. 2015 Dec;90(3):542-7. Doi: 10.1016/j.lungcan.2015.10.009. Epub 2015 Oct 9. PMID: 26477968
15. NK cells stimulated with PM21 particles expand and biodistribute in vive: clinical implications for cancer therapy. Cytotherapy. Accepted with revisions.
16. Pandey, V. Oyer, J.L., Igarashi, R.Y., Gitto, S.B., Copik, A.J., Altomare, D.A. Anti-ovarian tumor response of donor peripheral blood mononuclear cells is due to infiltrating cytotoxic NK cells. Oncotarget, in press.
17. Salvador-Reyes, L.A., Luesch, H. Biological Targets and Mechanisms of Action of Natural Products from Marine Cyanobacteria. Nat. Prod. Rep. 2015, 32, 478-503.
18. Wang B, Lee CW, Witt A, Thakkar A, Ince TA. Heat shock factor 1 induces cancer stem cell phenotype in breast cancer cell lines. Breast Cancer Res Treat. 2015 Aug; 153(1):57-66.
19. Chen, L., Borcherds, W., Wu, S., Becker, A., Schonbrunn, E., Daughdrill, G., Chen, J. Auto inhibition of MDMX by intra-molecular p53 mimicry. Proc. Natl. Acad. Sci. USA. In press. PMID:25825738
20. Pereira LHM, Reis IM, Rearegui EP, Gordon C, Sint-Victor, Duncan R, Gomez C, Bayers, Fisher P, Aymee, Perez A, Goodwin WJ, Hu JJ, Franzmann EJ. Risk Stratification System for Oral Cancer Screeneing. Cancer Prev Res 2016; 9: 1-11.
21. Franzmann E. Saliva as a diagnostic tool. MLO Med Lab Obs. 2015;47:24-5.
22. Lechner SC, Pereira L, Reategui E, Gordon C, Byrne M, Webb Hooper M, Le DJ, Abouyed M, Franzmann EJ. Acceptability of a Rinse Screening Test for Diagnosing Head and Neck Squamous cell Carcinoma Among Black Americans. Journal of Racial and Ethnic Health Disparities 2015;2:62-7.

Appendix I

Biomedical Research Long-term Impact Assessment

Executive Summary

Prepared Fall 2016

Key Findings

The Biomedical Research Advisory Council recommended that a survey be conducted in the summer of 2016 to assess the long-term benefits of research grants awarded by the Florida Department of Health through the James and Esther King Biomedical Research (King) Program and the Bankhead-Coley Cancer Research (Bankhead-Coley) Program. This report summarizes key survey results, particularly as they relate to economic impact and contributions to the field of study.

A total of 146 grant recipients responded to the survey, accounting for about 31% of the 471 total number of recipients from 2001 to 2015. Most respondents received grants through the King program (58%), with the remainder receiving grants through the Bankhead-Coley program (42%). Over three-quarters of respondents began receiving funding between 2006 and 2012, and 69% of respondents had funding end between 2008 and 2013. Regarding the grant funding received, **60% reported that research has continued beyond their original funding period, and is still being conducted.**

The most common mechanisms of support awarded were Discovery Science Grants[1] (14.5%), Bridge Grants[2] (15.2%), and New Investigator Research Grants[3] (26.8%). Lung cancer, breast cancer, cardiovascular disease, and stroke were the most common illnesses reported as research topics, collectively accounting for 47% of grants.

Research grant funds have resulted in establishing new jobs and business. Over half of respondents reported establishing new, permanent employee positions due to their funded research, and nearly half reported new hourly employment opportunities. **Overall, 272 permanent positions and 178 hourly positions were created due to this funding**. Of these 450 positions, 73% were filled by undergraduate students, pre/post-doctoral students, and lab/research technicians. Eight respondents reported new start-up companies resulting from their research, and another eight reported opening new clinics.

Nearly a third of respondents either filed for patents or acquired intellectual properties due to grant funding. Additionally, 8% reported the development of Investigational New Drugs or Investigational Devices. Over 80% of respondents reported subsequent publications of grant-funded research, most of which included journal articles and presentations.

[1] Intended to promote fundamental theoretical or experimental investigative research to advance knowledge without a specifically envisaged or immediately practical application.
[2] Intended to provide interim support for promising investigator-initiated research projects that have been highly rated by national panels of peer reviewers in recent federal competitions but were not funded due to budgetary constraints.
[3] Intended to foster development of new investigators so that they can undertake independent research that is competitive for national research funding. This mechanism is no longer offered for grant applicants.

More than half of respondents reported receiving follow-on funding[4], collectively totaling over $108 million. Most of this funding ($86 million) came from federal sources, with private ($6.5 million) and local ($5.2 million) sources providing a much smaller share. Of those recipients of follow-on funding, 88% reported federal awards averaging over $1.2 million, 45% reported private awards averaging nearly $180,000, and 41% reported awards from local governments averaging over $155,000.

Additional Comments from Survey Respondents:

- "This new investigator award launched my career. It was my first grant and I learned a lot from having it and has been instrumental in my progress as a scientist."

- The James and Esther King and Bankhead-Coley grant funding programs are absolutely essential to maintaining active research programs in Florida in today's extremely competitive national funding environment. Both programs will allow Florida researchers to stay competitive in contributing to the development of novel anti-cancer and anti-tobacco related disease treatments."

- "I am grateful to DoH-James & Esther King Biomedical Research Program for funding our project. This has allowed us to continue our research and submit grants for extra-mural funding to NIH and DoD."

- "The BC funding was critical to develop oncolytic myxoma virus as a novel candidate anti-cancer therapy, which has been now licensed by a biotech company (DNAtrix) that will be responsible for the development of first-in-human clinical trials in cancer patients."

- "The shared instrument grant has impacted numerous research groups and contributed to studies with diverse endpoints and goals covering many facets of cancer biology and patient treatment… This mechanism, much like the research infrastructure, contributes to a wide range of research projects and raises the level of scientific inquiry at the research institute and across the state. Thank you for supporting the efforts of my research program as well as the core facility structure at the Moffitt Cancer Center."

- "The receipt of grant funding from the JEK program was instrumental in my career. In addition to the poster and paper presentations at scientific conferences, and the journal publications in top-tier journals that resulted, getting this award made me more competitive in obtaining my first NCI R01 grant. I am very grateful for the opportunity to conduct this work and for the subsequent academic achievements that were a result of this project."

- "Since the funding of the NIR award we have established the Mayo Clinic Florida Registry for cerebrovascular disease and have collected almost 1000 subjects with blood, DNA, plasma and fibroblast/iPS cells collected s biospecimens. Without the NIR grant these studies would likely not have happened as it helped build the foundation for our stroke genetics lab on

[4] Refers to additional grant awards from federal, local, private, or other sources acquired as a result of research initially funded by the Bankhead-Coley or King programs.

the Florida campus. this registry now has both a study coordinator and a lab technician working on sample and clinical data collection."

- "This funding has had tremendous impact in the field of thyroid cancer research, especially development of new drugs. Cell lines developed have been distributed around the world."

- "I had bridge funding in 07-08. That funding saved my research program. Since then I have hired dozens of people, including several permanent positions. I have brought in over $3 million in federal funds and currently hold three active NIH grants. I have three patents, over 130 publications, and dozens of collaborations. My basic research has finally found a translational path, but it is not without decades of fundamental research into the basic underpinnings of what makes cells tick."

- "The New Investigator Award from Bankhead Coley really launched my career. I am extremely grateful for this award as it allowed me to keep my job and to progress in my career. Through it, undergraduate students who participated in summer internships received some training, I was able to hire two technicians, one of which continues to work in my lab and I trained my first post-doc. Scientifically, this work led to three publications showing novel activities for marine natural compounds against pancreatic cancer, with the potential of more as many leads were identified that will be pursued as more funding is secured."

- "The grant was instrumental in pushing the field of advanced imaging forward. As a result of this and other related investigations, our group has become a national leader in advanced imaging systems for early colorectal cancer, which also spilled over to other major research areas in advanced esophageal and pancreatic cancer imaging and therapy. We are immensely appreciative of this opportunity."

- "Bankhead Coley funding in my early career made it possible for me to launch my faculty career, indelibly change patient care, discover new mechanisms of disease, and create & retain numerous high-paying jobs. Bankhead Coley funding in my middle career allowed me to retain high functioning scientists who I fostered into productive inventors. However, the number of grants and amount of funding from Florida's Biomedical Research Program is a fraction of what similar sized states offer to foster biotechnology. We desperately need state economy-conscious lawmakers who act on the importance of Florida's biotechnology sector by investing real dollars in this program, rather than the shamefully low amount."

- "I am very grateful to have received this funding. As a new faculty member this was my first externally funded research proposal and it set me on a path for additional external funding. This provided an excellent start to my research career and facilitated my path to independence."

- "The Biomedical Research Program managed by the Florida Department of Health uses a robust peer reviewed funding mechanism and the projects are efficiently managed with low overhead costs. As a result, the research projects are of high quality and high impact and the investigators can focus on the research instead of preparing the

reports. The funding is vital to maintain research team and research infrastructure in the universities when the federal support is at an unattainable level to sustain the research. The cutting edge research being supported by the program will impact the state economy by providing educational opportunity and developing advanced technologies."

- "These state funds have been pivotal to advancing my research program to the next level and staying competitive in a national environment of dwindling resources. Thank you!"

- "These basic science research grants are absolutely critical for the advancement of biomedical research and biomedical research staff and institutions in Florida and require funding to award many more of these grants than has been occurring in recent years."

- "The Pre-SPORE funding we received enabled us to receive an NIH/NCI SPORE Grant worth over $12 million in total dollars. This is the most prestigious and largest clinical/translational award the NCI provides, and has brought great credit to the Moffitt Cancer Center and to the State of Florida."

- "These research grants are so important to the benefits of our community, from scientific insights to patient care."

- "The New Investigator Research Grant mechanism was a very valuable mechanism that was critical to helping me establish my research program. In the years since the grant was completed, I have gone on to further develop my original NIR grant topic leading to multiple additional publications and federal grants, and this work remains a topic of active research in my laboratory."

Appendix II

Biomedical Research Advisory Council

Strategic Goals and Tactics 2014

Published June 2014

http://www.floridahealth.gov/provider-and-partner-resources/research/FINAL-BRAC-Strategic-Goals-and-Tactics.pdf

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 seven-year period from 2009-2015 (the latest time-period that state data are available), the total number of cancer deaths was 293,174. 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

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

Stephen J. Gardell, Ph.D., Senior Director, Scientific Resources & Associate Professor, Sanford-Burnham Medical Research Institute; Seat: House of Representatives

Abubakr A. Bajwa M.D., FCCP, Division Chief, Associate Professor of Medicine, Medical Director Pulmonary Hypertension and Interstitial Lung Disease Clinic, Division of Pulmonary, Critical Care and Sleep Medicine, University of Florida College of Medicine; Seat: American Lung Association

John R. Wingard, M.D., Price Eminent Scholar and Professor of Medicine, Deputy Director for Research, University of Florida Health Cancer Center; Director, Bone Marrow Transplant Program, Division of Hematology/Oncology, University of Florida College of Medicine; Seat: Senate – Cancer Program (ACoS)

Allison Eng-Perez, Principal, Deloitte & Touche, LLP; Seat: Governor

Barbara A. Centeno, M.D., Senior Member and Director of Cytopathology and Anatomic Pathology Quality Assurance, Moffitt Cancer Center; Seat: House of Representatives

David A. Decker, M.D., Attending Physician, Orlando Veterans Administration Medical Center; Seat: Governor

Susan Vadaparampil, Ph.D., M.P.H., Senior Member, Department of Health Outcomes and Behavior, Moffitt Cancer Center and Research Institute; 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 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, intermediate goals have been identified that can be used to evaluate progress.

During the first year, the BRAC recommends issuing a funding opportunity for incidence/prevalence measurement targets so our ability to measure the health impact of the strategic plan can be improved. Within three years the BRAC recommends 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