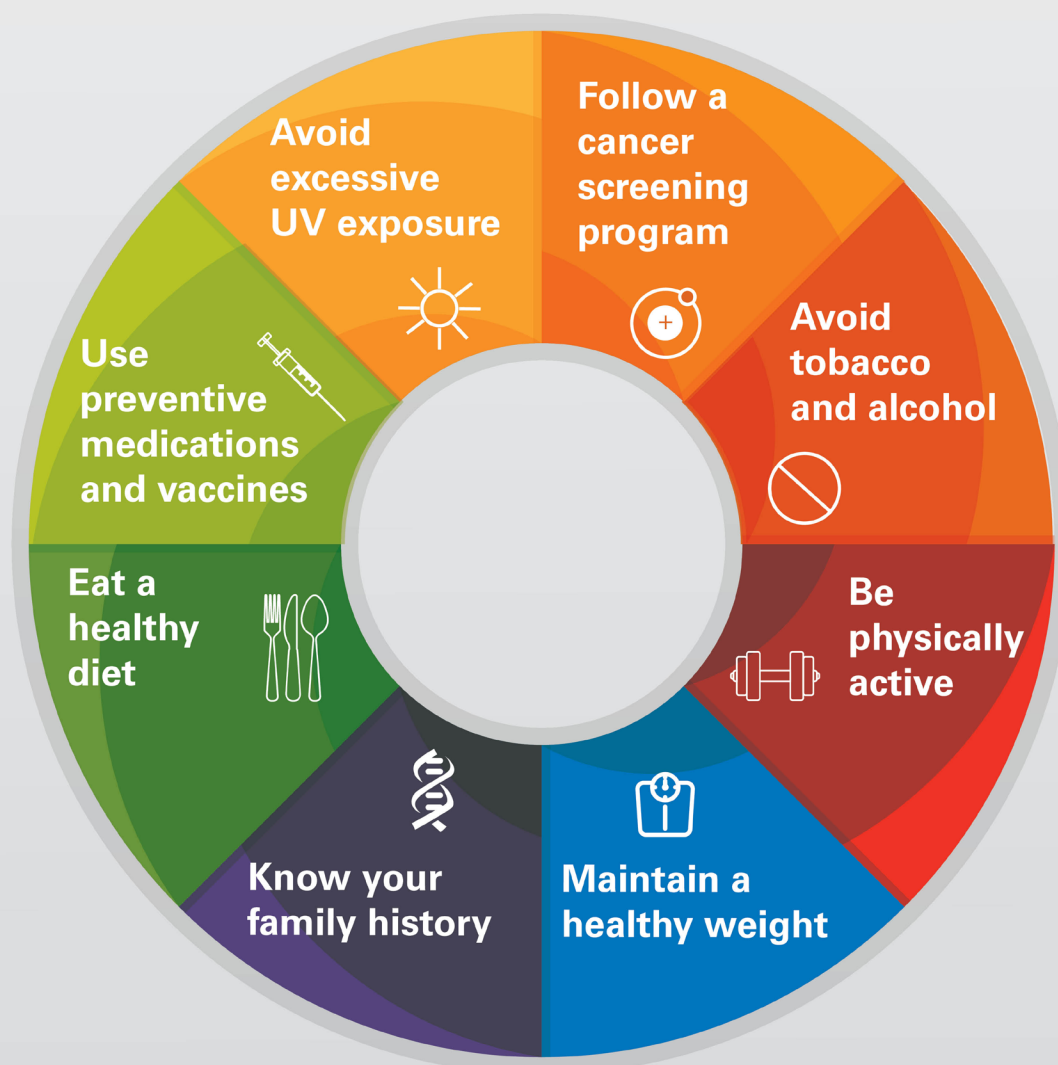


Duncan Family Institute

for Cancer Prevention and Risk Assessment

Report for Years 8 and 9



Did you know?

Up to 50% of all cancer deaths are preventable

Duncan Family Institute Staff
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Executive Director, Research Planning and Development
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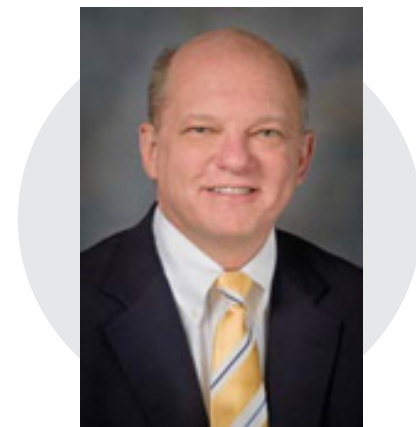
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To learn more about the work of the DFI, visit us on the web at www.mdanderson.org/duncanfamilyinstitute
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Division of Cancer Prevention and Population Sciences
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We would like to acknowledge the Division of Cancer Prevention and Population Sciences for their support.

A Message from the Vice President



I am pleased to provide you with the Duncan Family Institute of Cancer Prevention and Risk Assessment (DFI) report highlighting accomplishments from its eighth and ninth years of operations. The Institute continued its support for investigators discovering new knowledge about cancer risk and prevention and translating it into meaningful preventive interventions for both the clinic and the community.

The Institute's leadership reviewed its portfolio and added two new initiatives to expand its focus to research and cancer control affecting populations across Texas and in the Houston area who experience significant disparities in cancer risk, incidence and mortality. The first initiative is focused on reducing obesity-related cancer risk and cardiovascular disease in three of MD Anderson's cohorts – the Mexican-American Cohort, the Project CHURCH Cohort, and the High-risk Breast Cancer Cohort. The second initiative aims to develop a research co-operative of primary healthcare practitioners across Texas to develop ways to align cancer risk reduction practices with the unmet needs of their local communities. Two of our existing initiatives, the Clinical Cancer Prevention Research Core and the Center for Community-Engaged Translational Research, are expanding aims to reach traditionally underserved populations cared for at Harris Health's LBJ Hospital.

During the past two years, strategic initiative directors continued to facilitate and conduct high-priority research and advance clinical care. The Center for Energy Balance, in conjunction with the Women's Cancer, Colorectal and Chronic Lymphocytic Leukemia (CLL) Moon Shots™, supported three pilot projects aimed at developing effective and cost-efficient interventions to help manage weight, improve diet and increase physical activity in MD Anderson employees, families affected by hereditary cancers and survivors of CLL. The Integrative Health Initiative (IHI) launched its Healthy Living Weight Loss Program in the Cancer Prevention Center's Healthy Living Clinic while the Integrative Medicine Center delivered its IM FIT group program to help patients undergoing treatment with lifestyle-modification, weight-loss and improved fitness. The IHI provided support for the newly launched Healthy Heart Program led by Susan Gilchrist, M.D., which aims to improve cardiorespiratory fitness of cancer patients or those at high-risk of cancer. Perhaps the most impactful achievement is the codification of MD Anderson's plan of care through publication and dissemination of clinical algorithms in physical activity, nutrition and tobacco cessation for individuals at risk of cancer, patients in treatment and cancer survivors.

Research resources provide critical infrastructure to support scientists conducting innovative research. The Institute invests in resources to examine the role of diet in cancer prevention and progression, develop and implement technology-enabled behavioral interventions, connect communities and researchers to create long-term solutions to prevent cancer and improve health, study the economics and cost-effectiveness of care, and provide evidence-based tools so health care providers can partner to make difficult decisions in line with the values and preferences of the patient. Examples of the exciting and innovative work supported by DFI resources can be found in the following pages.

The Institute's Seed-Funding Research Program, designed to support the development of preliminary data for innovative research, awarded funds to fourteen new projects, which focus on improving behavioral and molecular preventive interventions or cancer survivors' quality of life. Investigators leveraged these investments to secure competitively reviewed grants from NCI and other funding agencies at a rate of over \$7 for every dollar invested.

Lastly, I'm pleased to report that Michela Capello, Ph.D., Johannes Farhmann, Ph.D. and Yue Liao, Ph.D. have been awarded DFI Mentored Junior Faculty Fellowships. Drs. Capello and Farhmann are members of the laboratory of Samir Hanash, M.D., Ph.D., Clinical Cancer Prevention and study aspects of blood-based biomarkers for early detection of cancer. Dr. Liao's research focuses on developing personalized and adaptive behavioral interventions using mobile and wearable sensor technologies to help people make and sustain healthier choices.

In closing, on behalf of the Duncan Family Institute Executive Committee, I offer our deepest gratitude to all those whose dedication to and passion for their work and for prevention enabled the past years' achievements. Finally, we offer our deepest admiration and respect to the Duncan Family, whose transformational generosity made the Institute possible, and to all of our new and sustaining donors, whose support underlies all that the DFI does and achieves.

Sincerely,
Ernest Hawk, M.D., M.P.H.
on behalf of the Executive Committee
Duncan Family Institute for Cancer Prevention and Risk
Assessment

DUNCAN FAMILY FOR CANCER PREVENTION AND RISK ASSESSMENT

Our Mission

To advance the discovery and translation of knowledge regarding cancer risk and prevention in the laboratory, the clinic, and the community. Cancer prevention is a broad field encompassing multiple scientific disciplines, thus the Institute advances a wide range of research, supporting scientists from diverse disciplines working in laboratories across MD Anderson's campus.



Duncan Family Institute programs have actively engaged with four of the Moon Shots™ disease site programs as well as with the Cancer Prevention and Control Platform. Details on how the DFI initiatives are interacting with the Moon Shots™ can be found throughout the report wherever the Moon Shot symbol appears.

Improving Body Composition, Diet, Physical Activity, and Fitness in Houston-area Adults at Increased Risk of Cancer

Network of Primary Care Physicians in Texas

Center for Energy Balance in Cancer Prevention and Survivorship

Center for Translational and Public Health Genomics

Premalignant Genome Atlas

Integrative Health

Seed Funding

Research and Clinical Programs encompass the Centers, Strategic Initiatives - a set of high-priority areas determined by the DFI's Executive Committee, and a Seed Funding program to cultivate new research directions.

INSTITUTE

Assessment,
Intervention and
Measurement (AIM)

Bionutrition
Research
Core

Research Resources are the critical components of the scientific infrastructure necessary to carry out state-of-the-science research. These resources are often not supported through traditional grant mechanisms or other funding sources.

Center for
Community-Engaged
Translational
Research

Clinical Cancer
Prevention
Research Core

Health Services
Research Core
Data Resource

Mexican
American
Cohort

Shared
Decision-Making
Collaborative

Educational Resources include fellowships to develop future generations of cancer prevention researchers and lectures and events to build the intellectual environment to engage the current generation.

Fellowships

Lecture
Series



RESEARCH AND CLINICAL PROGRAMS

The Duncan Family Institute is investing in research to discover how biologic, genetic, environmental, behavioral and social factors impact cancer development, investigate interventions to reduce cancer risk and translate preventive therapies and lifestyle interventions to help patients in our clinics and individuals and populations in the community.

Centers and Strategic Initiatives

The Institute's strategic initiatives program is intended to fund high-priority research areas. Criteria for selection of a strategic initiative are:

1. Scientific opportunity that advances the field, has great translational potential and/or is a priority of patients and/or the population;
2. Critical research need that fills a gap in our portfolio;
3. Provides a platform to launch something bigger; provides an opportunity for synergistic collaboration;
4. Has the potential to support itself over the long term (sustainability);
5. Little or no chance for support elsewhere and
6. Feasible with the available funds.

There are currently four strategic initiatives supported by the Institute: Center for Energy Balance in Cancer Prevention and Survivorship, Center for Translational and Public Health Genomics, Premalignant Genome Atlas, and Integrative Health Program. In FY17, the Duncan Family Institute Executive Committee implemented a process to refresh its portfolio, resulting in two newly funded initiatives: Network of Primary Care Physicians in Texas and Improving Body Composition, Diet, Physical Activity, and Fitness in Houston-area Adults at Increased Risk of Cancer. For the two year period of this report, the Duncan Family Institute's portfolio of strategic initiatives was highly productive, with affiliated faculty receiving or providing expertise toward \$28.8 million in awarded grants. Scientific results of researchers supported by and engaged with these initiatives were published in over 460 scientific articles.

Center for Energy Balance in Cancer Prevention and Survivorship

Center for Translational and Public Health Genomics

Premalignant Genome Atlas

Improving Body Composition, Diet, Physical Activity, and Fitness in Houston-area Adults at Increased Risk of Cancer

Network of Primary Care Physicians in Texas

Integrative Health Initiative

Center for Energy Balance in Cancer Prevention and Survivorship

Directors: Karen Basen-Engquist, Ph.D., M.P.H., Joya Chandra, Ph.D.

Facilitate and conduct state-of-the-science research to understand the relationships among physical activity, nutrition, obesity, and cancer, and use this knowledge to optimize interventions to decrease cancer risk and improve cancer outcomes

The Center advances prevention science by identifying and addressing knowledge gaps, facilitating collaborations to develop studies to close these gaps and focusing efforts on dissemination of diet and physical activity programs and activities. By fostering a collaborative, trans-disciplinary environment, the Center's research members ask and answer scientific questions related to:

- cancer prevention and survivorship-related interventions;
- the ways in which key energy balance concepts affect cancer biomarkers; and
- the biological and psychosocial mechanisms behind weight, eating behavior, and physical activity.

The research services provided by the Center include expert consultations referrals to potential collaborators. The Center develops networks of investigators and facilitates multi-disciplinary workgroups to bring together scientists with an interest in asking and answering research questions in energy balance-related topics.

Scientific Highlights

HEALTH4 Platform - In conjunction with the Women's Cancers, Colorectal and Chronic Lymphocytic Leukemia Moon Shots™, this platform supports 3 pilot projects aiming to test effective and cost-efficient interventions to help people manage weight, improve diet quality and increase physical activity to ultimately prevent cancer development or recurrence using a novel multi-phase



optimization strategy (MOST). This approach uses factorial designs applied to behavioral interventions to identify the most effective components. The HEALTH4 Families study, recruiting families who are at high risk for hereditary breast and ovarian cancers, was expanded with additional funding from Ardmore Institute of Health to deliver the intervention program to the over 200 individuals on the study wait list. The platform has expanded to pilot studies in other populations:

- o HEALTH4 MD Anderson (employees)
- o HEALTH4 Chronic Lymphocytic Leukemia (CLL) survivors
- o HEALTH4 Cancer Prevention Center patients

This novel approach to optimizing the Center's intervention work is providing a platform for effective interventions that do not require face-to-face contact.

(PIs: K. Basen-Engquist, S. Peterson, M. Cox, L. Strong, S. Schembre, E. Lyons, B. Arun, K. Lu, N. You, P. Lynch, L. Liang)

High Intensity Interval Training (HIIT) for Women at Heightened Risk for Breast Cancer

- In this study, investigators are testing the feasibility of high-intensity exercise compared to moderate continuous exercise in patients at high risk for breast cancer. This ongoing study is the first to use HIIT, an exercise modality that is associated with improved cardiorespiratory fitness outcomes, to evaluate the effect on risk biomarkers in this population.

(PIs: S. Gilchrist, A. Coletta)

Evaluating the Effect of Pre-surgical Exercise on Patient Fitness,

Pancreatic Tumor Biology and Chemotherapy Efficacy - The Center facilitated a collaboration between two research groups, one clinical and one laboratory based, to evaluate the efficacy of aerobic exercise in improving patient fitness (critical for surviving a major surgery) and modifying tumor biology (critical for maximum drug delivery) for patients with pancreatic ductal adenocarcinoma. The multi-disciplinary group has IRB-approved trials to evaluate changes in vascular structure in tumor specimens, as well as physical functioning, in patients who underwent a home-based exercise program consisting of aerobic and weight-bearing exercise through the

chemoradiation and rest phases between diagnosis and surgical tumor excision. After surgery, tumor samples were evaluated for changes in vascular structure, infiltrating immune cells, and markers of proliferation/apoptosis with the aim of understanding more about the impact of exercise on chemotherapy efficacy against the tumor. (PIs: M. Katz, A. Ngo-Huang, D. Fogelman, N. Parker, K. Schadler)

Steps2Health - This study, targeting cancer survivors, is a mobile intervention to deliver messaging to increase exercise self-efficacy in real time. This research builds on the findings from an earlier study where investigators showed the importance of daily self-efficacy in driving exercise behavior. The investigators leading this study completed the I-Corps workshop, an NSF developed program to identify valuable product opportunities that can emerge from academic research, and gain skills in entrepreneurship. They will be collaborating with MD Anderson's Innovation Center to create a prototype for the app and test this with cancer survivors. (PI: K. Basen-Engquist, E. Lyons)

Energy Balance Strategies for Enhancing Therapy and Improving Survivorship for Pediatric Cancers

- In this research program, investigators' long term goal is to implement diet and exercise interventions that will optimize treatment of pediatric cancer and improve quality of life for childhood cancer survivors. Projects include use of preclinical pediatric cancer models to test if moderate exercise and diet modifications can enhance treatment; and to test if moderate exercise and diet modifications can decrease the acute cardiotoxicity of anthracyclines. A third project aims to test feasibility of diet intervention delivery and compliance to pediatrics cancer patients and survivors. The investigators will use the results of these studies to seek extramural funding for a larger multi-investigator program.

(PIs: E. Kleinerman, J. Chandra, K. Schadler)

Tu Salud, ¡Si Cuenta!/Your Health Matters! - This study is evaluating the effectiveness of a 6-month, community-based family dyad intervention in promoting engagement in and maintenance of physical activity and healthy eating among Latino adults residing in three predominantly Latino communities in Houston, TX. Dyads are randomly assigned to the Tu Salud ¡Si Cuenta! intervention, which aims to build behavioral skills and social support for sustained healthy behavior change in Latino family dyads, or to a control condition focused on healthy homes. Both programs consist of six monthly home visits with a community health worker. (PI: L. Strong)



Accomplishments

- Recognized for earning MD Anderson a national reputation for its energy balance in cancer prevention and survivorship program and for raising the profile of this research area within the institution as demonstrated by the Center's productivity and broad institutional reach.
- Recruited Keri Schladler, Ph.D., assistant professor in Pediatrics, whose research interests are at the intersection of tumor vascular biology and the utilization of moderate aerobic exercise as a therapeutic adjuvant during cancer treatment or stem cell transplant.
- Named a co-director, Joya Chandra, Ph.D., Associate Professor, Pediatrics, who will help the Center build collaborations with basic scientists and provide resources for biomarker identification and analysis for clinical and population science researchers.
- Continued the Center's success in strengthening the institution's research impact in the increasingly important area of energy balance:
 - o Supported submission of 85 grants for new studies totaling \$82.1M and delivery of 27 active projects totaling \$14M (FY17).
 - o Identified 78 energy-balance related scientific papers and abstracts authored by MD Anderson faculty and published in FY16 and another 66 in FY17.
 - o Increased Center membership from 182 in FY15 to 193 in FY16 to 354 in FY17. Growth in faculty members increased from 102 in FY15 to 170 in FY17. The depth of faculty members and breadth of members in energy balance-related fields, such as registered dietitians and physical therapists, is a strength of the Center.
 - o Promoted energy balance educational opportunities, such as the national NCI-funded Transdisciplinary Research on Energetics and Cancer (TREC) Training Workshop where 25% of the selected fellows were from MD Anderson, and fostered the intellectual environment through sponsorship of special seminars and monthly lectures.
- Expanded infrastructure for energy balance research through the establishment of the Bionutrition Research Core (BRC).
- Established the Energy Balance Assessment Supplemental Funding mechanism, which supported two new projects in addition to the Center's continued support for 11 pilot studies.

- Convened and chaired the multi-organization "Translating Lifestyle Interventions and Practice" workgroup which led to the National Cancer Policy Forum of the National Academies of Sciences, Engineering, and Medicine public workshop "Incorporating Weight Management and Physical Activity Throughout the Cancer Care Continuum."
- Disseminated Active Living After Breast Cancer to 199 cancer survivors in the Houston area through partnerships with Project CHURCH to reach African-Americans and through the YMCA of Greater Houston to reach participants in their communities.

Future Plans

- Support new multi-disciplinary collaborative projects including trials of diet and physical activity interventions for ovarian cancer and CLL survivors, and BRCA and Lynch Syndrome carriers and family members; projects to enhance therapy and improve survivorship in pediatric cancers; and studies to test technology-based healthy eating, exercise and weight management interventions supported by Jason's Deli funds arising from the co-branded menu collaboration.
- Dr. McQuade in collaboration with Dr. Hwu, Dr. Daniel, Dr. Cohen, and the BRC will be pilot testing in healthy individuals the palatability and content of different diets of varied fiber and macronutrient composition to target the microbiome and immune parameters. The premise of this pilot work is to establish the feasibility and infrastructure for a larger feeding study of melanoma patients commencing immunotherapy, building on prior work in mice and humans, by Drs. McQuade and Wargo.
- Develop and test scalable weight management interventions in MD Anderson cohorts, including the Mexican-American Cohort, Project CHURCH and the Mammography Cohort.
- Implement Health4 in MD Anderson's Cancer Prevention Center and in Pasadena Independent School District through the Pasadena Vibrant Communities.
- Advance the Bionutrition Research Core, working with investigators to develop study ideas for projects using this new resource.
- Design a project to expand the CPRIT Prevention Program-funded Active Living after Cancer for Houston and El Paso cancer survivors.
- Continue to collaborate with the Cancer Prevention and Control Platform to identify and refine energy balance interventions for delivery in community settings.
- Engage in a strategic planning process to define Center priorities for the next five years.

Goals

1. Develop practice-changing research.
2. Expand transdisciplinary collaboration among researchers conducting energy balance research at MD Anderson.
3. Improve the infrastructure for conducting research on energy balance and cancer.
4. Increase awareness, knowledge and skills related to energy balance and cancer among researchers, health care professionals, trainees and the community.

Center for Translational and Public Health Genomics

Directors: Xifeng Wu, M.D., Ph.D., Alma Rodriguez, M.D.

Bridge the gap between epidemiologic discoveries and their translation into clinical and public health applications to benefit individuals at elevated risk for cancer, cancer patients, survivors and the general population

The Center for Translational and Public Health Genomics (CTPHG) aims to serve as an institutional hub for research and scientific exchange among investigators in translational epidemiology, public health genomics, pharmacogenomics, clinical outcomes and survivorship research. Resources made available to the Center are used to build biospecimen and data research resources to advance blood-based biomarker discovery, development and validation, and develop personalized risk prediction models. These resources plus Center members' epidemiology, biomarker technology and analytical expertise contributed to over twenty active projects. The Center supports resource development projects as well as educational activities to enhance the intellectual environment and expand research networks.

A notable success of the Center is its members' success in using the resources established with institutional investments to successfully compete for multiple NCI-funded projects that aim to identify novel rare genetic variants with intermediate effect size that predispose individuals to malignant disease. Each project involves discovery and validation phases and employs whole exome and targeted sequencing approaches to identify and validate key susceptibility loci using Center member developed software, such as the Variant Annotation, Analysis and Search Tool (VAAST). Somatic-germline interactions are being explored and risk models developed. These studies should contribute significantly to our understanding of cancer etiology and risk assessment in melanoma, ovarian, colorectal and pancreatic cancer. Center members provide guidance on study population, source epidemiologic data and biospecimens, access to biomarker discovery technology, and expertise in bioinformatics and biostatistics. Several of these projects are described in the scientific highlights.



Accomplishments

- Collected 27,874 patient residual blood samples in two years, for a total of 113,074 samples collected since 2010.
- Continued to develop the MD Anderson Cancer Patient Cohort, bringing together data from multiple institutional sources with biospecimens to establish a valuable research resource.
- Recruited and banked biospecimens from 2951 cancer survivors for the Long-term Survivorship Cohort, bringing the total number to 5739.
- Increased the Pediatric Cancer Cohort by 614 participants for a total of 1294. Recruited another 131 participants to the recently established Long-term Childhood Cancer Cohort.
- Center members developed assays, methods and infrastructure for blood-based biomarker research, personalized risk prediction model development and computational epidemiology studies.
- Supported 33 research proposals to peer review funding agencies totaling \$50.7M of which 7 for \$4.7M were funded.
- Supported 24 active projects totaling \$40.2M (FY17).
- Published 246 scientific papers and abstracts of which 45 were published in high-impact journals, including Science and Nature.

Goals

1. Build research infrastructure, including the Blood Specimen Research Resource (BSRR), MD Anderson Cancer Patients and Survivors Cohort and the Long-term Survivorship Cohort.
2. Discover, develop and validate blood based biomarkers.
3. Generate personalized risk prediction models and advance the field of computational epidemiology.
4. Build research networks through support and maintenance of collaborative biospecimen banks for clinical and community based studies.

Future Plans

- Continue innovative research to discover and validate biomarkers and molecular signatures for stratification of at-risk individuals using both global and targeted pathway approaches.
- Investigate the interplay among energy balance, dietary patterns, microbiome, host inflammatory status, genetics, and their roles in cancer risk/progression/survival.
- Expand research in long-term adult and pediatric cancer survivors including the study of late-effects (toxicities) and quality of life.
- Develop and validate risk prediction models with the goal of creating web-based risk calculators for clinical and public utilization.
- Enhance research infrastructure through expansion of the cancer patient and survivorship cohort.
- Support and extend research networks infrastructure to Houston-Area Locations, Sister Institutions and the Cancer Network.

Scientific Highlights

High-throughput Sequencing to Identify Novel Melanoma Susceptibility Genes

- Each year in the United States, over 75,000 individuals are diagnosed with melanoma and over 9,500 individuals die from the disease. When detected early, melanoma is highly curable, with 5-year survival rates of 98% for early stage disease. However, the survival rate drops precipitously for later stages, highlighting the importance of making advances in the ability to identify individuals at high risk of developing melanoma in conjunction with improvements in prevention, screening, and early detection. In this project, the investigators are conducting a hypothesis-free, genome-wide search for novel melanoma-susceptibility genes characterized by rare, protein-coding risk variants. The incorporation of somatic variation information will provide additional insight into the role of germline susceptibility variants in cancer progression. The integration of epidemiologic and exposure risk factors will further enhance the translational potential of this work, leading to more effective prevention, early detection, and treatment strategies for this deadly yet often preventable disease. (PIs: C. Huff, H. Zhao)

Discovery of Novel Rare Variants as Ovarian Cancer Susceptibility Factors

- Ovarian cancer is a rare cancer, with less than 25,000 new cases diagnosed each year in the United States. It is also among the most lethal cancers owing to the lack of effective screening measures and the "symptom-less" nature of the disease, resulting in frequent diagnoses of high-grade, invasive disease. To have a meaningful impact in survival for this disease, in parallel with advances in treatment options, improvements in risk assessment also need to be made that can assist in prevention and screening. Significant efforts in identifying common genetic variants associated with risk through genome-wide association and candidate gene studies explain less than 5% of the heritable risk of this highly lethal disease. The investigators hypothesize that rare variants in multiple genes individually confer an intermediate risk of ovarian cancer and that these variants can be highly informative in accurately predict ovarian cancer risk, while providing clues about the etiology of the disease. To test this hypothesis, the investigators will perform whole exome sequencing followed by targeted sequencing in a total of 8,000 ovarian cancer cases and 8,000 matched controls of European descent to identify the spectrum of rare genetic variation that contributes to ovarian cancer susceptibility. With the known differences in prognosis for European American (EA) and African American (AA) women diagnosed with ovarian cancer, researchers will also sequence the top candidate genes identified in the EA population in the largest, ongoing study of AA women with ovarian cancer. These novel variants will have potential to enhance ovarian cancer risk assessment and prediction, while providing needed insight regarding the etiology of the disease. (PIs: M. Hildebrandt, C. Huff)

Next Generation Sequencing to Identify Novel Colorectal Cancer Genes

- Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the US. Driven by common disease common variants hypothesis, genome-wide association studies only identified a number of common susceptibility loci that explained a small portion of CRC heritability. The goal of this project is to identify rare genetic variants with intermediate effect size that predispose individuals to colorectal cancer through a next generation sequencing approach. The specific aims are to identify novel susceptibility genes for CRC by conducting whole exome sequencing, internally validate the top 1,000 genes by targeted sequencing, externally validate the top 100 genes and build quantitative risk prediction model by incorporating epidemiologic factors, exposure factors, and genetic factors for the risk of CRC. This study will provide significant insight in the etiology of CRC and improve our

understandings of the genetic basis of CRC. The prediction model may help physicians identify individuals at high-risk of developing CRC who would benefit from intensive screening, surveillance and/or chemopreventive interventions. (PIs: Y. Ye, C. Huff)

Personalized Prognostic Prediction Models for Breast Cancer

Recurrence and Survival Incorporating Multidimensional Data - Breast cancer is a heterogeneous disease with distinct prognoses. To help establish guidelines for clinical decision-making with regard to personalized management of breast cancer, a number of prognostic have been developed since the early 1980s. However, validation of these published prognostic models using external patient populations has shown only modest discriminatory accuracy and a large amount of variability in breast cancer clinical outcomes remains unexplained. In this study, the investigators developed integrative, personalized prognostic models for breast cancer recurrence and overall survival (OS) that considered receptor subtypes, epidemiological data, quality of life (QoL), and treatment. The integrative prognostic models for breast cancer developed by the investigators exhibited high discriminatory accuracy and excellent calibration and are the first to incorporate receptor subtype and epidemiological and QoL data. The CTPHG provided data, epidemiology expertise, and computational epidemiology support. (Wu X, et al, J Natl Cancer Inst. 2017)

Point-of-Care Test of Exposure to Hepatocellular Carcinoma Risk

by V-Chip - Using the V-Chip microfluidics technology, an accurate and quantitative Point-of-Care Test based on measurement of key circulating biomarkers to monitor exposure to HCC risk is in development. The V-Chip will be validated in HCC cases and controls. This project aims to provide technology for self-monitoring of HCC risks and thereby aid in early detection and prevention. The Center provided guidance on biomarkers for V-CHIP development, access to the study population, epidemiologic data, and BSRR samples. (MD Anderson PI: X. Wu; NCI)

Discovery of Risk Loci and Genomics of Pancreatic Cancer by Exome Sequencing

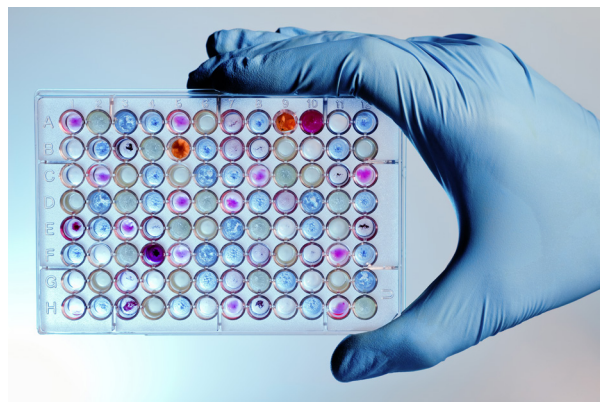
- Pancreatic adenocarcinoma (PaCa) is the 4th leading cause of cancer death in the United States and 8th leading cause worldwide. However, if caught at an early stage, there exist effective surgical treatments. A major difficulty with this is the lack of established prevention and screening strategies. The investigators aim to discover important genetic risk factors to aid in such a strategy, using exome and targeted sequencing of 4,400 pancreatic cases and 4,400 matched controls of European descent. This study leverages a strong environment of sample resources at MD Anderson Cancer Center and a well-constructed team of diverse expertise spanning fields of Epidemiology, Genomics, Pathology, Surgery and Computational Human Genetics. The analytical analysis are being conducted by leading experts in statistical genetics, who have made major contributions to the development of the advanced methods that will be used. Based on previous studies of familial aggregation of PaCa, and the relative paucity of findings to date from genome-wide association studies, the researchers expect there to be numerous genes with rare variation of intermediate to high risk for PaCa. Given the epidemiological and demographic data, the 2-stage study design and large patient resource, this study is well powered for successful identification of these genes. These results will offer new insights in the etiology of PaCa and, long-term, could lead to strategies for targeted surveillance of individuals at high risk for this disease. (PIs: P. Scheet, C. Huff)

Premalignant Genome Atlas

Directors: Xifeng Wu, M.D., Ph.D., Gottumukkala Raju, M.D.

Assess risk factors contributing to the progression of healthy individuals to those with precancerous lesions to those with cancer and determine molecular differences, which could serve as markers of risk or preventive response and/or cancer prevention targets

Cancer is often detected and treated at an advanced stage using cytotoxic chemo- and/or radiotherapy. The best hope to improve the prognosis of cancer is early detection or, better yet, preventive intervention of pre-cancerous conditions to prevent or slow progression to cancer. Given that most epithelial cancers are preceded by premalignant lesions, and that progression from these lesions to malignant tumors is a lengthy process that typically takes many years, there appears to be ample opportunity to stop malignant cancer from developing. However, a chief obstacle to progress is the inability to predict who will develop cancer among the millions of people that harbor premalignant lesions. The Premalignant Genome Atlas (PGA) seeks to overcome this challenge. This collaborative program enables systematic study of premalignant lesions by addressing epidemiological risk factors, clinical behaviors, host susceptibility factors and somatic biomarkers of progression. The intent is to amalgamate all these factors into comprehensive, integrative risk-prediction models for different cancers among patients with unifying premalignant lesions to empower personalized cancer prevention. These efforts are critical in that individuals with different risk levels may need vastly different preventive measures. Moreover, the biomarkers of progression identified from this program may become future targets of cancer prevention.



Accomplishments

- Expanded the PGA colorectal polyp study cohort with the addition of 624 patients recruited bringing the total to 3421. Participant epidemiologic, demographic and clinical data collection was enhanced through implementation of a web-based tool, PGA POLYP INQUIRE. The addition of stool sample collection from adenoma patients will enhance the cohort resource to support novel studies such as those aimed to improve our understanding of the microbiome.
- Continue collaboration with faculty in Head & Neck Surgery to expand biospecimen resources for oral premalignant lesion investigations to 207 participants.
- Submitted 6 grants totaling \$8.1M, of which 6 were funded.
- Supported 7 projects, totaling \$7.8M, of which 4 are ongoing.
- Published 25 scientific manuscripts and abstracts describing research results using PGA resources made possible through Institute investments.

Goals

1. Build premalignant lesion biobanks and construct cohorts of patients with premalignant lesions across multiple cancer types.
2. Identify biomarkers that predict the malignant progression of premalignant lesions using genome-wide molecular profiling.
3. Develop personalized risk prediction models for the malignant progression of premalignant lesions.

Future Plans

- Conduct integrative analyses of DNA mutation, RNA and small RNA sequencing data to identify common altered genes and pathways.
- Continue to build novel technology platforms and perform molecular and phenotypic profiling including gene expression, miRNA and microbiome profiling, exosome markers, and immune functional assays.
- Continue to expand the colorectal polyp study patient cohort and associated resources to include a focus on follow-up over time of adenoma patients with specific mutations to observe incidence of colon cancer.
- Strengthen the collaboration with McCombs Institute for the Early Detection and Treatment of Cancer and with other faculty conducting pre-cancer related research to develop novel ideas, including projects to test the hypothesis that characterization of somatic mutations and miRNA profiles can more accurately differentiate between low-risk precancerous lesions and those that are likely to progress to colorectal, gastric or oral cancer.
- Support junior faculty with resources and expertise to develop research directions in pre-cancer, such as the impact of diet on the microbiome and its relationship and integration of multi-dimensional data to advance our understanding of colorectal cancer risk.

Scientific Highlights

Profiling Circulating miRNAs in Colorectal Adenoma and Cancer

Patients Using NanoString Platform - Scientists continued their work to develop new methods to characterize the global alterations of circulating miRNAs as these are emerging as promising biomarkers for colorectal cancer and colorectal adenoma. Investigators assessed the serum levels of 800 miRNAs in a discovery set of 21 patients with CRC, 19 with adenoma and 21 health controls using the NanoString miRNA analysis platform. Significantly differentially expressed miRNAs were examined further in a validation cohort using Fluidigm quantitative polymerase chain reaction assays. The results suggested that circulating miRNAs can distinguish patients with CRC and those with adenoma and may represent a novel biomarker for the early, noninvasive detection of CRC. (Zhang, J et al, Cancer 2017)

Global Circulating Metabolite Profiling of Healthy Controls, Colorectal

Adenoma and Cancer - Patients with colorectal adenoma polyps are at higher risk for developing colorectal cancer. However, the development of improved and robust biomarkers to enable the screening, surveillance, and early detection of these polyps and of colorectal cancer continues to be a challenge. It is thought the progression of premalignant lesion to cancer may involve profound metabolic changes. In this project, researchers aimed to identify biomarkers of progression to CRC through metabolomic profiling of human serum samples using a multistage approach. Results suggest the potential utility of circulating metabolites as novel biomarkers for the early detection of CRC. (Long Y, Cancer 2017)

Gene Expression Profiling of Colorectal Adenoma



- Investigators in this ongoing project aim to develop laboratory methods and bioinformatics pipelines to identify differentially expressed genes (DEG) that may predict the early development or progression of adenoma which may become biomarkers of early detection for colorectal cancer. To date, investigators

have conducted somatic mutation profiling of colorectal adenoma patients. Major findings of this study include: conventional (tubulovillous) adenomas and sessile serrated adenomas had similar mutation frequencies, but the genes involved substantially differed; both novel and known colorectal cancer (CRC)-related mutations with driver patterns were observed in adenomas; and a 20-gene panel could distinguish colorectal adenomas from CRC. (Lin, S et al, Gut, 2017) As a follow-up work on this study, investigators conducted RNA sequencing (RNAseq) and applied newly developed laboratory methods to identify a 30-gene panel that could discriminate adenomas and CRC from normal tissues. Further research in independent prospective studies is required to validate and explore the clinical utility of these and other findings as diagnostic signatures for early detection of adenomas and CRC.

Gut Microbiome: Links between Obesity and Colorectal Neoplasia

- Evidence increasingly suggests that the gut microbiome's role in early colorectal cancer etiology extends beyond the pro-carcinogenic activities of specific pathogens and is largely influenced by the wider microbial community of commensal bacteria. Investigators conducted an epidemiologic study among cancer-free colonoscopy patients with known and varied risks of colorectal neoplasia. The researchers collected fasting blood and a stool sample at one month post colonoscopy. A key question was the feasibility of home and mail-based fecal sample collection in conjunction with web-based dietary assessments. Researchers found that colonoscopy patients, as well as healthy members of the community, were eager to participate in studies of diet and gut bacteria. Results of characterizations suggest biologically

plausible associations between microbial (functional gene content) pathways important to cancer risk (e.g., one-carbon, lysine, carbohydrate and fatty acid metabolism) with dietary factors and circulating adipocytokines involved in immunity, inflammation, and glucose metabolism support the functionality of these diet-microbe relationships. (Daniel C, Cancer Research 2017)

Ongoing Work:

Profiling Somatic Expression of Cancer-related Genes in Colorectal

Adenomas Using HTG EdgeSeq - In this technology development project, researchers aimed to characterize the transcriptional landscape of cancer-related genes in paired colorectal adenomas and adjacent normal tissues using a novel platform involving next-generation sequencing (NGS). The advantages of this technology include small sample size without extraction of DNA or RNA and high throughput workflow. Formalin-Fixed Paraffin-Embedded tissues can be used as well as other forms of frozen tissues and cells. Findings from the pilot project show that there are differentially expressed genes in normal, early and advanced adenomas and that several of these are found in pathways associated with immune / inflammation-related function, consistent with our understanding of the role of inflammation in the etiology of CRC.

Impact of Obesity on Colon Adenoma and Colorectal Cancer

Development - Epidemiological studies have linked obesity with increased cancer risk. However, most studies only collected BMI information at study enrollment. In this project, scientists conducted a case-control study to examine the role body mass index and obesity with the aim of determining the influence of body mass index and obesity on the risk of developing of colon adenomas and colorectal cancer. Initial results indicate obesity at younger age is likely to contribute to both the development of colorectal adenomas and colorectal cancer--the latter with stronger effect suggesting weight control should start early adulthood for the prevention of colorectal malignancy.

Oral microbiome and the Risk of Progression of Oral Premalignant

Lesions (OPLs) - In this exploratory project, researchers aimed to characterize the oral microbiome in OPL patients and to correlate oral microbiome with the progression of oral premalignant lesions and risk factors of oral cancer (e.g., smoking and alcohol drinking). The results of microbiome profiling of the 100 study participants (21 with OPL, 26 with oral cancer and 53 healthy controls) were that OPL samples showed higher within sample species diversity (alpha diversity) and between sample diversity (beta diversity) than control or cancer samples, especially in saliva and tongue scraping samples. Surprisingly, no significant difference in diversity was seen between oral cancer and normal samples, suggesting distinct microbiome in the OPL patients. There were indications that age and smoking status might influence microbiome diversity; however, none of the host factors (including BMI and gender) significantly affected microbiome diversity, suggesting directions for further studies.

Profiling Circulating miRNAs in Oral Premalignant Lesion and Oral

Cancer Patients using NanoString Platform - Similar to the study in colorectal cancer patients, investigators profiled the global alterations of serum miRNAs for progression of oral premalignant lesion using NanoString technology. Preliminary results demonstrated feasibility and promising lines of inquiry, but more work is required to replicate results.

Improving Body Composition, Diet, Physical Activity and Fitness in Houston-area Adults at Increased Risk of Cancer

Directors: Karen Basen-Engquist, Ph.D., M.P.H., Susan Gilchrist, M.D.

Intervene in high-risk populations to reduce the risk of obesity-related cancer and cardiovascular disease in Texas adults

In this newly established initiative, the collaborators will use a novel approach to test delivery channels for a weight management intervention in unique MD Anderson-supported cohorts, such as the Mexican-American Cohort, Project CHURCH, High-risk Breast Cancer Cohort and the developing Mammography Cohort. The results of the studies and data will provide a rich resource of highly diverse and well-characterized participants for investigators to use in developing larger projects competitive for funding from extramural sponsors, such as NCI and ACS, both of which have identified weight management its association with cancer risk as a funding priority.

Goals

1. Provide an evidence-based weight management program (based on the Diabetes Prevention Program) using “low-touch” technology-based delivery strategies to overweight and obese individuals in well-characterized MD Anderson cohorts and patient populations (e.g., MAC, CHURCH, high-risk breast cancer and mammography cohorts). Intervention components will be tested using the Multiphase Optimization Strategy involving random assignment to different intervention delivery components.
2. Create a data resource for investigators focused on predictors of project participation; effects of intervention components on weight, nutrition, physical activity, and fitness; and the relationship between nutrition/dietary intake, physical activity, fitness, body composition, and cancer risk.
3. Create a resource guide for investigators which will include Houston-area resources available for cohort members related to nutrition/physical activity/weight management.



Accomplishments

- Defined the initiative and obtained internal funding.
- Secured collaborator commitment.
- Initiated start-up activities.

Future Plans

- Establish infrastructure, including data use and sharing policies and procedures
- Organize a committee of investigators, patient advocates and regulatory experts to develop cohort and subcohort measures and measurement procedures.
- Hire Program Coordinator.
- Finalize qualitative data gathering (i.e., focus groups, interviews).
- Begin intervention pilot planning.
- Registering systematic review(s) with PROSPERO (internal prospective register of systematic reviews).

Network of Primary Care Physicians in Texas

Director: Sanjay Shete, Ph.D.

Realize measurable impact on reducing the burden of cancer across all communities in the State of Texas through development and implementation of a research co-operative that empowers local practitioners to better align practice to the unmet needs of their community

Emerging evidence from Healthy People 2020, the Health Information National Trends Survey (HINTS), the Texas Cancer Plan and impactful epidemiologic studies highlight key gaps and unmet needs in cancer prevention and outcomes across Texas. Such resources reveal that Texas has underperformed compared to other states in several key categories and substantial disparities are evident. Importantly, among the 254 counties in Texas, 167 did not meet the Healthy People 2020 objective of decreasing the overall cancer death rate, and several counties have witnessed an alarming increase in cancer mortality. The under- and un-insurance rate in Texas remains the highest in the nation and 177 out of 254 counties are rural with limited access to medical care. Critical issues in Texas include the 4-fold higher incidence rate of hepatocellular carcinoma in South Texas Hispanics versus non-Hispanics whites, and the fact that HPV-associated cancers are projected to increase by 65%. Moreover, in Texans over the age of 50, compliance with USPSTF guidelines for CRC screening is dismal (41st among 50 states).



Powered by these data and shortfalls, and bolstered by NCI's enhanced interest in its Cancer Centers' actions to address catchment area priorities, the Duncan Family Institute is investing resources to develop a network of primary care physicians (PCP) across Texas. This network will serve to build bridges that facilitate intensification of MD Anderson's catchment area activities in cancer prevention, early detection and control. The consortium provides a new and unique approach to overcome current barriers and gain geographic access to the full spectrum of Texas' population. The network infrastructure will support research studies designed to give all Texans an opportunity to benefit from what we know about how to prevent cancer.

Goals

1. Forge collaborations and develop a Texas-based network of PCPs to provide an infrastructure for discovery, development and dissemination of cancer prevention knowledge. Leverage engagement with practice-based research networks (PBRN) operative within Texas and catalyze development of a similar activity in Northeast Texas. Partner with relevant societies and service-based resources to develop a physician network that represents the diverse primary care physician workforce in Texas, including those working in rural, frontier, and community health center settings.
2. Develop and conduct surveys of the newly developed PCP network to assess knowledge gaps and current practice relevant to cancer prevention and screening. Key topics may include: cancer screening; tobacco cessation; vaccination; UV exposure; obesity prevention and diet; physical activity guidelines; hepatitis C screening; mental health; patient health literacy.
3. Identify gaps and needs of the PCP network. Perform descriptive analyses to summarize the data into information useful to intervention research scientists for development and testing of new approaches to delivering cancer prevention services to Texans.

Accomplishments

- Define the initiative and successfully compete for internal funding.
- Establish an Internal Advisory Board of research, clinical and public health leaders, including individuals who have had a major role in authoring the Texas Cancer Plan, and supplement with external experts.
- Explore opportunities for priority projects based on catchment area needs assessments.

Future Plans

- Assess catchment area needs informed by the Cancer Center Support Grant Population Health Survey (PI: S. Shete) and the Community Health Needs Assessment 2018, plus key stakeholder interviews.
- Build bridges between primary care providers and community oncologists.
- Identify knowledge gaps on cancer care and prevention.
- Understand barriers to participation in research.
- Launch pilot research/educational projects that reflect catchment area needs.
- Develop a portfolio of impactful research projects to extend the reach of MD Anderson cancer prevention research across the State, to promote health equity and, long-term, reduce health disparities.

Integrative Health Initiative

Directors: *Therese Bevers, M.D., Gabriel Lopez M.D., Ernest Hawk, M.D., M.P.H., Lorenzo Cohen, Ph.D.*

Optimize health, quality of life and clinical outcomes of patients and families through exceptional clinical care, research and education in integrative health services across the cancer continuum of prevention, active treatment and survivorship

MD Anderson's Integrative Health Initiative (IHI) expands the institution's multidisciplinary care model to include additional evidence-based behavioral and complementary clinical services for patients receiving care across the cancer continuum: prevention, active treatment and survivorship. By providing personalized services tailored to individual patient needs, the IHI aims to achieve better patient health outcomes. The IHI was approved by MD Anderson's Executive Committee in 2010 and embarked upon a process to establish or enhance clinical services in five domains of care: Nutrition, Physical Activity, Tobacco Treatment, Psychosocial Needs, and Complementary Therapies.



Clinical and Scientific Highlights

- Published clinical algorithms in physical activity, tobacco cessation and nutrition to codify MD Anderson's plan of care in these domains and disseminate these to health care professionals.
- Designed and piloted a Healthy Living Weight Loss Program in the Cancer Prevention Center's (CPC) Healthy Living Clinic.
- Delivered the Integrative Medicine Center's (IMC) IM FIT Group Program, version 2.0, to help patients with lifestyle-modification for weight-loss and improved fitness for patients undergoing or who recently completed cancer treatment.
- Provided support to the Healthy Heart Program, a new cardio-oncologist led intervention to improve fitness & mitigate existing cardiovascular risk factors in patients at high-risk for cancer and/or individuals treated for cancer.
- Launched in-clinic integration with the Breast Center to facilitate patient access to IMC healthy lifestyle clinical services.
- Continued the Comprehensive Lifestyle Change study to understand if changing multiple risk factors will lead to changes in biobehavioral processes and clinical outcomes in women with breast cancer.
- Conducted clinical trials to address questions related to symptom management, including a pilot study of massage for symptom reduction in chemotherapy-induced peripheral neuropathy, a project to assess the impact of meditation over a two-week period, and a couples-based yoga program for lung cancer patients and caregivers.

Goals

1. To provide evidence-based personalized services in five domains of care for patients across the cancer continuum: prevention, active treatment, and survivorship.
2. To assist cancer prevention patients and cancer survivors seen in the Cancer Prevention Center in adopting a healthy lifestyle.
3. To work closely with cancer patients seen in the Integrative Medicine Center and their oncology treatment team to help maximize therapeutic benefit while minimizing adverse side effects from their cancer treatment.

Accomplishments

- Provided over 8,000 prevention and survivorship patient interventions (Cancer Prevention Center) and over 17,000 interventions to cancer patients in treatment (Integrative Medicine Center) during a two-year period.
- Designed a web-based approach for the IOPRO data collection tool to assess patient symptoms, quality of life and motivation to seek Integrative Medicine Center services; expanded data collection to inpatient and group programs; published findings.
- Collaborated with corporate alliance partner, Jason's Deli, to develop co-branded menu items to deliver a healthy eating message in a casual dining environment.
- Provided subject matter expertise on cancer prevention and risk reduction to MD Anderson's online newsletter "Focused on Health" and for initiatives, such as the Texas Medical Center challenge to institutions to promote healthy eating through menu item spotlight labeling.
- Published 28 articles and abstracts to disseminate findings from research studies and clinical practice experience.
- Submitted 15 grants totaling \$12.3M and supported 6 active projects totaling \$3.8M.

Future Plans

- Explore expansion of domains of care to UV protection and HPV vaccination.
- Expand Healthy Living Clinic program to all prevention patients (CPC).
- Expand engagement with the Breast Center (IMC).
- Continue the collaboration with the rapidly growing Healthy Heart Program (CPC).
- Continue to explore financial sustainability, including through third-party payers (CPC).
- Develop delivery pathways for the Healthy Living Weight Loss Program and IM Fit 2.0 to support continuous program entry and other approaches to expand the reach of these initiatives.

The Healthy Living Clinic Weight Loss Pilot Program

The Healthy Living Clinic (HLC) launched a weight loss pilot in FY17 with a goal to help patients with a body mass index (BMI) greater than or equal to 30 kg/m² safely lose weight and increase physical activity via intensive behavioral therapy for obesity. The pilot was modeled after the Diabetes Prevention Program (DPP), which is an evidence-based, CDC-approved weight loss program and has been successfully shown to slow and prevent development of Type 2 diabetes. The DPP curriculum was adapted for weight loss in a cancer prevention setting since cancer is associated with similar behaviors as diabetes (obesity, low physical activity, poor diet quality, etc.).

1. To help patients with a BMI greater than or equal to 30 kg/m² safely lose 5-7% total body weight via 16 weeks of intensive behavioral therapy for obesity
2. To increase patients' physical activity over the duration of the 16 week behavioral intervention
3. To improve patient knowledge and self-efficacy to facilitate long term, sustainable lifestyle changes including healthy eating habits, goal setting, and coping with stress and challenges

Program Details

The program involved two phases: a comprehensive phase and a maintenance phase. The comprehensive phase aimed to provide education and support necessary for participants to implement recommended lifestyle changes through 16 weekly sessions. The maintenance phase provided monthly visits for ongoing accountability to assist patients in maintaining lifestyle changes. Both phases consisted of in-person visits with a medical provider and a DPP certified lifestyle coach.

Changes in diet, exercise behavior, and quality of life were measured by validated patient-reported questionnaires (ASA-24, Godin, and PROMIS Global 10) at baseline and post-intervention. The HLC Weight Loss Program has successfully implemented two cohorts using MD Anderson Cancer Center employees in efforts to determine clinical and operational feasibility.

Program Highlights

Cohort 1

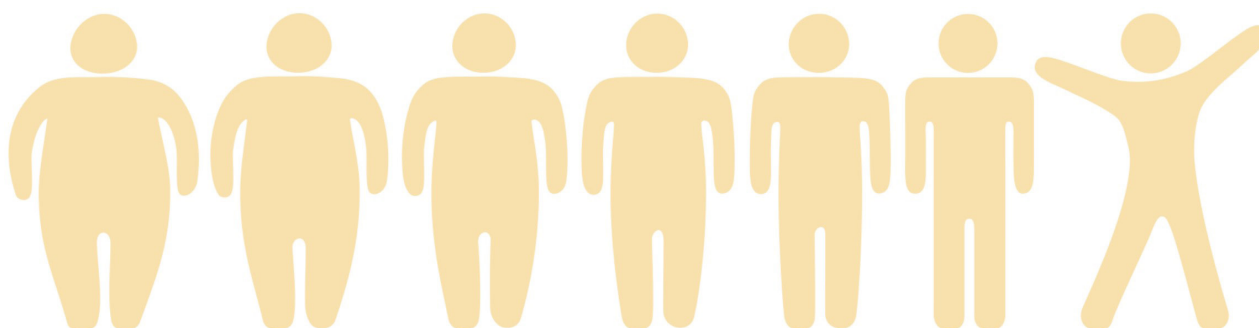
The pilot concluded in June 2017, with 21 of 30 patients completing the entire program. Eighteen participants lost some amount of weight and 20 participants experienced a decrease in waist circumference. Of those who lost weight, the average percent weight loss was 7% (15 lbs). The ASA-24 Healthy Eating Index (HEI) scores increased from baseline but were not statistically significant. The GODIN physical activity scores increased significantly between baseline and midpoint assessments and between the baseline and post intervention assessments. The changes in PROMIS scores for physical and mental health were not statistically significant over time though there was more improvement between the baseline and midpoint.

Cohort 2

The second cohort concluded in March 2018, with 25 of 41 patients completing the entire program. Fifteen participants lost some amount of weight and 14 participants experienced a decrease in waist circumference. Of those who lost weight, the average percent weight loss was 3% (7 lbs). Preliminary data from the validated questionnaires was collected and requires future analysis.

Future Plans

- Evaluate and analyze results from Cohort 2 to determine statistical significance and programmatic outcomes
- Explore various intervention delivery models including telehealth platforms
- Plan and implement third cohort of the HLC Weight Loss program
- Expand program services to all patients in MD Anderson's Cancer Prevention Center



SEED FUNDING RESEARCH PROGRAM

Supporting the Development of Preliminary Data for Innovative Research

The DFI's Seed Funding Program provides financial support to investigators working to generate the preliminary data necessary to improve competitiveness for extramural support for larger and innovative hypothesis-driven studies. Funding is awarded through a peer review process.

Awards are available to faculty throughout MD Anderson and support work across the continuum of cancer prevention research, from prevention to early detection to survivorship.

The institute competitively awarded seed funds to fourteen new projects, which are briefly described on the following pages. The DFI awarded nine of these awards to investigators residing in departments outside the Division of Cancer Prevention and Population Sciences, realizing the Institute's promise of reaching across disciplinary boundaries to advance prevention research.

Seed Funding Highlight

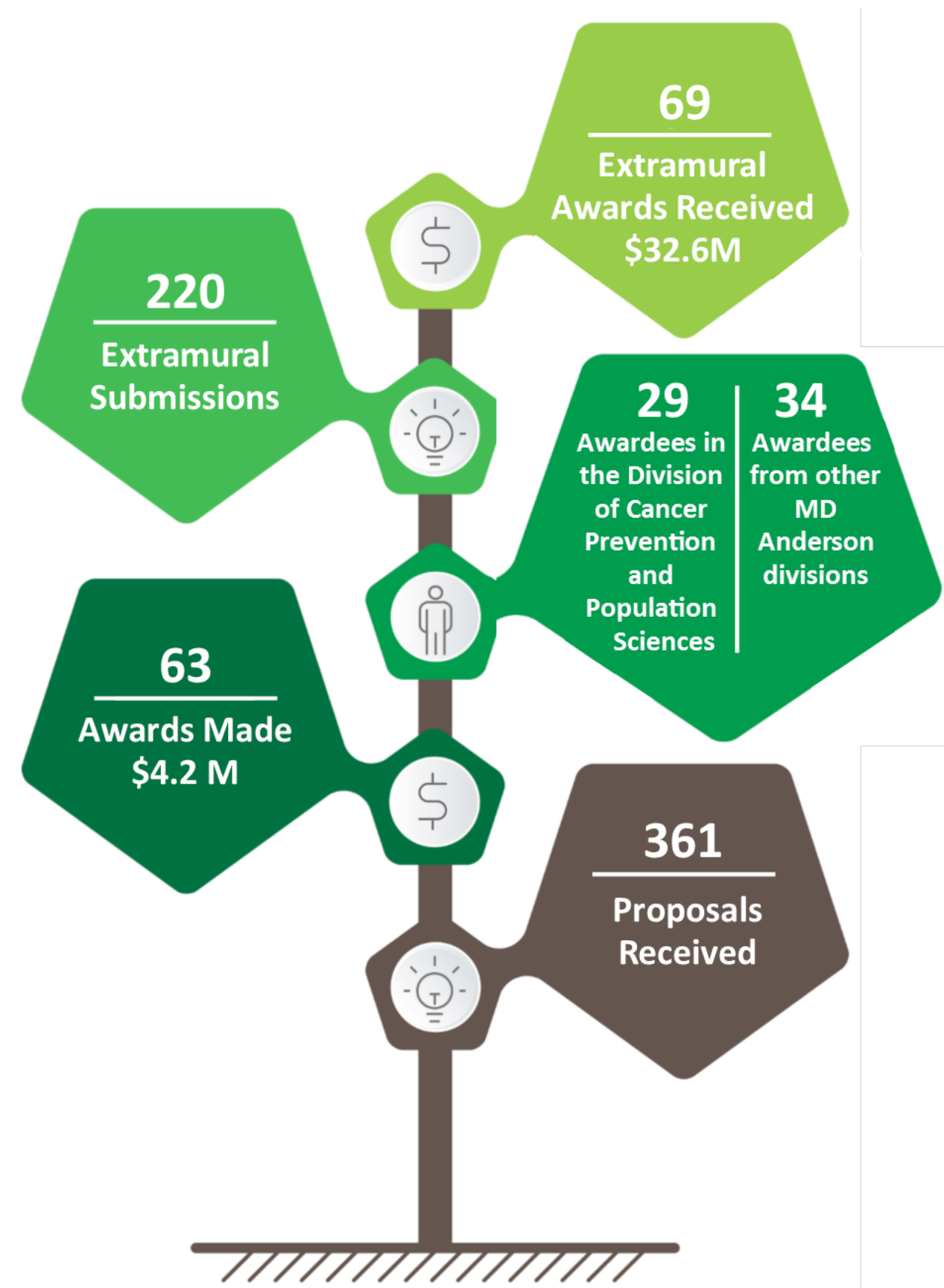
"Food Deserts in Houston? Increasing Fruit and Vegetable Consumption to Reduce Cancer Risk" *Conquest, Spring 2017*

Through a research study named Project FRESH (Food Resources Encouraging Sustainable Health), MD Anderson is combating the health problems associated with living in Houston's food deserts – areas without much access to healthy foods such as fresh fruits and vegetables. Members of New Faith Church in Central Southwest Houston who enroll in Project FRESH receive two free, 15-pound bags of fresh produce each week for eight weeks, as well as recipes and health tips. Produce is provided by Brighter Bites, a nonprofit organization that makes nutrition education and fresh fruits and vegetables available at schools in Houston, Dallas and Austin. The feasibility of implementation in churches was tested as well. McNeill is studying how this intervention improves church members' diet and well being.

McNeill hopes to offer even more health-related programs to churches in the future. And, unlike most traditional health education efforts, these programs will be tested for effectiveness to promote healthier lifestyles. "Most people understand what they're supposed to do to improve their health, but they often don't know how to do it," says McNeill.

"That's what we're doing through Project CHURCH. Trying to find innovative ways to help people do the things they want to do and reduce their risk of cancer."



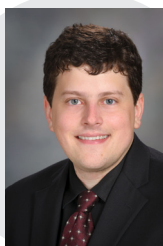


Seed Funding Return on Investment 2009 - 2017

Investments in Seed Funding Awards yielded substantial return in extramural funding.

SEED FUNDING AWARDEES

Seed Funding Research Program Round 11: 2 awards



Jeffrey Engelmann, Ph.D.
Behavioral Science

"Increasing Working Memory Capacity in Smokers: A Preliminary fMRI Study"

Working memory refers to a brain process that enables us to simultaneously manipulate multiple pieces of information and control our behavior. Previous research has shown that poor working memory is associated with relapse in smokers who are trying to quit. In this study, we will test whether two weeks of in-home, computerized cognitive training is capable of improving working memory capacity in smokers. If we find that cognitive training improves working memory capacity, we will conduct future studies in which we will assess the efficacy of cognitive training as an adjunct to standard smoking-cessation interventions. In the long run, it may be possible to improve smoking-cessation rates through the use of easily-administered, cost-effective cognitive training.



Qiang Shen, M.D., Ph.D.
Clinical Cancer Prevention

"Targeting Glucose Metabolism for Breast Cancer Prevention"

Currently available drugs for breast cancer prevention can only prevent a portion of ER-positive breast cancer. Effective preventive therapies are therefore urgently needed for the unpreventable/resistant ER-positive and all ER-negative breast cancers. In this regard, we have developed a new class of anti-cancer agents including HJC0152 that target and reprogram glucose metabolism and energy production. HJC0152 has demonstrated significant effects on reducing ER-negative breast cancer development in animal models by inhibiting pre-cancerous changes, making it a promising chemoprevention drug candidate for future breast cancer prevention.

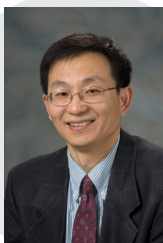
Seed Funding Research Program Round 12: 2 awards



Isabelle Bedrosian, M.D.
Breast Surgical Oncology

"Targeting of miRNA-140 and its downstream pathway for prevention of triple negative breast cancer"

Unlike advances made in breast cancer treatment, progress in breast cancer prevention has been far more limited, in part because the understanding that this cancer constitutes not one but several diseases has not been widely applied in prevention research. Further, little is known about the molecular changes that occur during the development of the different types of breast cancer, limiting the ability to develop prevention strategies that are relevant to subtypes of the disease. The goal of our research is to define the molecular map of the precancerous state by subtype in order to identify subtype-relevant opportunities for targeted prevention. Because of its more aggressive biology and lack of drugs for prevention, we have focused on the triple negative breast cancer subtype using a model that represents a spectrum of progression ranging from normal to pre-cancer then cancer. We have identified a number of molecular changes that are key drivers of the disease in the early transition from normal to precancer. In this study we will focus on targeting these molecular aberrations to develop innovative approaches to prevent triple negative breast cancer early on when treatments are more likely to be successful. To quickly benefit the high-risk patients, one of the strategies we will test includes repurposing a safe drug (statin, an FDA approved cholesterol lowering drug) that targets a pathway we have identified as relevant to the early precancerous steps in this type of breast cancer. The results of this proposal if successful will serve as the basis of developing clinical trials of novel targeted agents for prevention of triple negative breast cancer in at risk women.



Xiangwei Wu, Ph.D.
Clinical Cancer Prevention

"MDM2 inhibitor for pancreatic cancer chemoprevention"

p53 is a crucial tumor suppressor that stops tumor development in most species and is the most frequently inactivated gene in human cancers. Although about 50% of cancer patients harbor mutant p53, many tumors at early stages of tumor development retain wild-type p53. The presence of wild-type p53 in cancer precursor lesions presents an opportunity for chemoprevention by activating p53 to suppress tumor progression. The MDM2 protein is a key negative regulator of p53 and plays a primary role in antagonizing p53 through direct interaction. Small molecule MDM2 inhibitors that block the MDM2-p53 protein-protein interaction would liberate p53 from MDM2, thereby restoring the tumor suppressor function of wild-type p53. We hypothesize that enhancement of wild-type p53 functions by blocking MDM2-p53 interaction in precursor lesions using MDM2 inhibitor is an effective approach for cancer prevention. We propose to test this hypothesis in mouse model pancreatic cancer. If succeed, our study will pave a new way for pancreatic cancer chemoprevention.

2016 Survivorship Seed Funding Research Program: 5 awards



Kyle R. Noll, Ph.D.
Neuropsychology



Chelsea Pinnix, M.D., Ph.D.
Radiation Oncology



Dimpy Shah, Ph.D.
Infectious Diseases



Shirley Su, M.B.B.S.
Head and Neck Surgery



Lori Williams, Ph.D.
Symptom Research

“A Comprehensive Naming Approach to Language Mapping for Surgical Resection of Glioma”

Glioma is a type of brain cancer with poor prognosis. Early detection and surgery to remove as much of the tumor as possible is critical to optimizing the quality-of-life of glioma patients. However, this type of surgery carries the risk of damaging normal regions of the brain that control critical functions like speech and language. To minimize these risks, direct cortical stimulation (DCS) is used during glioma surgery to localize those regions of the brain responsible for language and thus guide surgery. However, this method remains largely unstandardized and has various limitations. This project addresses some of these limitations and seeks to improve the intraoperative mapping of particular brain functions related to speech and language in order to maximize the amount of patient language functioning that is preserved.

“Identification of Cardiac Toxicity Risk Based on Cardiac Dose Volume Relationships Among Patients Treated with IMRT for Hodgkin Lymphoma Across the Treatment Eras”

Combined modality therapy with doxorubicin-based chemotherapy followed by consolidative radiation therapy (RT) to the mediastinum is the standard of care for limited-stage Hodgkin lymphoma (HL). Cure rates are excellent; however, many survivors face long-term effects of the therapy which are associated with considerable morbidity and, in some cases, mortality. The specific cardiac RT doses that predispose to long-term toxicity are largely unknown. This study seeks to identify threshold RT doses and characterize dose-volume relationships to various cardiac structures that result in increased risk of late cardiac toxicity among a large cohort of patients treated for HL. This work represents the first study to correlate RT-induced cardiac toxicity with actual doses delivered to cardiac structures based on individual patient CT scans at the time of RT delivery. These data have enormous potential to significantly contribute to new RT dose-constraint guidelines for lymphoma patients that will be treated with mediastinal RT.

“Bronchiolitis Obliterans in Hematopoietic Stem Cell Transplant Survivors”

Bone marrow transplant is an important treatment option for many blood cancers; however, long-lasting complications such as bronchiolitis obliterans syndrome (BOS) may develop in up to 15% of cancer survivors. BOS may lead to lung function decline, worsening of quality-of-life, and death. The current definition of BOS does not capture the disease at an early stage in which it may be treatable and is suboptimal for the medical care of cancer survivors. In this project, Dr. Shah seeks to develop a new definition of BOS which would help clinicians identify it at an early disease stage. The investigators aim to better define BOS by identifying the level of decline of lung function that corresponds with higher mortality. Various risk factors for BOS will also be studied, including having viral pneumonia or not receiving treatment for viral infection at an early stage. This work will help clinicians to identify cancer survivors who may have early stage disease that may be treatable.

“MD Anderson Symptom Inventory, Skull-base Module: Developing a Disease Specific Instrument to Evaluate Quality-of-Life in Patients with Skull-base Tumors”

Patients with skull-base tumors often report significant reductions in quality-of-life, even many years after completing treatment. However, very little is known regarding the quality-of-life profile for these patients and there are very few instruments specific to this disease that can provide researchers with the needed data and information. The goal of this project is to deliver a user-friendly, universally applicable and validated instrument for use in clinical care and research. The investigators plan to develop a skull-base-specific module of the MD Anderson Symptom Inventory. This module would rate the severity of numerous general and disease-specific symptoms on a scale of 1-10. The instrument proposed in this work will help standardize reporting in research and identify targets for improvement. And it will likely have significant impact on clinical practice by facilitating monitoring of patients and early intervention.

“Pilot Study to Compare Symptom Burden of Generic Imatinib and Gleevec”

New cancer drugs are often extremely expensive. But generic versions of these drugs, once they become available, are usually cheaper and can ease the financial burden associated with some cancer therapies. In order to make informed decisions about switching to generic drugs, information about their side effects, effectiveness against the cancer and financial costs is needed. The drug Gleevec® is used to treat chronic myeloid leukemia (CML) and its generic version, imatinib, became available in 2016. This provides an ideal opportunity to begin to understand the impact on patients of a switch in the new cancer therapies from brand-name to generic drugs. The primary aim of this research is to explore any differences in symptom burden in survivors with CML who remain on long-term, name-brand Gleevec® versus those who change to generic imatinib.

2017 Survivorship Seed Funding Research Program: 2 awards



Grace Smith, M.D.
Radiation Oncology

“Financial Toxicity in Cancer Survivors: A Study to Understand the Road to Resilience and Recovery”

For cancer patients, the financial burden of cancer treatment is comprised of many dimensions—not just direct out-of-pocket costs, but also subsequent debt, medical bankruptcy, and disrupted employment—and this phenomenon is now recognized as the “financial toxicity” of cancer treatment. Younger, working-aged patients, women, and medically underserved cancer patients are at especially high risk for financial toxicity. For working-age cancer survivors, disrupted employment, especially unwanted unemployment, is one of the most impactful and long-lasting consequences of financial toxicity, lasting even years after cancer treatment and cure. Though we know disrupted employment occurs in as many as 30% to 50% of cancer survivors, we know very little about what factors predict employment outcomes after treatment, and more importantly, what are the most intervenable factors that can help improve this cancer survivorship toxicity. Our research uses a patient-centered approach to characterize, from a survivor perspective, the risk factors that worsen—and the mitigating factors that improve—resilience and recovery from adverse employment outcomes occurring over the cancer survivorship trajectory.



Elisabeth Vichaya, Ph.D.
Symptom Research CAO

“Is Fatigue during Cancer Survivorship a Result of Reduced Cellular Energy? Investigating Mitochondrial Functioning in Relation to Fatigue”

Fatigue is one of the most common and distressing symptoms experienced by cancer survivors. Unfortunately, the mechanisms underlying its development and persistence are poorly understood. Based on newly emerging data, we propose to study the role of mitochondrial dysfunction in the persistence of fatigue in breast cancer survivors. Disruption of mitochondrial function caused by cancer and cancer treatment may result in a chronic reduction in cellular energy production capacity that may lead to the experience of fatigue.



2017 CCSG Prevention and Population Science Research

Seed Funding Initiative: 3 awards



Susan Peterson, Ph.D.
Behavioral Science

“Utilizing the Texas Cancer Registry to Improve BRCA1/2 Testing in Texas: A Feasibility Study “

This project will test the feasibility of using the Texas Cancer Registry (TCR) to identify the prevalence of genetic testing for BRCA1/2 gene mutations in cancer survivors of triple-negative breast cancer (TNBC) or high-grade serous ovarian cancer (HGSOC), and their at-risk relatives. We also will determine awareness and access to genetic counseling and testing services among patients who have not had counseling and testing, as well as awareness and access to risk management options for mutation-positive patients. Finally, we will assess the feasibility of utilizing a patient navigation approach to facilitate access to BRCA education, genetic counseling, genetic testing, and risk management options (for mutation-positive patients).



Tina Shih, Ph.D.
Health Services Research

“Capacity Constraints for Lung Cancer Screening Facilities in Providing Smoking Cessation”

The purpose of this project, entitled “Capacity Constraints for Lung Cancer Screening Facilities in Providing Smoking Cessation” is to understand whether the current healthcare system has sufficient capacity to deliver lung cancer screening for individuals at high risk for lung cancer. We are especially interested in understanding the availability of lung cancer screening facilities in geographic areas with a higher proportion of residents who are smokers. If a shortage of screening facilities were identified in certain geographic areas, we will further explore the contributing factors. In addition, we will study factors facilitating and hindering the delivery of smoking cessation interventions in lung cancer screening facilities. We will conduct this project using a combination of quantitative and qualitative research methods. The project team includes faculty at MD Anderson with expertise in economics, implementation science, tobacco cessation research, and survey methodology. Finding from this research will help policy makers identifying geographic areas with greatest need for public health effort to improve its capacity in delivering lung cancer screening.



Grace Smith, M.D.
Radiation Oncology

“Cancer Patients In TexAs (CAPITA) Registry”

We are creating the Texas Community Feedback Survey: CAncer Patients In TexAs (CAPITA) to understand the needs and experiences of cancer patients and survivors across Texas. Understanding “patient-reported outcomes (PROs)” is a critical need, in order to inform the design of treatments and survivorship plans in a way that will be meaningful to patients—that is, patient-centered. Therefore, our research team is partnering with the Texas Cancer Registry to establish an approach to regularly survey and communicate with diverse cancer patients across Texas, to understand their needs for information and quality of life support resources.

enhance scientific interaction and productivity.

There are currently seven research resources: Assessment, Intervention and Measurement (AIM), Bionutrition Research Core, Center for Community-Engaged Translational Research, Clinical Cancer Prevention Research Core, Health Services Research Core Data Resource, Mexican-American Cohort, and Shared Decision-Making Collaborative. Investigators using these resources published research results in over 200 scientific articles, many of them in prestigious journals in their field.



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Assessment, Intervention and Measurement (AIM)

Bionutrition Research Core

Center for Community-Engaged Translational Research

Clinical Cancer Prevention Research Core

Health Services Research Core Data Resource

Mexican-American Cohort

Shared Decision-Making Collaborative

Assessment, Intervention and Measurement (AIM)

Director: Susan Peterson, Ph.D., M.P.H., Co-director: Karen Basen-Engquist, Ph.D., M.P.H.

Provide expertise in the science of collecting and managing patient-reported outcome and behavioral data; development and implementation of energy balance and technology-enabled behavioral interventions, and measurement and analysis of patient-generated health data.

The Assessment, Intervention and Measurement (AIM) resource supports the development and implementation of research studies asking and answering questions, primarily in cancer prevention and control, across a range of settings and populations. The common link across these diverse studies is the need for specialized expertise in three areas. Demand for expertise in collecting and managing patient reported data, the first area, is driven by the increasingly important need for patient-reported outcome data in many treatment trials to evaluate the impact of treatment on quality of life and symptoms, for example, and in survivorship studies, and cancer prevention research. AIM's second area of focus is in the development of energy balance and other technology-enabled behavioral interventions. Given the increasing evidence of the impact of healthy weight and physical activity in cancer survival and recurrence, more investigators are including fitness, body composition and physical functioning assessments as part of their research, and in testing exercise and weight management interventions. Increasingly, researchers are testing Web and mobile applications for delivery of behavioral assessments and behavior change interventions. Finally, AIM serves as a centralized repository for the unique expertise required for measurement and analysis of patient-generated health data.



AIM is a merger of the eHealth Technology Resource and the Patient Reported Outcomes and Survey Research core resource. As a result of a planning process, leaders determined in early 2017 that these two resources, providing complementary services, could be more effective and efficient if merged to create a single seamless experience for researchers. The result was the creation of AIM, with services in three key areas.

First, the combined resource provides services in **Assessment**, including identification of measurement tools and development of data collection procedures. Services also include design and development of data collection methods for clinic and community settings (including in-person, mailed, telephone, and commercially-available or customized Web and mobile surveys) and customized platforms for Web and mobile surveys, ecological momentary assessment (EMA), physical activity and functioning assessments, and sensor applications.

Intervention services include the delivery of physical functioning and exercise interventions, and the development of Web and mobile applications for behavioral interventions focused on cancer prevention (e.g., tobacco cessation) through cancer survivorship (e.g., managing treatment side effects in head and neck cancer survivors). AIM provides support to investigators for physical functioning and exercise interventions including: VO2 Max testing for cardiorespiratory fitness, venous blood draws, anthropometric measurements, a range of physical function tests, strength assessment using the Biodex system, DXA scans for body composition and bone mineral density, and initialization and data management of accelerometers to measure physical activity.

Measurement services include development of study tracking and questionnaire databases, data entry, computerized randomization modules, scoring of questionnaires and measurement tools, and psychometric analysis. AIM staff design and develop recruitment and participant tracking databases specific to the research project as well as single and double entry databases for questionnaire data. The statistical analyst assists with the development of data entry guidelines, quality control measures and procedures for handling missing data. AIM programming staff develop simple or adaptive randomization modules based on the specific needs of the study and design computer-assisted or web-based data collection applications. The statistical analyst has the training to set up and analyze/interpret computerized adaptive tests for PROs using tools developed by the Patient-reported Outcomes Measurement Information System (PROMIS) network. Staff provide scored datasets for analysis purposes and can provide psychometric analysis, and have extensive experience handling the large amounts of data generated from studies that utilize EMA and accelerometry.

Goals

1. Collect, manage and analyze patient-generated health data.
2. Conduct assessments and interventions in energy balance research.
3. Develop behavioral assessment and intervention tools utilizing Web, mobile and other technology applications.

Accomplishments

- Established AIM as an innovation hub for the science of collecting and managing patient-generated health data, in energy balance assessment and intervention, and behavioral intervention development and implementation utilizing Web, mobile and other technology applications.
- Supported MD Anderson Moon Shots™ research, including projects focused on melanoma, HPV, lung cancer and women's cancers.
- Serves as the Survey Core (led by Dr. Peterson) for a 5-year Multi-Investigator Research Award funded by the Cancer Prevention Research Institute of Texas (CPRIT), titled Comparative Effectiveness Research on Cancer in Texas. (MD Anderson PI: S. Giordano)
- Supports a Cancer Center Support Grant Supplement Award for a population survey of cancer risk factors in Texas. (PI: S. Shete, NCI)
- Developed a Web site for middle and high school educators to expand scalability of the ASPIRE youth online tobacco cessation program to the Houston Independent School District, the 7th largest school district in the U.S. (PI: A. Prokhorov)
- Supported development of components of 23 funded research projects whose total value is \$41M.
- Contributed to research reported in 31 scientific papers and abstracts.

Science Supported by the Resource

Longitudinal analysis of patient-reported outcomes and cosmesis in a randomized trial of conventionally fractionated versus hypofractionated whole-breast irradiation - This study compared longitudinal patient-reported outcomes and physician-rated cosmesis with conventionally fractionated whole-breast irradiation (CF-WBI) versus hypofractionated whole-breast irradiation (HF-WBI) within the context of a randomized trial. AIM provided assistance with protocol and survey design to assure methodological rigor and reproducibility in PRO data collection. (Swanick C, 2016)

A Comprehensive Lifestyle Randomized Clinical Trial: Design and Initial Patient Experience - This article describes the design, feasibility, adherence to the intervention and data collection, and patient

experience of a comprehensive lifestyle change randomized trial of a multiple-behavior intervention focusing on diet, exercise, and mind-body practice along with behavioral counseling to support change. AIM provided fitness assessments and assistance with data collection. (Arun B, 2017)

Developing mobile phone text messages for tobacco risk communication among college students: a mixed methods study - This paper describes the development of a text messaging program that informs about risks of conventional and new tobacco products for community college students age 18-25 years. Findings showed a gap in awareness of risks of using new tobacco products, indicating a need to target messaging on this topic. AIM developed the online survey and text messaging application. (Prokhorov AV, 2017)

Future Plans

- Expand options for mobile data collection and analysis by offering support for commercially available mobile platforms, in response to increasing requests from faculty for electronic survey options, as well as the increased use of mobile technology by our patients.
- Expand availability of resources and services to our faculty given growing interest in incorporating physical activity into their research (e.g., establishment of an exercise video library can increase accessibility of exercise demonstrations and instructions to investigators).
- Develop new web and mobile applications to support research projects, with a focus on applications that integrate with institutional clinical systems and with mobile and wearable sensors.
- Acquire capabilities for large scale data analysis and development of computational algorithms, and utilizing cloud technology to securely share data and applications with institutions and internationally.
- Expand reach across the institution through increased promotion of AIM's services.

Bionutrition Research Core

Directors: Susan Schembre, Ph.D., Carrie Daniel-MacDougall, Ph.D.

Assist investigators who examine the role of diet in cancer prevention and progression to conduct state-of-the-art nutritional science research by establishing best dietary assessment practices and by providing the resources necessary to plan and conduct human feeding studies.

The Bionutrition Research Core (BRC) was established as a Duncan Family Institute Strategic Initiative in June of 2015 with the goal of assisting MD Anderson Cancer Center investigators in their efforts to study the links between diet and cancer. The BRC is the first and only MD Anderson resource providing services to facilitate nutrition research along the cancer continuum. The formalization of the BRC aligns with the recent establishment of an Office of Nutrition Research across the NIH and the Office's Interagency Committee of Human Nutrition Research National

The BRC is equipped to provide services in three main areas: nutrient-controlled feeding studies, dietary assessment, and nutrition education and counseling. Investigators seek the services of the BRC for assistance with screening potential subjects for dietary investigation, development and implementation of study-specific research diets, assistance with nutrition-related protocol development and implementation, consultation and training regarding best practices for dietary data collection, computerized analysis of dietary intake using the Nutrient Data Systems for Research software and advanced statistical analysis of collected dietary data. The BRC also provides instructions for dietary regimens, study-related nutrition education, and research related clinical- and community-focused nutrition counseling and education.



Goals

1. Improve the infrastructure for conducting nutrition science research.
2. Assist investigators to conduct high impact state-of-the-art nutrition science research.
3. Standardize best dietary assessment practices.
4. Provide applied nutrition research opportunities.

Accomplishments

- Developed start-up infrastructure to include expertise, core business systems and governance committee.
- Marketed core services to targeted groups of clinical and behavioral science researchers resulting in six new studies in planning or start-up, including two pharma-funded pharmacokinetic (PK) studies with investigators in Investigational Cancer Therapeutics (ICT) with two more planned and an ACS-funded crossover trial (BE GONE), two NIH-funded studies (Take Charge and Tu Salud Si Cuenta), and a Moon Shot-funded trial (Health4).
- Disseminated best practices for dietary data assessment and analysis through research team training, consultation, and data processing and analysis.
- Established an Applied Nutrition Research Internship.
- Included on 32 grants totaling \$36M.
- Supported 5 active projects with a value of \$2.7M and completed 8 projects valued at \$3.2M (FY17).
- Published 5 articles and abstracts.

Science Supported by the Resource

Project Take Charge: Using continuously measured glucose concentrations to enhance weight loss by improving the self-regulation of energy intake

Obesity is now the number one ranked cause of cancer in non-smokers. Similar to smoking, at least 30% of all cancers are linked to poor diet and obesity suggesting a significant reduction in cancer incidence with sustained improvements in dietary intake and maintenance of a healthy weight. Despite global health promotion efforts, current weight control and dietary intervention paradigms have not been optimally effective at reducing cancer risk. This is, in part, due to stalled innovations in the field. The goal of Project Take Charge, an NCI-funded research grant, is to examine the effect adding anew dietary modification and weight control intervention methodology that uses continuous glucose monitoring as real-time biological feedback to proactively guide decisions about 'when' to eat to an evidence-based behavioral weight loss intervention. Dr. Schembre was awarded a NSF National I-Corps Team grant in 2016 to implement customer discovery and business development for commercialization of a technology-based, proactive decision-making support system to improve health behaviors related to obesity and diabetes management in clinical populations. A portion of the funds were used to develop a functional prototype of the Project SENSE technology. Subsequently she was invited to participate in the University of Texas Venture Mentoring Service to continue developing the technology towards commercialization. The BRC's test meal preparation and delivery services were an integral component of the product development process. (PI: S. Schembre; IRG, NIH, and NSF)

Tu Salud Si Cuenta: Reaching Latino family dyads to increase physical activity and healthy eating

The goal of this NIH-funded project is to evaluate the efficacy of a 6-month, community-based family dyad promoted intervention to promote engagement in and maintenance of physical activity and healthy eating among 650 Latino adults residing in three predominantly Latino communities in Houston, TX. The BRC provided team training to collected dietary data using the NCI's Automated Self-Administered 24-hr (ASA24®) Dietary Assessment Tool and conducted the nutrition analysis of the collected data from the ASA24 and a food frequency questionnaire. (PI: L. Strong; NIH)

Phase 1 Dose Escalation Trials - Pharmaceutical companies and clinical trial investigators are increasingly interested in understanding the effect of food on how a drug is absorbed by the body and its therapeutic benefit and adverse effects at varying doses. The BRC is a unique resource at MD Anderson that provides macronutrient and calorie controlled test meals for early phase, pharmaceutical company-funded clinical trials testing new therapies.

BE GONE trial - Beans to enrich the gut vs. the negative effects of obesity: Legumes are the perfect prebiotic package – rich in resistant starch (fiber), essential amino acids (protein), and beneficial bioactive compounds (e.g., antioxidants and phytonutrients) that feed and promote beneficial gut bacteria. Enriching the usual diet with legumes may have important anti-inflammatory effects mediated by changes in the gut microbiome that may improve gut and overall health to lower risk of recurrence in overweight/obese patients with a history of colorectal cancer. These hypotheses have yet to be tested in colorectal cancer survivors. The goal of this study is to test the feasibility and efficacy of a relatively simple dietary intervention of dry beans implemented within the patient's usual diet. The intervention will examine changes in the gut microbiome, blood metabolites, and obesity- and inflammation-related biomarkers of cancer risk. Long-term goals of this research include larger, multi-center trials and the establishment of new evidence-based dietary recommendations for colorectal cancer survivors. The BRC provided guidance on the logistics of distributing the intervention beans; consumption ideas and recipes; and product specifications. (PI: C. Daniel-MacDougall; IRG and ACS)

MOST Pilot Tests to Optimize the Delivery of Energy Balance Interventions (HEALTH4Families, HEALTH4MDAnderson, HEALTH4CLL survivors)

A growing body of evidence supports the benefits of physical activity and healthy weight for reducing cancer risk and recurrence in cancer survivors and high risk families. Traditional approaches to testing behavioral interventions generally test a combination of intervention components without the abilities to identify the most effective ones. These pilots employ a multi-phase optimization strategy (MOST), which optimizes interventions using factorial designs to identify the most active intervention components. The BRC is providing diet data collection analysis services related to the dietary assessment components. (PIs: K. Basen-Engquist, S. Peterson, L. Strong, S. Schembre, M. Cox, S. Myneni, B. Arun, K. Lu)



Future Plans

- Build additional collaborations with clinical and basic science researchers.
- Investigate strategic alliances with industry partners.
- Increase operating capacity in response to demand through addition of staff, expansion of dietetic intern program and collaboration with the Assessment, Intervention and Measurement core.
- Evaluate user satisfaction to monitor BRC delivery quality and adapt services to researcher needs.

Center for Community-Engaged Translational Research

Director: Lorna McNeill, Ph.D., M.P.H.

Connect communities and researchers to create long-term solutions to prevent cancer and improve health

The Center for Community-Engaged Translational Research (CCETR) offers researchers a broad range of services to connect with communities to develop and implement research, including: assistance with developing community-engaged research questions, identifying community research partners, facilitating research collaboration agreements with community partners, developing clinical trial recruitment plans for minorities and women, writing grant narrative sections, responding to reviewer feedback on clinical trial recruitment, and providing technical assistance to ensure project implementation and dissemination. CCETR also leads efforts to track and report progress on minority and women participation in clinical trials, helping researchers to ensure equitable access to interventional clinical trials for all patients with cancer.

Goals

1. Facilitate research development and implementation between MD Anderson investigators and diverse communities.
2. Establish and maintain equitable research partnerships.
3. Increase the capacity of investigators to recruit and retain diverse patients to clinical studies.



Accomplishments

- Awarded two significant grants: Komen Graduate Training in Breast Cancer Disparities Research and an NCI P20 with University of Houston to train undergraduate students, doctoral students and postdoctoral fellows in cancer disparities research.
- Engaged community and internal audiences on minority and women participation in clinical trials, including an annual clinical trial awareness event – Aware for All Houston, Be Your Own Advocate! attended by over 200 community members.
- Delivered multiple health education and capacity building training to over 1500 African American and Hispanic community members.
- Supported submission of 27 grants totaling \$55M of which 6 were funded for a total of \$7.9M.
- Supported 13 ongoing projects funded at \$22.4M in FY17.
- Published 38 scientific papers and abstracts.
- Presented 11 training sessions on cancer disparities, population demographics, cultural competence and other topics, reaching more than 500 individuals.
- Invited by the American Cancer Society of Clinical Oncology to participate on an expert panel for developing guidelines on patient physician communication.

Future Plans

- Lead new cross institutional partnerships in disparities to include: develop pathways to engage Harris Health LBJ Hospital patients in cancer prevention studies, start-up the University of Houston collaborative partnership grant, and explore a Texas Southern University collaboration to identify ways to extend MD Anderson's expertise to strengthen TSU health-related educational programs.
- Train and launch the first Citizen Scientist cohort in early 2018; recruit second cohort.
- Expand and further develop patient navigation to clinical trials through collaborative research to understand the role of trust in minority clinical trial participation, development of resources to re-establish the navigator program, and reporting of clinical trial participation demographic data to internal Moon Shot and clinical research leaders.
- Scale up community partnered cancer prevention research nationally through engagement with MD Anderson's Cancer Network sites beginning with studies to inform priorities for future collaborative intervention research.
- Continue close collaborations with the Faith Health and Family Collaborative and Project CHURCH.

Science Supported by the Resource

Active Living After Breast Cancer/Active Living After Cancer (ALABC)

- Cancer survivors are encouraged to participate in regular physical activity to improve cardiovascular fitness, reduce fatigue, enhance quality of life and, potentially, reduce risk of cancer recurrence and increase long-term survival. ALABC is a program to help cancer survivors become more physically active. Participants are taught behavioral and cognitive skills to add moderate intensity physical activity into daily life. In addition, the program provides support related to quality of life issues and health faced by breast cancer survivors. ALABC fills a distinct niche: the need for low-cost or free programs that are accessible to low-income and medically underserved cancer survivors. The program was implemented in church settings, enhancing African American participation, via CCETR's connections to two large African American churches and expertise in partnering with the African-American faith-based community. An additional four churches have committed to participate, providing an opportunity for scientists to learn how best to help African American cancer survivors increase their physical activity and gain support for quality of life and other health issues they may face. (PI: K. Basen-Engquist; CPRIT)


Citizen Scientist Program - Engaging community members in clinical research can increase its quality and relevance and is key to successful translation of scientific discoveries for public health benefit. Yet it remains a complex challenge. CCETR leaders identified the need for and designed a novel Citizen Scientist program, which establishes a network of diverse community members who are trained to participate as active members of research teams. Initially intended to support the UT Health/MD Anderson Center for Clinical and Translational Sciences' Community Engagement Component, which uses community participatory research methods and dissemination science to accelerate the "discovery-to-delivery" continuum, the Citizen Scientists will be available to all MD Anderson researchers who seek community input to improve clinical trial and research study designs so they reach their intended populations. CCETR identified and convened community leaders to provide initial advice and ongoing feedback on program design, developed program goals and structure, designed the curriculum to include specific learning objectives and core competencies and developed the training modules in topics ranging from human subjects and biomedical research to methods of community engagement.

Engaging Asian Stakeholders to Create a Shared Understanding of

Cancer Risk - Cancer is the leading cause of death among Asian Americans and cancer risk increases with greater acculturation. The CCETR team is partnering with HOPE Clinic (Federally Qualified Health Center) and a broad range of stakeholders to develop strategies for addressing cancer risk and prevention in the five largest Asian communities in Houston: Indians, Vietnamese, Chinese/Taiwanese, Filipinos, and Pakistanis (representing over 500,000 people). Using community-based participatory research, CCETR scientists and staff will engage researchers, healthcare providers, community members and organizations, and other stakeholders using a variety of

methods to enhance our understanding of cancer risk in Asian groups, which will address an unmet need for community action and education around cancer. MD Anderson and HOPE Clinic, a Federally Qualified Health Center serving a large proportion of Asians, will lead this effort. Other stakeholders are representatives from the Houston Health Department, Light & Salt Association, Philippine Nurses Association of Metropolitan Houston, and Vietnamese American Medical Association of Greater Houston, to name a few. Initial activities will include development of an advisory board, collection of data on cancer risk factors from our target populations, and strengthening the capacity of stakeholders and community members to actively participate in patient-centered outcomes research through workshops and training opportunities. (PI: L. McNeill; PCORI)

Healthy (now Be Well®) Communities - The Be Well® Communities



initiative aims to mobilize communities to promote wellness and stop cancer before it starts. This initiative, conceived by cancer prevention scientists and health promotion experts, was supported by CCETR staff in its design, development and early start-up phases. During the planning phase, the CCETR team joined with Cancer Prevention and Control Platform staff to gather health and socioeconomic data about Harris County communities, interview key community leaders, and create a repository of evidence-based interventions that could be implemented to mitigate cancer risk factors. The combined CCETR and Cancer Prevention and Control Platform team partnered with Harris County Public Health and the Houston Food Bank on a successful BUILD Challenge Grant, with aims to implement a new food system in north Pasadena that is healthy, sustainable, affordable, accessible, and community-supported.

National Outreach Network (NON) Community Health Educator (CHE)

- The goal of this facilitated education and outreach NCI-funded project is to plan, conduct and assess cancer-focused community education and outreach activities to underserved communities across MD Anderson's catchment area, with specific emphasis on African American populations. A community health educator was integrated into key initiatives at MD Anderson and in relevant Geographic Management of Cancer Health Disparities (GMAP) Region 3. The CHE facilitated education and outreach activities for multiple initiatives at MD Anderson, including the Faith Health and Family Collaborative (education and outreach), Lymphoma (patient navigation training), Project EMPACT (minority participation in clinical trials), MD Anderson Survivorship Clinic, Cervical Cancer Moonshot, Community Relations and Education (education and outreach), and Urology (facilitating new relationship with 100 Black Men of America). CCETR provides expertise and extends its network to the CHE in addition to managing the grant-related aspects of the initiative. (PI: L. McNeill; NCI Cancer Center Support Grant Supplement – National Outreach Network (NON) P30CA016672)

Clinical Cancer Prevention Research Core

Directors: Powel Brown, M.D., Ph.D., Therese Bevers, M.D., Abenaa Brewster, M.D., M.H.S.

Expertise and resources for collaborative translational and clinical research investigating risk assessment and risk reduction interventions, cancer risk and early detection markers, and cancer screening

The Clinical Cancer Prevention Research Core (CCPRC) provides expertise and resources through its two arms, the Clinical Trials Support (CTS) group and the High Risk Breast Cohort and Biorepository (HRBC).

The Clinical Trials Support group provides expertise for the development, implementation and conduct of clinical prevention research in all phases including: investigator-initiated National Cancer Institute (NCI) multicenter chemoprevention Phase II and III clinical trials, multicenter cooperative group Phase III clinical trials, industry sponsored clinical research and investigator-initiated clinical research studies. Research nurses and data coordinators support cancer prevention research using novel modalities including topical chemoprevention agents and preventive vaccines. They provide regulatory, compliance and operational expertise that would not otherwise be available to investigators, and especially to junior investigators, during the critical phases of clinical trial approval and start-up. NCI medical monitors and others have recognized them for their expertise in the conduct and data management of cancer prevention clinical trials, factors critical to high quality clinical trial outcomes.

The High Risk Breast Cancer repository is designed to prospectively follow cancer-free women at high risk of developing breast cancer with the serial collection of biological specimens, clinical and epidemiological data, and clinical outcomes. It provides a ready-access resource for researchers interested in developing breast cancer risk and early detection research study protocols, including the High Intensity Interval Training (HIIT), Alliance Metformin Study and the Preventive Therapy Improvement Project (PIP).

The Clinical Cancer Prevention Research Core is positioned to extend cancer prevention research to populations representative of the greater Houston area by collaborating with leaders from the MD Anderson Oncology Program at Lyndon B. Johnson Hospital, Community-Engaged Translational Research and Clinical Research Support Center to pool existing resources and expertise. Meeting this goal is essential to ensuring that the institution's cancer prevention research priorities are inclusive of underserved populations.

Goals

1. Provide expertise to conduct collaborative translational and clinical research investigating cancer risk, to include interventions to assess and reduce cancer risk, screen for cancer and detect it at its earliest stages through biomarker discovery and intercept cancer through prevention interventions.
2. Develop and maintain a ready-access resource for researchers investigating biomarkers, lifestyle risks and other risk factors used to predict invasive breast cancer.



Science Supported by the Resource

A Randomized, Double-blind, Placebo-controlled Study of 4-hydroxytamoxifen Topical Gel in Women with Mammographically Dense Breast

- This MD Anderson investigator-initiated, multicenter project is a double-blinded, randomized study of 4-hydroxytamoxifen (4-OHT) topical gel will compare the percent change in mammographic density from baseline to 12 and 24 months as a surrogate marker breast cancer risk. The CCPRC supported all aspects of protocol management including recruitment, enrollment, clinical/data management and regulatory compliance. (PI: B. Arun; NCI)

Bexarotene in Preventing Breast Cancer in Patients at High Risk for Breast Cancer

- In this phase I trial, clinical research scientists are studying the side effects and best dose of bexarotene in preventing breast cancer in patients at high risk for the disease. Drugs used in chemotherapy, such as bexarotene, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. The primary objective of this trial is to determine the recommended phase II dose of topical bexarotene 1% gel for evaluation in healthy women. The CTS unit of the CCPRC provided protocol management expertise. (PI: P. Thomas; NCI)

Alternative Dosing of Exemestane in Postmenopausal Women with Stage 0-II ER-Positive Breast Cancer: A Randomized Presurgical Trial

- This pre-surgical phase IIb, randomized, double-blind, multi-center study for postmenopausal patients with histologically confirmed ER-positive breast cancer (Stage 0-II) will compare exemestane standard dose regimen versus two alternative, less frequent dose regimens. The CCPRC provided expertise to advance all aspects of protocol management including recruitment, enrollment, clinical/data management and regulatory support. (PI: P. Thomas)

A Multicenter Phase II Study of Docosahexaenoic Acid (DHA) in Patients with a History of Breast Cancer, Premalignant Lesions or Benign Breast Disease

- This is a multicenter project, funded by the National Cancer Institute Division of Cancer Prevention (NCI DCP) and administered through the MD Anderson Phase I/II Prevention Consortium. This study will determine if treatment with docosahexaenoic acid (an omega 3 fatty acid) as compared

to placebo reduces normal breast tissue levels of inflammatory biomarkers in overweight women with a history of breast cancer, premalignant or benign breast lesions. Protocol management, including recruitment, enrollment, clinical/data management and regulatory support provided by the CCPRC CTS resulted in a near-perfect closeout by NCI monitors and recognition for the value this expertise provides to the success of these complex clinical trials. (PI: E. Cook; Co-PI: P. Brown; NCI)

Phase II Trial of Weekly Erlotinib Dosing to Reduce Duodenal Polyp Burden Associated with Familial Adenomatous Polyposis

- This multicenter study will evaluate the efficacy and toxicity of a 6-month intervention for erlotinib 350 mg/week in FAP patients. Change in duodenal polyp burden will be assessed pre and post intervention. The CCPRC research nurses and staff provided expertise for protocol management, including recruitment, enrollment, clinical/data management and regulatory support. (PI: E. Vilar-Sanchez; NCI)

A System-Level Approach to Improve the Uptake of Antiestrogen Preventive Therapy among Women with Atypical Hyperplasia and Lobular Cancer In Situ

- The low uptake of antiestrogen preventive therapy among women at high risk of developing breast cancer remains a challenge. Clinical leaders implemented a performance improvement program to increase the uptake of preventive therapy among women with atypical hyperplasia (AH) and lobular cancer in situ (LCIS). A performance improvement program was implemented at MD for patients with a new (<6 months) or existing (≥6 months) diagnosis of AH/LCIS. The program consisted of an audit of eligible women who were recommended and prescribed preventive therapy and the provision of clinical performance feedback to providers. The baseline uptake of preventive therapy was estimated from patients enrolled in a high-risk breast cohort. Baseline uptake of preventive therapy was 44%. Ninety-eight percent of patients registered to the program received a recommendation for preventive therapy. The overall prescribing of preventive therapy to patients with a new or existing diagnosis was 82%. The results showed that a system-level approach improved the uptake of preventive therapy. Identifying women at the time of diagnosis of AH/LCIS and offering a strong recommendation are key components for improving acceptance and adherence with preventive therapy. (A. Brewster, et al., Ca Prev Res, 2018)

Future Plans

- Enrich the HRBC with African American and Hispanic women at high risk of developing breast cancer by expanding the HRBC to the MD Anderson Oncology Program at LBJ.
- Expand the CTS with the recruitment of patients onto cancer prevention clinical trials from the MD Anderson Oncology Program at LBJ and the Houston-area Locations (HALs).
- Develop synergistic cancer prevention collaborations and increase prevention options for high risk populations, including those with Familial Adenomatous Polyposis, Hereditary Nonpolyposis Colorectal Cancer and elevated risk for breast cancer.
- Increase research utilization of the High Risk Breast Cohort and Biorepository by raising awareness through presentations and collaborations.
- Promote participant retention in the HRBC through continued use of advanced technology for data collection, reminders, and newsletters.
- Promote availability of the CCPRC and Cancer Prevention Center (CPC) for inter-institutional prevention collaborations as well as to site-specific Moon Shot Program teams.

Accomplishments

- Contributed active support, during FY17, to 26 projects that had a total value of \$7.5M.
- Supported a total of 16 Phase I, II or III clinical trials and 20 laboratory and population science research studies since inception in 2011.
- Increased utilization of the HRBC to a total of 7 projects supported by 6 active grants, with another 3 in submission.
- Supported the submission of 23 projects to extramural funding sources of which 14 were funded for a total value of \$8.6M.
- Results of multiple projects supported by the CCPRC were published in scientific journals (11 publications; 3 in high impact journals).
- Clinical Trials Support personnel recognized by NCI for participant accrual and data quality.

Health Services Research Core Data Resource

Director: Sharon Giordano, M.D., M.P.H.

Acquire and maintain data resources to conduct the highest quality health services research, to include the study of health care delivery, economics of care, cost-effectiveness, quality of care, and treatment outcomes



Health Services Research (HSR) is a multidisciplinary field that is growing rapidly due to increasing national attention to issues of health care cost, quality, and delivery. The current realities of the U.S. health care system are that it is one of the most costly in the world, with the cost of care growing at an unsustainable trajectory, and yet significant gaps exist in health care quality and care coordination. Health services researchers ultimately aim to optimize health care delivery and improve outcomes for patients and populations. Data resources, such as SEER-Medicare, Marketscan and Texas Cancer Registry databases, are critical to investigate health services questions.

Accomplishments

- Supported submission of 18 grants totaling \$14.2M, of which 10 were funded, totaling \$2.3M.
- Supported 22 projects, totaling \$3.2M.
- Published 48 scientific papers and abstracts, including several in highly ranked journals, such as “Cost and complications of local therapies for early-stage breast cancer” in the Journal of the National Cancer Institute.
- Obtained nearly \$4.0M in external funding for sustaining this core resource.

Goals

1. Create a core data resource consisting of large datasets to promote HSR studies at MD Anderson.
2. Acquire, maintain, and update large databases to be used by MD Anderson researchers.
3. Maintain licenses, data use agreements, and confidentiality agreements to ensure regulatory compliance with the use of such database.
4. Provide guidance and analytic support on studies using these databases.

Science Supported by the Resource

Health Services Career Development: Improving Medical Decisions

in Ovarian Cancer - Although it is well accepted that optimal therapy for advanced ovarian cancer remains a combination of tumor debulking surgery and platinum/taxane based chemotherapy, there is still an ongoing heated international debate focused on whether it is better to start with primary debulking surgery (PDS) or neoadjuvant chemotherapy (NAC). The goals of this project are to build a decision analytic model that incorporates the best published evidence supplemented by primary analyses of outcomes with PDS or NAC in national and MD Anderson databases, and patient preferences and experiences (assessment of symptom burden) when starting treatment with primary debulking surgery or neoadjuvant chemotherapy. This project will also entail the design and iterative testing of a shared medical decision tool prototype that combines predictive clinical factors with interactive values clarification methodology to support patients and physicians in the complex process of deciding on primary treatment for advanced ovarian cancer. Overall, these studies will impact women with gynecologic malignancies through meaningful, patient centered, health services research. These data will be informative for both patients and clinicians when making difficult treatment decisions, will identify new and potentially modifiable determinants of clinical outcomes in ovarian cancer, and will form the basis for a prototype decision tool to test in a prospective, multi-site, randomized controlled trial for women with advanced ovarian cancer, that will be proposed in a larger extramural grant application. Input for the model will be identified from published sources in addition to primary analyses utilizing large national databases available through the Core. (PI: L. Meyer; NCI)

Technology Diffusion in Cancer: Geographic Variations, Facilitators,

Outcomes, and Costs - The goal of this study is to examine the impact of technology diffusion in medical, radiation, and surgical oncology on the costs and outcomes of cancer care, focusing on the top five most expensive cancers: female breast, colorectal, lymphoma, lung, and prostate cancer. Once complete, the results of the study will provide a comprehensive evaluation of the current state of technology diffusion for all modalities involved in the treatment of cancer, with special attention on market and organizational characteristics tied to providers' financial incentives. Findings from our study will assist policy makers in the design and planning dissemination and implementation strategies to maximize the benefit of effective new treatments while taking into consideration of the cost implications to the cancer care delivery system. To achieve the study aims, investigators will describe the pattern of technology diffusion in medical, radiation, and surgical oncology in the top five most expensive cancers and assess the geographic variation of the diffusion pattern. They will examine factors associated with the diffusion of new technologies and those that contribute to the geographic variations in new technology diffusion. They will also evaluate the impact of the diffusion of new oncologic technologies on health outcomes and whether the impact would be modified by guideline adherence. Finally, researchers will estimate the effect of the diffusion of new oncologic technologies on the cost of cancer care and geographic variation in healthcare spending, and explore for each cancer whether these new technologies are substitute or complementary to existing treatment. The project uses the Core's SEER-Medicare and MarketScan data to address the research questions. (PI: Y. Shih; NCI)

Health Services Research in Neuroendocrine Tumor in the SEER-

Medicare Population - The objective of this project is to analyze and determine incidence, prevalence, survival, trends in treatment patterns, health resource utilization and outcomes of people with neuroendocrine cancer in the Medicare population, due to the lack of published information on this population. Findings from this study will help to determine the burden of illness, co-morbidities, late diagnosis versus early diagnosis and patients' clinical pathway leading to the diagnosis of neuroendocrine cancer. The HSR Core Data Resource is providing all of the data being used for this project. (PI: C. Shen; Industry-sponsored)

Comparative Effectiveness Research on Cancer in Texas (CERCIT)

- The overall objective of this multi-investigator/multi-institutional project is to generate evidence that will assist patients and their physicians in individualized decision making when faced with choices among different options in screening, treatment and end of life care in cancer. This will be targeted through the analysis of insurance claims, cancer registry, and survey data to assess outcomes of different tests and treatments. A project example is an initiative focused on lung cancer screening with low dose CT (LDCT), recently approved by CMS and insurance companies. CMS has mandated a counselling/shared decision making (SDM) visit prior to receipt of LDCT. The HSR core data resource is providing Texas Medicare charge data from 2009-2019 in order to determine the patterns of counselling/SDM and also receipt of LDCT lung cancer screening. The product of this project will help shape public policy and practice in optimizing the impact of cancer screening activities for Texas. In other projects, the investigators will assess the toxicity experienced by older patients with invasive colorectal, breast, and lung cancer during initial chemotherapy using TCR-Medicare and SEER-Medicare data, and how the toxicity varies by type of chemotherapy. The HSR Core Data Resource is providing the data for this project. (PI: S Giordano, et al.; CPRIT)

Future Plans

The Health Services Research Core Data Resource's success in generating extramural funding to provide support beyond the Duncan Family Institute startup funding will allow the Core to continue its investments in resources to advance the science it supports. Plans include:

- Continue to purchase, license and update data to maintain resources of value to health services researchers.
- Strengthen the core resources by collaborating with the Texas Cancer Registry.
- Seek additional support from CPRIT and other external funding agencies with an interest in asking and answering health services research questions.
- Broaden the resource to support patient reported outcomes and other health services-related research areas through intramural and extramural collaboration.

Mexican-American Cohort

Directors: *Wong-Ho Chow, Ph.D., Hua Zhao, Ph.D.*

Study cancer and chronic disease risks in a population undergoing social change, develop population-specific prevention strategies for cancer and cancer-predisposing conditions, and serve as a valuable resource to advance population science

Mexican Americans represent the largest and fastest growing ethnic minority in the U.S. and are the largest Hispanic subgroup in the U.S. and Texas. The Mexican-American community in Houston through its long presence has established distinct neighborhoods and cultural practices that now includes first through fourth generation Americans, thus offering a great insight into the effects of acculturation. This community has a high prevalence of diabetes and obesity, and it has seen for the first time a major shift to where cancer has surpassed cardiovascular diseases to become the leading cause of death. Nevertheless, segments of the Cohort population have a higher than average prevalence of poor access to health care and are under-served and under-represented in health-related research.

MD Anderson's Mexican American Cohort, Mano A Mano, is a unique resource, providing a well-characterized population to facilitate health-related research. Studies using the Mexican American Cohort data and biological samples, integrating acculturation, sociodemographic and epidemiologic/behavioral information along with biomarkers, could yield insights into the identification of individuals at high risk of developing specific types of cancer and other chronic diseases. These insights can inform scientists about how to develop and tailor cancer prevention and health promotion programs and implement these to improve health outcomes in this population.



Goals

1. Identify and understand risk and protective factors for cancer and other chronic diseases as they emerge in a population undergoing social changes.
2. Utilize epidemiological, behavioral and genetic risk factors to develop cancer prevention strategies aimed at reducing morbidity and mortality among Mexican Americans in the Houston area.
3. Serve as an infrastructure to advance the mission of MD Anderson Cancer Center to eliminate cancer by supporting institutional and inter-institutional collaborations among researchers interested in asking and answering questions regarding cancer prevention and risk reduction in the Cohort population.

Accomplishments

- Continued recruitment with 26,676 participants from 18,696 households enrolled as of June 30, 2017.
- Improved follow-up rate to 66.3% overall, with a rate of 69.4% for participants enrolled after 2005, in part due to upgrading tools to locate participants previously lost to follow-up.
- Joined NCI's Cohort Consortium and provided descriptive data to the Cancer Epidemiology Descriptive Cohort Database to share cohort information and encourage collaboration.
- Partnered with Community Relations and Education to disseminate information about the Cohort to community members and potential Cohort participants.
- Participate in the new NCI-led Hispanic Cohort Consortium and the Consortium of Metabolomics Studies (COMETS).
- Advanced development of 8 research proposals submitted to peer review funding agencies totaling over \$16M and actively supported 1 project totaling \$1.7M.
- Provided samples, data and expertise to research studies for which results were published in 20 scientific papers and abstracts.
- Enhanced Cohort infrastructure through engagement with the Center for Health Statistics at the Texas Department of State Health Services to link Cohort data to mortality data to support research to evaluate mortality risks in relation to exposure and molecular data.
 - Initiated laboratory analyses to characterize various molecular markers using stored biological samples from the Cohort, enhancing the data resources to support investigators testing hypotheses in the Cohort population.
 - Supported 4 graduate student trainees with Cohort resources to advance their research projects.
 - Followed-up for incident cancer with participants and through linkage with the Texas Cancer Registry (TCR) records. 822 cancer cases have been identified. As expected, breast cancer is the most common malignancy among women (189/612; 31%) whereas prostate cancer is the most common among men (54/210; 26%) in this cohort.

Future Plans

- Support and extend research networks infrastructure to Houston-Area Locations, Sister Institutions and the Cancer Network.
- Continue to strengthen the Cohort infrastructure through projects such as:
 - Link to the Texas vital statistics records for analysis of mortality risks.
 - Include a geographical information system environmental component to explore the environmental determinants in chronic diseases.
- Disseminate information about Cohort resources to expand collaborations with researchers whose studies included the Cohort population through website redesign and content enhancement, among other activities.

Science Supported by the Resource

Genomics of Chronic Liver Disease and Hepatocellular Carcinoma in the Hispanic Population in Texas - Hepatocellular carcinoma (HCC) is the fastest growing cause of cancer-related death in the United States. It is critically important to identify individuals at high risk for this disease and implement effective strategies for early detection. In this NCI-funded research study, the investigators are targeting liver cirrhosis, the main risk factor for HCC, with the aim of improving cancer survivorship in these. The investigators have identified novel biomarkers through extensive studies and will now evaluate the capacity of these to detect preclinical disease and determine the longitudinal changes in these biomarkers that are predictive of HCC development. This study has a number of high-impact translational applications: spare patients from unnecessary imaging tests; identify at-risk patients and trigger the decision to perform MRI instead of ultrasound in patients under surveillance; and detect lesions at an early stage allowing for curative treatment. These clinical applications would significantly reduce the cost of HCC surveillance and improve survival of HCC patients. The Mexican American Cohort served as a resource for data and biological samples in support of Dr. Beretta's multiple grant applications and for an ongoing molecular discovery project that is in data analysis. (PI: L. Beretta)

Social-demographics, Health Behaviors, and Telomere Length in the Mexican American Mano A Mano Cohort - Investigators examined associations among social-demographics, lifestyle behaviors, and relative telomere length (RTL) in peripheral blood leukocytes, as well as longitudinal relationships among major chronic diseases, weight gain, and RTL, in a sample of 12,792 Mexican Americans aged 20 to 85 years in the Mano a Mano, the Mexican American Cohort. As expected, RTL was inversely correlated with age, and positively correlated with levels of education, self-insurance, body mass index (BMI), and sleeping time per day. RTL was inversely correlated with sitting time per day. In longitudinal analysis, the researchers found that longer RTL was modestly but positively associated with increased risks of overall cancer. These results suggest in Mexican Americans support the idea that social demographics and health behaviors can affect biological mechanisms, in this case – telomere length. (Zhao, H. et al, Oncotarget, 2017)

Acculturation, Sociodemographic and Lifestyle Factors Associated with Compliance with Physical Activity Recommendations in the Mexican-American Mano A Mano Cohort - Few Mexican-Americans meet national U.S. physical activity recommendations yet being physically active is important for health. In this study, researchers conducted a cross-sectional analysis to investigate the sociodemographic, acculturation and lifestyle factors that were associated with meeting physical activity recommendations in Mexican American Cohort participants. In this group of 21,551 Cohort members, less than half of all men and less than a quarter of all women met U.S. physical activity recommendations. Having some college education, greater acculturation and current alcohol use were each associated with greater likelihood of meeting physical activity recommendations in all groups except US-born men. Higher body mass index was associated with lower odds of meeting recommendations in US-born and Mexico-born women. The results suggest that tailored interventions to increase Mexican-Americans' activity levels to achieve health benefits should consider education, acculturation and alcohol use. (Chrisman, M. et al, BMJ Open, 2015)

Acculturation and Diabetes Risk in the Mexican American Mano a Mano Cohort - Scientists leading this study used the data and other resources of the Cohort to investigate the association between acculturation and diabetes risk in the Mexican-American Cohort. Cohort participants (15,975) recruited between 2001 and 2014 provided information on language use, birth country and duration of U.S. residence and these were used to assess acculturation. Participants self-reported a physician's diagnosis of diabetes during annual follow-up and this was validated in a small subset of participants with 98% agreement. The researchers found that diabetes risk was higher among immigrants with 15+ years of residency in the U.S. compared to those with less than five years. Neither language acculturation nor birth country were significantly associated with diabetes risk, suggesting that diabetes risk increases with longer duration in the U.S. (Anderson, C. et al, Am J Public Health, 2016)

Plasma MicroRNA Signature Predicting Weight Gain among Mexican-American Women - There is growing evidence that circulating microRNAs (miRNAs) play an important role in obesity. However, whether they can contribute to adult weight gain is unclear. In this study investigators defined a training set of 40 nonsmoking, healthy women identified from the Mano a Mano Mexican American Cohort study and then defined global circulating miRNA profiles in plasma samples. Statistical analyses were used to assess the effects of plasma miRNAs on significant weight gain during a 5-year follow-up. Plasma miRNAs associated with significant weight gain were further validated in two additional testing sets. Investigators found that circulating miRNAs play important roles in obesity and weight gain and suggest new targets for understanding the mechanisms of weight gain and developing weight loss intervention strategies. (Zhao, H. et al, Obesity, 2017)

Identifying Demographic and Psychosocial Factors Related to the Escalation of Smoking Behavior among Mexican American Adolescents - Cigarette smoking is the leading preventable cause of death in the United States; smoking in Mexican-American adolescents, a rapidly growing population, remains a major concern. Factors associated with escalation or progression along the smoking trajectory have not been studied in adolescent Mexican Americans. A better understanding of escalation is needed for cancer prevention and overall health. In this study, scientists analyzed data from 1,328 Mexican American adolescents who joined the Mexican American Cohort in 2005–06 and were able to use a subset of these data for a total of 973 participants. At baseline participants provided demographic, acculturation and psychosocial data, and reported their smoking status using the Minnesota Smoking Index. Those that never tried a cigarette or only had a few puffs in their life were included in this study. The primary outcome of interest, escalation in smoking status, was defined as moving up the Minnesota Smoking Index by 2010–2011. Researchers found that 283 (29%) escalated their smoking status and 690 (71%) remained the same. Factors associated with increased risk for smoking escalation including being older, male, having higher levels of anxiety, intending to smoke, having friends who smoke and having parents' friends who smoke. Higher levels of subjective social were protective against smoking escalation. In contrast to previous work in smoking experimentation, parents' friends influence was a stronger predictor than the family household influence. Preventive interventions for Mexican American youth could address this risk factor to reduce smoking escalation. (Shete, S. et al, Prev Med, 2017)

Shared Decision-Making Collaborative

Director: Robert Volk, Ph.D.

Enhance the quality of decision-making in cancer prevention by providing patients and their health care providers with evidence-based tools to work in partnership to make difficult decisions in line with the values and preferences of the patient

The Shared Decision-Making Collaborative (SDMC) supports research in shared decision-making (SDM) by bringing together MD Anderson's growing decision science faculty with its world-class clinical faculty, working in collaboration to design, evaluate and implement novel strategies for engaging cancer patients and their health care providers in making difficult decisions about cancer prevention. The collaborative serves as a "research laboratory" to stimulate new approaches to shared decision-making by providing an infrastructure to encourage multidisciplinary collaboration, to conduct feasibility studies of novel interventions, and to create essential preliminary data to pursue large-scale, extramural funding.

Goals

1. Rapidly develop of new state-of-the-art patient decision support tools for preference-sensitive decisions in cancer prevention, as nominated by MD Anderson faculty.
2. Conduct research of implementation of shared decision making programs and the impact of decision support tools on the quality of cancer care delivered at MD Anderson and its partners.

Accomplishments

- Established the Research Education and Collaborators in Health (REACH) Registry of patients and community members who are willing to be contacted about participating in advisory and/or prototype testing groups has enrolled participants from Volunteer Services and from the community with the help of the Center for Community Engaged Translational Research.
- Continued to increase SDMC scientist national and international presence, collaborations, and resources through roles on International Patient Decision Aid Standard Collaboration, the National Quality Forum's committee for certification of patient decision aids, and collaborations with the American Cancer Society on various cancer screening projects.
- Expanded SDMC toolkits to include resources on two additional topics: Values Clarification and Decision Coaching, in addition to presentations, illustrative examples, and resource libraries.
- Supported submission of 44 grants totaling \$39.4M of which 15 totaling \$10.5M were awarded.
- Supported 14 active and 6 completed projects valued at \$18M.
- Published 44 scientific papers and abstracts.
- Approved as a developing core in the Cancer Center Support Grant renewal application.

Future Plans

- Complete Cycle 1 projects, extend these to larger initiatives competitive for extramural funding, including from the Patient-Centered Outcomes Research Institute (PCORI) and disseminate results.
- Launch up to two additional topics.
- Explore creating a web presence and a web-based research platform for broadening access to SDM-C research, tools, and training.
- Expand topic areas to include treatment decision-making.
- Seek Center status to strengthen resources for responding to clinical demand for patient decision-support tools.

Science Supported by the Resource

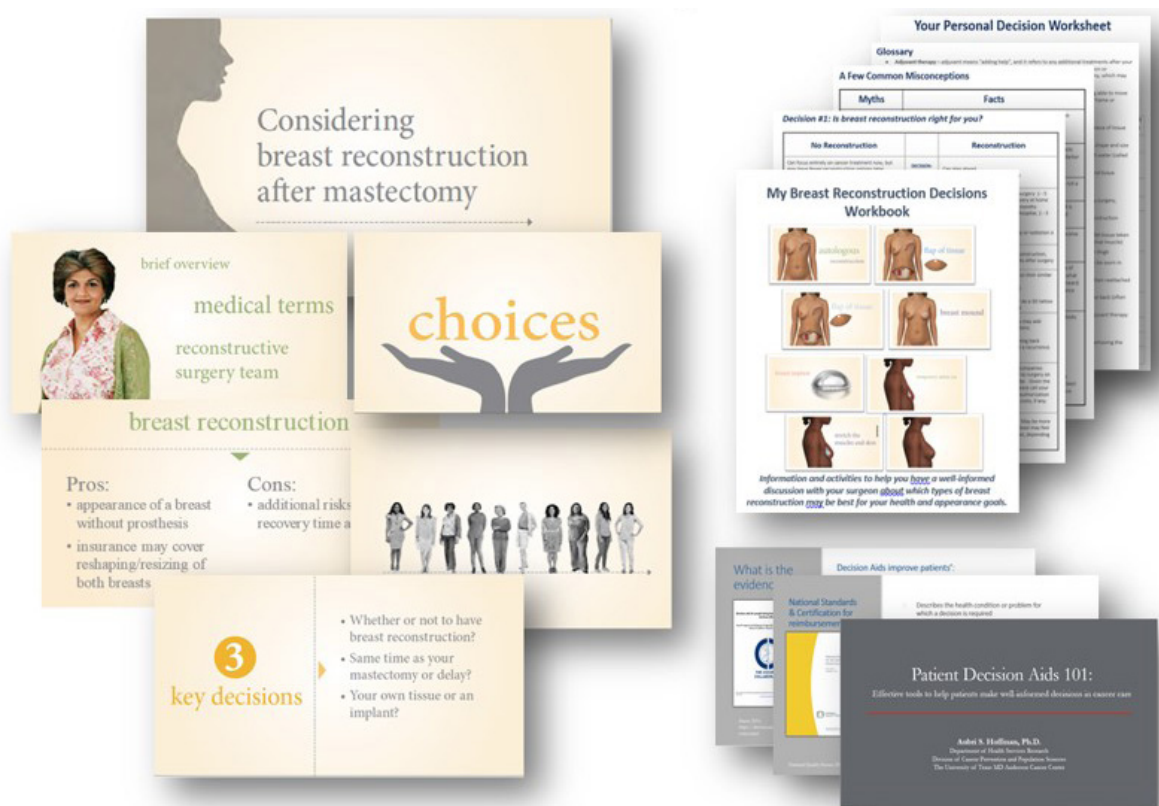
Testing the feasibility and effectiveness of a decision aid/decision coaching intervention for lung cancer screening with low-dose computed tomography - Medicare now requires patients to have a patient counseling and shared decision-making visit with a health care provider before screening for lung cancer with low-dose computed tomography. In this project, scientists evaluated the impact of implementing the decision aid/decision coaching intervention on the quality of screening decisions and its impact on clinical workflow by using time-motion-studies. Data from the evaluation suggests that implementing the SDM intervention in the screening setting resulted in patients being more informed about risks and benefits of lung cancer screening and having a better shared decision-making process. In addition, implementing the SDM intervention did not increase the time patients were in clinic. Fidelity to the decision coaching intervention satisfied Medicare's criteria for a patient counseling and shared decision-making visit. (Leads: M Godoy, L. Lowenstein)

Pathways to Fertility: Testing a Web-based patient decision aid for women with cancer - Few women with a new diagnosis of cancer are provided information about their options for fertility preservation before they initiate cancer treatment. *Pathways* is a patient decision aid website that provides up-to-date information about fertility preservation and other family-building options, as well as structured support for making well-informed, values-based decisions. This study is testing the implementation of *Pathways* at point-of-care and producing a model of web-based delivery of patient decision aids for future SDMC projects. Initial data indicate that *Pathways* improves women's knowledge of the available options and reduces decisional conflict. Final results will assess the potential impact of *Pathways* for improving referrals to fertility specialists, increasing utilization of fertility preservation, and decreasing long-term fertility-related distress and regret. (Leads: T. Woodard, A. Hoffman; Alliance NCORP Research Base grant, 1UG1CA189823)

Prevention of primary breast cancer with medications for risk reduction

- Women at increased risk of breast cancer because of a diagnosis of lobular carcinoma in situ or atypical hyperplasia can greatly reduce their chances of developing breast cancer by taking preventive medications. Unfortunately, many women are not offer preventive therapy or decline taking therapy because of inaccurate expectations of harm. The goal of this early-stage project is to produce a shared decision-making intervention for patients and providers to increase the uptake of anti-estrogen preventive therapy among high risk women. Intervention components include a decision aid web page and video for women at high-risk of breast cancer. (Leads: A. Brewster, T. Bevers, R. Volk)

Considering breast reconstruction options - Breast reconstruction is an option for women with breast cancer who have a mastectomy. Unfortunately, conversations between patients and reconstructive surgeons are sub-optimal and patients later experience regret and dissatisfaction with their choices. Stakeholders are engaged in developing and testing a new decision aid to help breast cancer patients address three related decisions: whether or not to have reconstruction, the type of reconstruction they prefer, and the timing of the reconstruction. The decision aid has the potential to improve knowledge, reduce decision regret, and improve preparedness for meeting with their plastic surgery team, which in turn may increase patient satisfaction and improve the quality and patient-centeredness of care. (Leads: G. Reece, A. Hoffman)



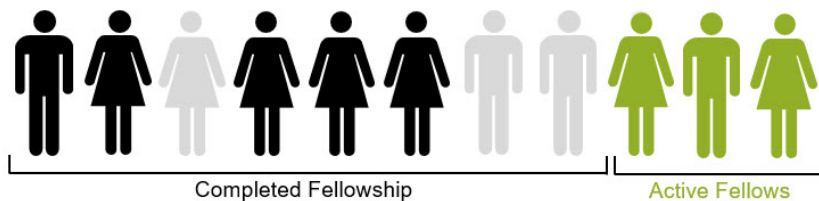
MENTORED JUNIOR FACULTY FELLOWSHIP

Support the critical transition of individuals from training positions to tenure track junior faculty

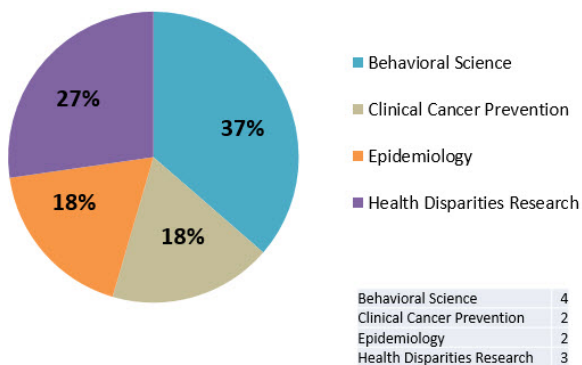
The Duncan Family Institute's competitively awarded fellowships are designed to bridge the gap in funding between postdoctoral training and independent researcher status. They provide the mentoring and financial support for instructor-level faculty to focus on developing their research questions, generating preliminary data, and enhancing their publication record to compete successfully for peer-reviewed extramural grants — an early and critical milestone on the path to research independence.

The DFI Fellowship is one of the most productive initiatives in the Institute's portfolio. Over 60% of individuals completing the fellowship are in tenure-track faculty positions.

The Fellows are a diverse group with 64% being female. Their expertise covers a range of scientific disciplines including: Behavioral Science, Clinical Cancer Prevention, Epidemiology and Health Disparities Research.



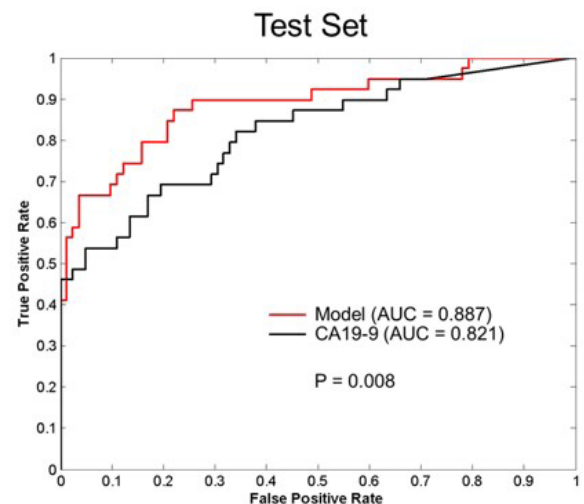
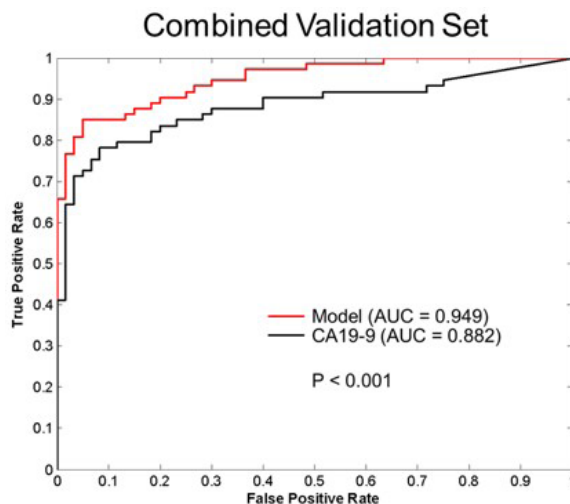
63% of individuals who completed the fellowship are in tenure track positions





Reduction in cancer mortality requires significant advances in risk assessment, preventive interventions, and early detection. This is particularly applicable to pancreatic ductal adenocarcinoma (PDAC), which, with a 5-year survival rate of 7% and a mortality rate comparable to its incidence rate, represents the fourth leading cause of cancer death in the United States. 15-20% of PDAC patients present with localized disease and have a 5-year survival rate approaching 30%, suggesting that mortality could be reduced by early diagnosis. Given the low incidence of disease, imaging technologies are not practical in terms of cost-effectiveness and invasiveness for screening. The only accepted blood-based biomarker for PDAC, CA19-9, is informative for symptomatic PDAC patients, but lacks the specificity needed for early detection in asymptomatic subjects.

Dr. Capello will pursue a research path aimed at the development of minimally invasive plasma-based biomarker panels for PDAC risk assessment and early detection. Success in this endeavor will further allow pursuit of research beyond early detection and address the more challenging goal of preventive intervention. Achieving these objectives will have a significant impact on reducing PDAC mortality. Of special interest is profiling the anti-tumor immune response as a source of biomarkers in the form of autoantibodies to tumor antigens. Identification of such antigens could also allow for development of immunotherapeutic approaches and vaccines.



Model: TIMP1 + LRG1 + CA19-9
Resectable-PDAC vs Healthy Controls

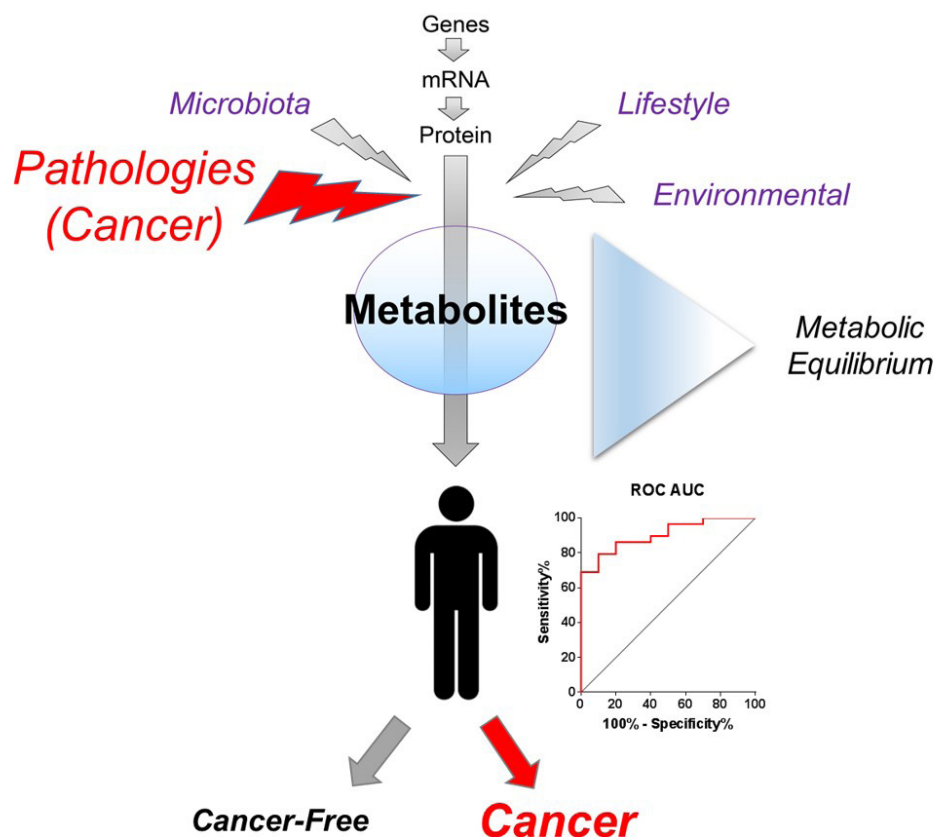
The combination of three plasma protein biomarkers shows a very good performance in discriminating early-stage pancreatic cancer patients from healthy subjects.



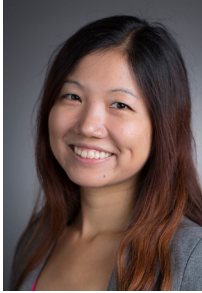
Achieving significant reductions in cancer mortality will be largely contingent upon realization of improved strategies to determine cancer risk, detect cancer early and implement preventive intervention strategies. This is exemplified in lung cancer, the leading cause of cancer mortality in both men and women in the United States. The current lung cancer screening strategy by low-dose computerized tomography (LDCT) is largely confined to high-risk smokers with 30+ packs per year smoking history, current smoking status or having quit in the last 15 years and that are between 55 and 80 years old. However, these criteria are only applicable to ~27% of all lung cancer patients. Consequently, there is a critical need for screening strategies for individuals at increased risk for lung cancer who do not meet current screening criteria. Additionally, LDCT-positive scans are confounded by high false positive rates (96%) due to the inability to adequately distinguish non-cancerous solid pulmonary nodules (SPNs) from malignant SPNs. Thus, there are two distinct but related clinical predicaments: identification of

individuals at increased risk of developing lung cancer independent of pack-years of smoking and improved strategies for early diagnosis of lung cancer and stratification of LDCT-positive nodules into benign or malignant SPNs. For these applications there is an immediate clinical need for early detection biomarkers with high sensitivity and specificity.

Using metabolomics technology as his primary platform, Dr. Fahrman is pursuing a research path aimed at the development of minimally invasive plasma-derived biomarker panels for lung cancer risk assessment and early detection. Achieving this goal has the potential to reduce lung cancer mortality and guide treatment strategies. Of special interest is the integration of metabolomics with other 'omic' technologies and basic research methodologies to better link observations in blood to tumor origin, thereby increasing the robustness of candidate biomarkers and their probability of successful translation into clinical utility including immunotherapeutic approaches and vaccines.

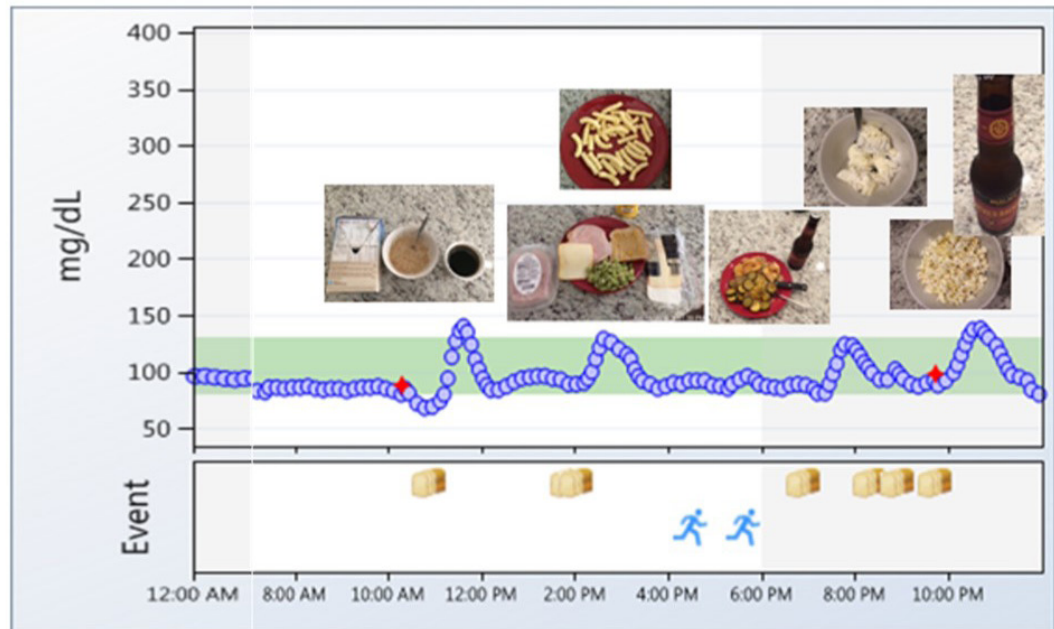


Blood-derived metabolites have the capacity to identify individuals at risk of developing or actively harboring cancer. The greater the specificity and sensitivity of the metabolite the more promising it is as a risk stratification or early detection biomarker.



High levels of blood glucose and insulin are associated with an increased risk of developing several types of cancers, such as the breast, endometrium, colon, liver, kidney, and pancreas. In addition to avoiding foods (e.g., sugar sweetened foods and beverages) that could lead to a spike in blood glucose levels, physical activity (ranging from a 10-minute session of high intensity workout to half-hour slow walking) or mere interruption of prolonged sitting have shown effects in reducing post-meal blood glucose and glucose variability within the following day. Besides the acute beneficial changes in glucose levels, regular physical activity also improves functional and mental well-being, helps with weight management, and prevents a number of chronic diseases such as type 2 diabetes and cardiovascular disease. However, about half of American adults are not sufficiently active to achieve these health benefits.

Dr. Liao's research focus on developing personalized and adaptive behavioral interventions using mobile and wearable sensor technologies. Her project aims to incorporate wearable body sensors to provide objective and actionable data on the biological antecedents and consequences of daily physical activity and sedentary behaviors. Dr. Liao plans to integrate data from continuous glucose monitors and heartrate monitors to educate high-risk population (i.e., overweight and obese prediabetics) about the acute benefits of physical activity and increase their motivation in physical activity engagement. Dr. Liao's research goal is to provide insights and guidance at critical decision points to help individuals modify their daily health-related behaviors to reduce their cancer risks.



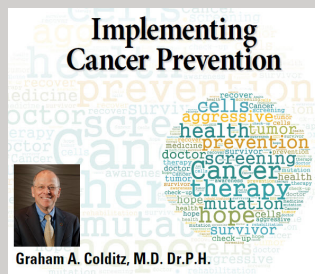
Real-time data capture of continuous glucose monitoring over a 24 hour period.

SUPPORTED SEMINARS

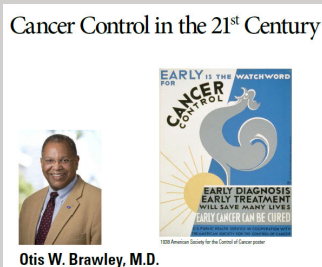
The Institute contributed to enhancing the intellectual environment in support of the current generation of scientists by co-sponsoring speakers in collaboration with the Division of Cancer Prevention and Population Sciences' Cancer Prevention and Control Grand Rounds lecture series.

Internationally renowned experts addressed a wide range of real-world issues relevant to cancer prevention. DFI supported five lectures in FY16 and six in FY17.

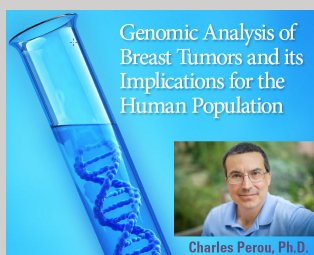
FY16 SPEAKERS



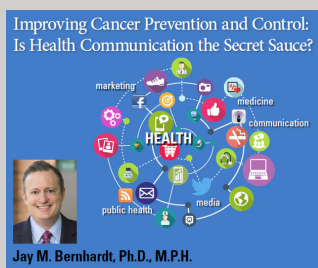
- **Graham A. Colditz, M.D., Dr.P.H.**
Niess-Gain Professor of Surgery; Professor of Medicine; Chief, Division of Public Health Sciences, Department of Surgery, Washington University School of Medicine; Associate Director, Prevention and Control, Alvin J. Siteman Cancer Center



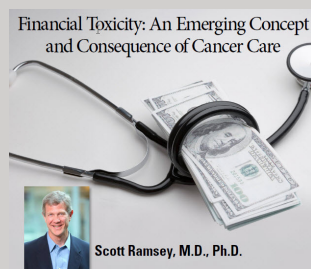
- **Otis W. Brawley, M.D.**
Chief Medical and Scientific Officer, American Cancer Society



- **Scott Ramsey, M.D., Ph.D.**
Director, Hutchinson Institute for Cancer Outcomes Research, Fred Hutchinson Cancer Research Center, Public Health Sciences Division



- **Jay M. Bernhardt, Ph.D., M.P.H.**
Dean, Founding Director, Center for Health Communication; Walter Cronkite Regents Chair; Everett D. Collier Centennial Chair, Moody College of Communication, The University of Texas at Austin



- **Charles Perou, Ph.D.**
The May Goldman Shaw Distinguished Professor of Molecular Oncology; Professor of Genetics and Pathology & Laboratory Medicine, Lineberger Cancer Center, The University of North Carolina at Chapel Hill



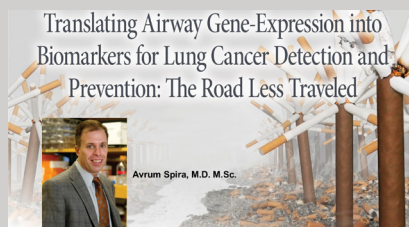
- **K. Vish Vismanath Ph.D.**
Lee Kum Kee Professor of Health Communication, Harvard T. H. Chan School of Public Health (HSPH); Dana-Farber Cancer Institute (DFCI), Director, Center for Translational Health Communication Science, DFCI/HSPH, Director, Harvard Chan India Research Center, Co-Director, Lee Kum Sheung Center for Health and Happiness



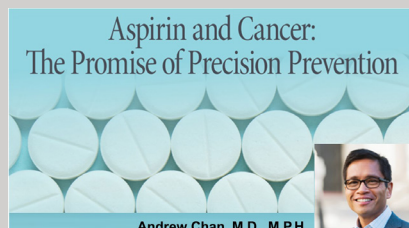
- **Muin J. Khoury, M.D., Ph.D.**
Director, Office of Public Health Genomics, Centers for Disease Control and Prevention



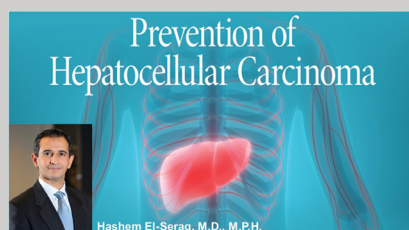
- **Sally Cowal**
Senior Vice President, Global Cancer Control, American Cancer Society



- **Avrum Spira, M.D., M.Sc.**
Chief, Division of Computational Biomedicine, Boston University School of Medicine; Director, Translational Bioinformatics Program, Clinical and Translational Science Institute; Director, Boston University - Boston Medical Center Cancer Center



- **Andrew Chan, M.D., M.P.H.**
Associate Professor, Medicine, Massachusetts General Hospital, Harvard Medical School, Channing Division of Network Medicine, Brigham and Women's Hospital



- **Hashem El-Serag, M.D., M.P.H.**
GI Section Chief at the Michael E. DeBakey VA Medical Center; Chief, Gastroenterology and Hepatology Section; Professor, Medicine and Gastroenterology; Director, Texas Medical Center Digestive Diseases Center; Leader, Cancer Prevention and Population Sciences Program, Baylor College of Medicine

GOVERNANCE AND OVERSIGHT

The Duncan Family Institute for Cancer Prevention and Risk Assessment is guided by the Executive Committee. Members include the Vice President for Cancer Prevention and Head, Division of Cancer Prevention and Population Sciences, the chairs of the five departments within the Division, the directors of the Institute and Division centers, and the Vice President for Health Policy. The Executive Committee continued its focus on ensuring excellence through annual reviews of its initiatives and in exploring ideas to sustain the Institute's diverse programs spanning MD Anderson's four mission areas: research, clinical care, education, and prevention.



DUNCAN FAMILY INSTITUTE EXECUTIVE COMMITTEE

Vice President, Cancer Prevention and Population Sciences
 Director, Center for Energy Balance in Cancer Prevention & Survivorship
 Medical Director, Cancer Prevention Center
 Chair, Clinical Cancer Prevention
 Chair, Behavioral Science
 Vice President, Health Policy
 Chair, Health Services Research
 Chair, Health Disparities Research/Director, Center Community Engaged Translational Res
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 Chair *ad interim*, Epidemiology
 Director, Center for Translational and Public Health Genomics
 Associate Professor, Epidemiology representative

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 P. Brown, M.D., Ph.D.
 P. Cinciripini, Ph.D.
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 J. Robinson, Ph.D. (FY17)
 S. Shete, Ph.D.
 X. Wu, M.D., Ph.D.
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