

Making Cancer History*

The Duncan Family Institute at-a-glance 2013

Peer reviewed publications

\$201\square In awarded grants leveraging investments in research resources and strategic initiatives

Fellowships completed, developing the next generation of research pioneers

A Message from the Vice President

I am pleased to provide the fifth annual report of the Duncan Family Institute for Cancer Prevention and Risk Assessment. Anchored by the Division of Cancer Prevention and Population Sciences, the Duncan Family Institute engages world-class clinical and research scientists dedicated to discovering and translating the best of evidence-based cancer prevention research.

During the past year, the Institute sustained its six Strategic Initiatives, representative of the diverse fields that are cancer prevention and population science. Researchers in the Center for Translational and Public Health Genomics led molecular and genomic studies to better understand the pathogenesis of various cancers, so as to identify targets for the prevention of these diseases. With support from the recently launched Center for Energy Balance Research in Cancer Prevention and Survivorship, investigators contributed to over 11 clinical and



population-based research studies involving testing of dietary, physical activity or healthy lifestyle interventions in diverse populations, including Mexican-Americans, African-Americans, and cancer survivors of different races and ethnicities.

Most importantly, research results are moving from our laboratories into the clinic and community. In the clinic, the Integrative Health (IH) initiative matured this past year, providing over 2,300 patient interventions to address diet, physical activity, psychosocial, and tobacco cessation needs for patients across the cancer continuum. The Ask-Advise-Connect (AAC) smoking cessation intervention, a product of earlier Institute-supported research, is now being disseminated into real-world settings where it is expected to greatly assist individuals who want to quit smoking. Investigators were awarded a Medicaid Delivery Service Reform Incentive Payment project valued at over \$1.1M to implement AAC in 12 federally qualified health care clinics providing care to underserved populations. Harris Health, a safety net health care system, is implementing AAC in many of its family practice clinics.

Our Seed-funding Research Program continues to support investigators as they seek to develop the preliminary data necessary to compete for peer-reviewed support for larger studies. This year, we received 34 proposals and made five awards focusing on primary prevention based on molecular targets for colorectal, breast and skin cancers; and received 18 proposals and made two awards in collaboration with the Survivorship Research Working Group addressing quality of life issues in cancer survivors.

The Institute launched an important new resource, the Health Services Research Core Data Resource, to support scientists seeking novel solutions to improve health care delivery, safety, availability, and affordability; of increasing importance in this era of rapidly escalating health care costs and large disparities in both access to, and quality of, care. We were pleased to learn the e-Health Research Resource, which develops technology-enabled intervention tools such as applications for smartphone use in behavior change studies, was competitively awarded NCI Cancer Center Support Grant funding as a developing shared resource, placing this valuable research infrastructure on a path towards sustainability.

Developing the next generation of prevention and population science researchers is an Institute priority. We awarded a new Duncan Family Institute Mentored Junior Faculty Fellowship to Diana Stewart, Ph.D. Dr. Stewart's research focuses on how health literacy affects smoking cessation outcomes in low socioeconomic populations. Dr. Claire Adams, a previously funded Fellow, launched her career as an independent scientist with her appointment to a tenure-track faculty position.

In closing, on behalf of the Executive Committee, I want to extend our deepest appreciation and gratitude to all those who make the work of the Duncan Family Institute possible. It is these individuals with their dedication to and passion for their work in prevention that enabled the past years' achievements. Finally, we offer our deepest admiration and respect to the Duncan family, whose kindness and generosity made the Institute possible, and to all of our new and sustaining donors, whose support makes possible the Institute's work.

Sincerely,

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

Execut Jan gros



Advancing the discovery and translation of new knowledge about cancer risk and prevention in the laboratory, the clinic and the community

The Duncan Family Institute was established in 2008 through a generous gift from the Duncan Family to foster collaboration among scientists, clinicians and community practitioners committed to advancing the science and practice of cancer prevention. Cancer Prevention is a broad field and the Institute supports a wide range of research, engaging scientists from multiple disciplines. The Institute is committed to the discovery and translation of new findings, and our research investments reflect this commitment. We currently allocate Duncan Family Institute funds to three areas: Research and Clinical Programs (60%), Research Resources (30%), and Education and Excellence (10%).

Research and Clinical Programs

The Duncan Family Institute's Seed-funding Research program and Strategic Initiatives support individual investigators with promising new ideas and teams of researchers and clinicians who are making novel discoveries and moving prevention and population science and practice in new directions.

The Seed-funding program provides financial support to investigators working to develop the preliminary data necessary to improve competitiveness for extramural support for larger, innovative hypothesis-driven studies. Funding through this program is competitively awarded through a peer review process that engages scientists from Texas Medical Center institutions in the review of early stage proposals.

The Strategic Initiatives program supports a set of high-priority research areas determined by the Executive Committee of the Duncan Family Institute. Criteria include meeting a critical research or clinical need, scientific opportunity with great translational potential, future priority of patients and/or the population, little or no chance for support elsewhere, and opportunity for synergistic collaborations. There are currently six initiatives supported by the Institute: Integrative Health (IH), the Center for Translational and Public Health Genomics (CTPHG), the Premalignant Genome Atlas (PGA), the Center for Energy Balance in Cancer Prevention and Survivorship, the Tobacco Transdisciplinary Research Program (TTRP), and Project BRaNCH, formerly known as Navigating Familial Cancer Risk in Hereditary Colorectal Cancer Syndromes.

Investigators associated with these initiatives participated in 81 submitted grants with total costs of over \$80M and were engaged in 17 awarded grantfunded studies with total costs of over \$8M. They authored over 18 peer-reviewed publications describing the results of their research.

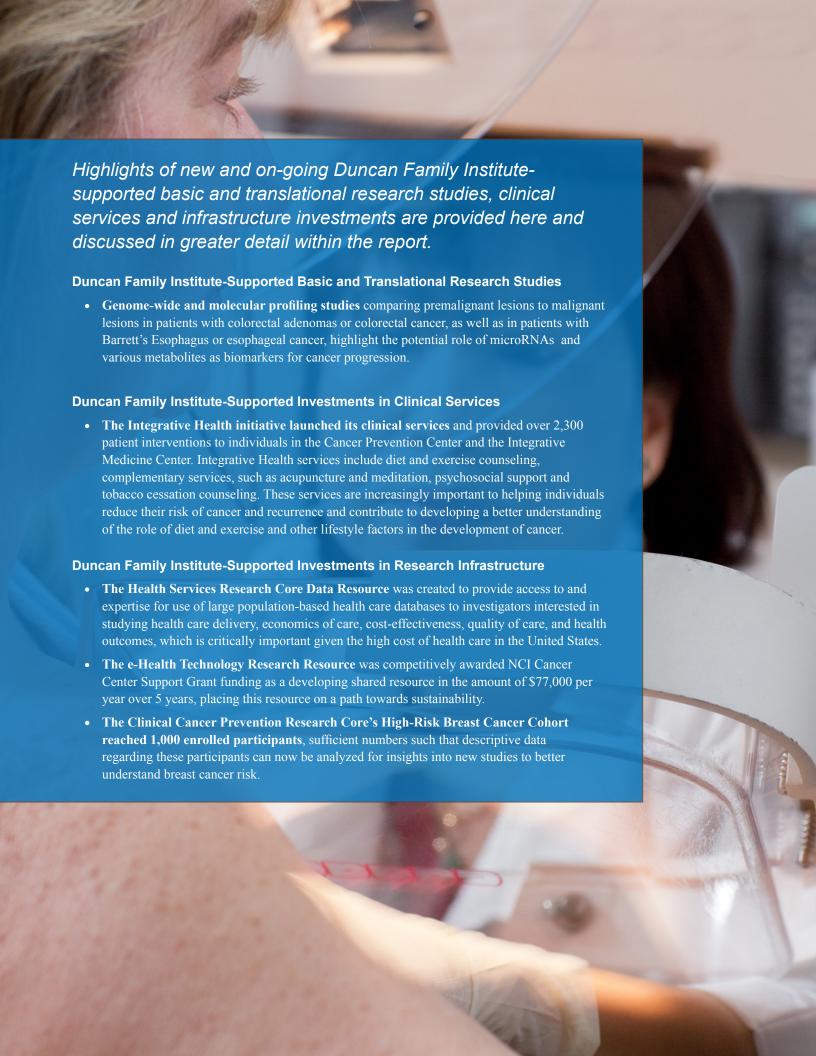
Research Resources

Critical to research progress is investigator access to cutting-edge scientific technologies, biospecimens, data, and expertise to enhance scientific interaction and productivity. These essential research infrastructure components are often not funded through traditional grant mechanisms or other sources of funding dedicated to research projects and programs, but are necessary for scientists to compete successfully for external funding from the National Institutes of Health (NIH), National Cancer Institute (NCI), the Cancer Prevention and Research Institute of Texas (CPRIT) and other peer-review funding agencies. There are currently five research resources: the Mexican-American Cohort (MAC), the Clinical Cancer Prevention Research Core (CCPRC), e-Health Technologies; the Center for Community-Engaged Translational Research (CCETR), and the newest, Health Services Research Core Data Resource (HSRCDR). The Institute research resources provided support for over 58 grant submissions totaling over \$101M and actively supported 37 funded studies with total costs of over \$21M. Results of studies supported by these resources were disseminated through 26 peer-reviewed publications.

Education and Excellence

This component of the Institute supports fellowships to develop future generations of cancer prevention researchers and sponsors lectures and events to build the intellectual environment to engage the current generation. It is also the component through which the Institute's programmatic investments are stewarded through its governance and administrative management. This group sets priorities and makes award decisions, meeting regularly to review progress of funded initiatives.







Ms. Therese Bevers Unit 1322 P.O. Box 301439 Houston, TX 77230-1439

October 28, 2013

Dear Ms. Bevers:

I want you to know that I am extremely grateful for the work that Rachel King and Alicia Austin are doing on nutrition, exercise, and cancer prevention. I have found that being accountable to a monthly phone call helps me stick with my goals for healthy living. I believe that losing weight is primarily a matter of will power, and I have read research that says that will power has its limits. Since I have been working with Rachel, and with her encouragement, I am really making progress toward my weight and fitness goals. It would be so easy sometimes to just give up, but knowing that I will be receiving a call keeps me motivated.

Last week I told her that I am worried that if I reach my goals and she stops calling, I will just gradually gain weight again, and she said that she is only three years into a ten-year project. This was wonderful news! I hope it won't take me seven years to stabilize, but it is comforting to know that her support will be available long-term.

I have been in Weight-Watchers a couple of times before, but I much prefer the freedom from meetings and personal contact of your approach.

Thank you, thank you!

Marilyn Rambow

Sincerely,

Marilyn Rambow

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We competitively awarded seed funds to seven new projects, five of which focus on primary prevention based on molecular targets for colorectal, breast and skin cancers; and two of which address quality of life issues in cancer survivors. In keeping with the transdisciplinary and cross-cutting nature of an institute, the DFI awarded four of these seven new 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. These investigators and their awards are indicated below with an asterisk (*).

All investigators receiving awards from the Institute provide annual progress reports to the Duncan Family Institute Executive Committee. Updates on a selection of grants awarded in previous years are also included here.

Prevention and Risk Assessment Seed Funding Awards



*Targeting low molecular weight-E/Cdk2 pathway for the prevention of breast cancer

Said Akli, Ph.D., assistant professor, Department of Experimental Radiation Oncology

Triple negative breast cancer patients have limited treatment options outside of non-specific standard chemotherapy. Recent studies from Dr. Akli's laboratory establish that short forms of cyclin E are over-expressed in 70% of all triple negative breast cancer and that mice expressing those forms are completely protected against breast cancer when cyclin dependent kinase 2 (Cdk2) is not expressed. The drugs seliciclib and dinaciclib are potent inhibitors of Cdk2. The investigators aim to test if these two drugs can prevent breast cancer in their mouse model. They will also identify the genes whose expression is modulated by the two drugs in vivo using gene expression microarrays and biomarker analysis. Results of this study are expected to provide the preclinical rationale for the development of cyclin-dependent kinase inhibitors for the prevention of human triple negative breast cancers, especially those with low molecular weight cyclin E overexpression.



*The role of LONGf, a novel long non-coding RNA, encompassing the risk SNP rs6983267, in colorectal cancer predisposition

George Calin, M.D., Ph.D., professor, Department of Experimental Therapeutics

The genetic mechanisms leading to many familial forms of colorectal cancer (CRC) are not known. This study will examine the involvement of a non-coding RNA, termed CCAT2 (Colorectal Cancer Associate Transcript 2), in CRC predisposition. CCAT2 encompasses a genetic variant previously associated with colon cancer susceptibility. The central hypothesis of this proposal is that CCAT2 may influence the risk of CRC development through this variant. Investigators aim to identify the clinical significance of CCAT2 in CRC predisposition by using a large cohort of RNA samples from the Familial Cancer Registry. Using a transgenic mouse model, they will seek to demonstrate CCAT2 involvement in CRC predisposition. The identification of the roles of CCAT2 in the predisposition to CRC will not only offer new insights into the molecular mechanisms and signal transduction pathways altered in colorectal cancers, but will also be of great clinical significance in identifying new diagnostic molecular markers of CRC risk and offering a potential target for prevention.



Using ultraviolet epidermal mosaicism to predict skin cancer risk

Paul Scheet, Ph.D., associate professor, Department of Epidemiology

The vast majority of skin cancers, which affect millions of individuals annually, can be attributed to excessive, but preventable, UV radiation exposure. While population-based screening for skin cancer is effective at reducing skin cancer mortality, it is impractical and expensive. In this study, the research team will develop a DNA-based method to identify individuals most at risk for developing skin cancer. Using chronic UV-exposed human skin tissue and mouse models, the researchers aim to characterize the effect of UV exposure on genetic mosaicism, the existence of heterogeneous mixtures of cells. Such mosaicism could serve as a marker for risk and may ultimately be used to identify individuals most in need of aggressive surveillance for skin cancers.



Breast cancer risk in Mexican-Americans: a pilot study evaluating metabolites in plasma

Sara Strom, Ph.D., associate professor, Department of Epidemiology

Breast cancer is the most commonly diagnosed cancer and the leading cause of cancer death among Hispanic women in the United States. In 2012, more than 17,100 new invasive breast cancer cases and 2,400 breast cancer deaths occurred in Hispanic women. Early detection of breast cancer is the most important factor associated with successful treatment. Currently, there are no blood-based biomarker tests for early diagnosis of breast cancer. The investigators will make innovative use of robust proteomic technologies to identify pre-diagnostic markers. The results of this research will contribute to advancing the field of breast cancer early detection and prevention in Hispanic women. This research approach may also be relevant to identify individuals in other ethnic and racial groups who may be at risk.



Discovering new targets for chemoprevention in familial adenomatous polyposis

Eduardo Vilar-Sanchez, M.D., Ph.D., assistant professor, Department of Clinical Cancer Prevention

Familial Adenomatous Polyposis (FAP) is a genetic condition that is diagnosed when a person develops more than 100 premalignant polyps in the colon and rectum. The average age for polyps to develop in patients diagnosed with FAP is in the mid-teens; and more than 95% will have multiple polyps by age 35. There is almost a 100% chance for this patient population to develop colorectal cancer if preventive measures are not taken. In this study, the investigators will identify important genetic alterations that result in polyp formation in FAP, which could lead to identification of new preventive measures not only for patients and families with this condition, but also for colorectal cancer occurring in the general population. In addition, the study of polyps in the high-risk setting of FAP offers a model to understand colon cancer development in populations at average risk.

Survivorship Seed Funding



*BK Virus infection in hematopoetic stem cell transplant survivors and renal outcomes

Ala Abudayyeh, M.D., assistant professor, Department of Emergency Medicine

BK virus is a non-enveloped, encapsulated DNA virus that belongs to the Papovaviridae family. It is increasingly being recognized as an important outcome predictor when the cellular immune system is impaired, particularly after renal and hemopoietic stem-cell transplantation (HSCT). It occurs in up to 70% of HSCT survivors and is associated with prolonged hospitalization leading to severe hematuria in 8-27% of patients. In this project, researchers will retrospectively review the stem cell transplant survivors at MD Anderson to test the hypothesis that BK virus infection is a marker of poor renal outcomes and overall poor patient prognosis in the HSCT survivor population. This study aims to clarify the role of BK virus infection in the renal and overall survival outcomes of HSCT survivors to help formulate better screening and prevention protocols for this vulnerable patient population.



*Does radical therapy result in substantial long-term sexual and urinary functional decline compared to active surveillance in men diagnosed with prostate cancer?

Brian Chapin, M.D., assistant professor, Department of Urology

Good clinical care of patients with prostate cancer includes careful and standardized assessment of functional and oncologic outcomes. Standardization is lacking in current research practice for survivorship outcomes in patients with prostate cancer. Erectile dysfunction and urinary incontinence are two well-known side effects resulting from the surgical treatment of prostate cancer that can significantly affect a survivor's quality of life. The long-term social and psychological impact and the realization that many prostate cancers have minimal lethal potential, have led to active surveillance programs for low/intermediate risk disease. This, too, has the potential for significant psychological, physical and possibly oncologic sequelae. The primary goal of this study is to compare long-term (>3yrs) sexual and urinary functional outcomes in patients with and without radical therapy for low/intermediate risk disease. Measurements will be made using a web-based, validated, standardized, patient-reported quality of life questionnaire. This will allow the investigative team to determine if long-term functional outcomes after surgery are durable and whether they differ from the natural decline in function as a result of aging, aiding in the counseling and long-term care of prostate cancer survivors.

Updates on Previously Funded Projects



Feasibility of a couple vs. an individual-oriented mood management intervention for distressed lung cancer patients

Cindy Carmack, Ph.D., associate professor, Department of Palliative Care Medicine
In this study, Dr. Carmack and colleagues are pilot testing a web-based couple-oriented counseling intervention compared to a web-based patient only counseling intervention in 40 lung cancer patients who are experiencing psychological distress. The goal of this project is to determine if a couple-oriented counseling intervention is more effective than a patient only approach. The investigators will assess the effects of both interventions on patient psychological functioning, health behaviors, treatment adherence, and symptom burden and on spouse psychological functioning, health behaviors, and caregiver burden. In the study's first year, Dr. Carmack and her team developed the study materials and



Blocking a novel Wnt agonist for cancer prevention

begun recruiting patients.

Jae-II Park, Ph.D., assistant professor, Department of Experimental Radiation Oncology Dr. Park and his team have been studying a novel molecule, WR2, that is only detected in colon cancer and positively controls the tumor-promoting Wnt signaling pathway. Investigators proposed to determine the role of WR2 in regulating tumor development and to further develop the efficient neutralizing methods. In the first year of the project, the investigators determined the molecular mechanism of WR2-mediated Wnt/β-catenin activation and have partially determined WR2's tumorigenic role in colon cancer. This work has led to two scientific publications in respected journals and a third is in press.



A social network approach to improve genetic risk communication Susan K. Peterson, Ph.D., M.P.H., associate professor, Department of Behavioral Sciences

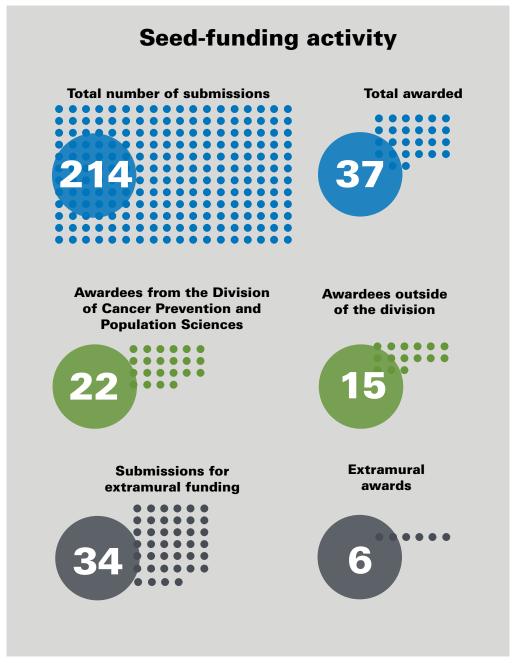
To address barriers to realizing the full benefits of genetic counseling in hereditary cancers, Dr. Peterson proposed an intervention called My Family Garden, a web-based, secure social networking tool to enable the collection and sharing of family history and cancer risk information in families with hereditary cancer. In its first year, investigators completed construction of a preliminary social media prototype and recruited and interviewed 16 individuals with Lynch Syndrome for focus group feedback regarding experiences with family communication about genetic information, the use of the internet and social media for communicating personal health information, and prototype preferences.

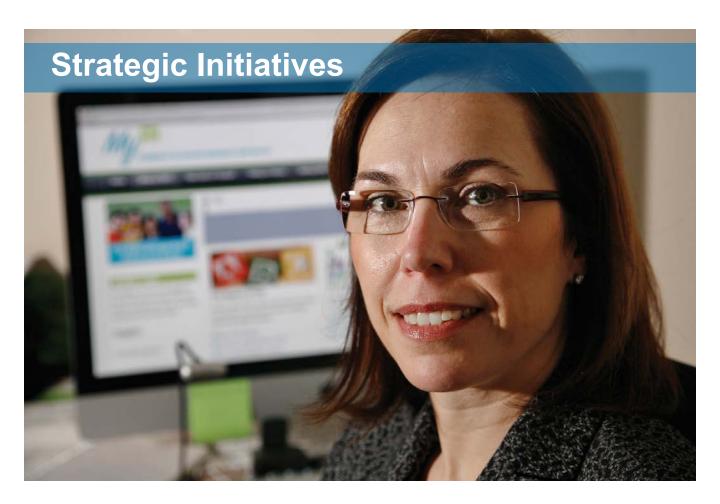


Preventing sexual dysfunction in women on aromatase inhibitors

Leslie Schover, Ph.D., professor, Department of Behavioral Science

The primary aim of this study is to reduce rates of sexual dysfunction in post-menopausal women using aromatase inhibitors (AIs) for the treatment of breast cancer. Approximately 10% to 25% of women discontinue AIs in the first year of treatment because of their negative side effects, with sexual side effects being among the most distressing. This study includes both a cross-sectional benchmark survey and a randomized trial. In the first year of this study, Dr. Schover and her team completed the benchmark survey, mailing 296 questionnaires to women identified as meeting study eligibility requirements, with at least 41% of these women returning their questionnaires. This survey assessed sexual function, arthralgias and other co-morbidities, and adherence to AIs. The team also began recruiting patients for the randomized trial portion of this study.





During fiscal year (FY) 2013, we continued to provide support to the Premalignant Genome Atlas Program, the Center for Energy Balance in Cancer Prevention and Survivorship, the Tobacco Transdisciplinary Research programs, the Center for Translational and Public Health Genomics, the Integrative Health initiative, and Project BRaNCH. Over the past year, investigators affiliated with the Institute's strategic initiatives contributed to over 81 submitted grant proposals totaling over \$80 million and were awarded 17 grants (total costs \$8 million)

Bridging Relatives and Navigators for Colorectal Health (Project BRaNCH)

(formerly Navigating Familial Cancer Risk in Colorectal Cancer Syndromes)

Co-Directors:

Susan Peterson, Ph.D., M.P.H., associate professor, Department of Behavioral Science Y. Nancy You, M.D., M.H.Sc., F.A.C.S., assistant professor, Department of Surgical Oncology

Background

This initiative has the potential to augment MD Anderson's cancer prevention services by extending cancer surveillance and prevention to at-risk families of patients with a major hereditary colorectal cancer (CRC) syndrome. Project BRaNCH investigators propose to implement a new care delivery model in cancer genetics and to create a scalable platform for this delivery model that could be expanded across high-risk families of individuals seen at MD Anderson and potentially adopted nationwide.

Scientific Progress

In its first year, the Project BRaNCH group undertook a comprehensive assessment of current clinical cancer genetics needs related to the identification of at-risk family members of MD Anderson patients with a hereditary colorectal cancer

gene mutation. The assessment included a review of the current process for identifying, referring and providing genetic counseling and testing to index colorectal cancer patients who are seen at MD Anderson. Current standard of care regarding genetic counseling for these patients presumed to be at risk for hereditary colorectal cancer involves referral for a genetic counseling consultation, risk assessment, and evaluation of the need for germline genetic testing and counseling for disclosure of results. Those patients whose mutation test results, family history, and/or clinical factors are positive for a hereditary cancer syndrome will be referred to the Familial High Risk Gastrointestinal Cancer Clinic (FHRGICC) for ongoing management of their hereditary cancer risk. Patients also are given a copy of their mutation test results and a detailed letter explaining risk assessment and genetic testing outcomes for distribution to family members and other clinical providers. While genetic counseling may be provided to those patients who are followed in the FHRGICC, and to any of their relatives who choose to be seen at MD Anderson, any pro-active contact and/or follow-up of at-risk family members is presently outside the scope of current standard care. Based on this evaluation, there was consensus that the focus of a navigation program should include (but may not be limited to) the following:

- 1. Provide a liaison between genetic counselors and mutation-positive index patients as part of their ongoing high risk management in the FHRGICC.
- 2. Facilitate the dissemination of information to at-risk relatives of index patients regarding familial cancer risk.
- 3. Initiate and maintain contact with index patients and at-risk family members (with appropriate consent) to facilitate education, referrals (to MD Anderson or local services), and other aspects of hereditary cancer risk management (e.g., access to high risk surveillance and management services).
- 4. Implement processes for ongoing contact with index patients and relatives to ensure continuity of care.
- 5. Coordinate with physicians, genetic counselors and researchers associated with the FHRGICC for data collection, research, and clinical support.

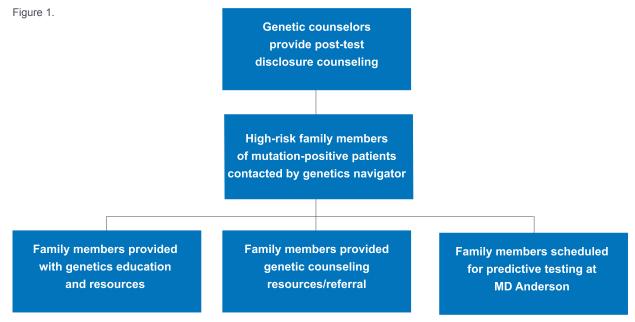


Figure 1. Schematic of cancer genetics navigation for outreach to high-risk families. Such a model will facilitate outreach, genetic counseling and testing, patient education, family communication, and management of high-risk family members.

Through this assessment process, the team also defined the initial priority population for the clinical genetics navigation program. The group will focus on families of individuals with a known heritable mutation for Lynch syndrome. This population represents a large (n=282 mutation carriers) index patient population, and guidelines for identifying at-risk relatives of index patient mutation carriers and for cancer risk management are well-established. Based on this assessment, a patient navigator was hired into the role of program coordinator in Surgical Oncology.

Finally, the Project BRaNCH team undertook a comprehensive review to understand the evidence base for educational and communication interventions for hereditary cancer risk assessment and counseling, with a focus on web-based resources. While over 20 publications and other sources were identified that described systematic strategies (including web-based) for

the collection and interpretation of family cancer or other health information, there are a limited number of studies that have evaluated the impact of such strategies on improving knowledge and accurate perceptions of disease risk, or on achieving risk-appropriate behavior change. Other studies identified decision aids related to hereditary colorectal cancer genetic testing and counseling, including paper-based and web-based decision aids. This information will be used to guide the development of e-Health and other resources.

Future Plans

Training of the new patient navigator will occur in the first quarter of FY14. The priority population for recruitment and enrollment in the high risk registry, as noted above, includes index patients with known Lynch syndrome mutations and their family members. Contact will be initiated with more recently diagnosed patients, with outreach to their first-degree relatives; subsequently, the group will proceed with contact to patients who have been diagnosed less recently, and simultaneously will expand family recruitment to second-degree relatives and successive generations, as appropriate.

IT infrastructure enhancement is on-going and will likely continue into FY15, as the group expects to identify emergent needs from their initial target population that may not have been otherwise anticipated.

The investigators anticipate continued development of manuscripts and abstracts to disseminate findings from data collection during the ongoing research efforts as well as the new data collection that will be initiated in year 2. With the success of the efforts to expand and recruit families of Lynch syndrome index patients, the team expects that this population will provide an infrastructure for multidisciplinary, extramurally funded research.

Publications — Study Results for Research Supported by Project BRANCH

Lynch HT, Snyder C, Stacey M, Olson B, Peterson SK, Buxbaum S, Lynch PM. Communication and technology in genetic counseling for familial cancer. Clin Genet. 2013 Nov 8. doi: 10.1111/cge.12317. [Epub ahead of print]

The Center for Energy Balance in Cancer Prevention and Survivorship

Director:

Karen Basen-Engquist, Ph.D., M.P.H., professor, Department of Behavioral Science

Background

The Center for Energy Balance in Cancer Prevention and Survivorship is a research center for professionals who are studying diet, physical activity, and obesity and its impact on cancer. The Center fosters a transdisciplinary approach by bringing together basic, clinical and population scientists and practitioners in a collaborative environment. Membership is open to faculty, staff, and trainees. The Center was established at the end of FY12 and defined the following specific aims:

- 1. Develop practice-changing research and data resources in five focus areas (see Figure 2).
- 2. Increase 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.

Scientific Progress

The Center completed its first year of funding, during which it participated in the submission of 20 grant proposals (seven pending review and two awarded) related to energy balance and cancer; assembled an advisory committee of key institutional research leaders to provide input on center activities and priorities; formed a transdisciplinary journal club which held six sessions with 20-30 attendees each; and developed communication and tracking tools, including a website, a Twitter feed, and an RSS feed for tracking publications. In addition, the Center has organized a work group on visceral adiposity to increase communication and collaboration among faculty members interested in the relationship between visceral adiposity at time of diagnosis and disease outcomes and progression. A second workgroup on the use of accelerometers in energy balance research is in development.

As the Center aims to build the intellectual community of energy balance researchers and facilitate transdisciplinary collaboration among these researchers, it is hosting an energy balance retreat in February 2014. Plans for the retreat are well underway and are being overseen by a planning committee consisting of 12 faculty members from clinical, translational and population research areas. The Center plans to recruit for two faculty positions to strengthen energy balance research infrastructure and sustain the Center's efforts beyond the initial start-up period.

Finally, the Center has played a role in 11 clinical and/ or population-based research studies within the last year. All studies involve testing either dietary, physical activity, or healthy lifestyle interventions in various populations, including Mexican-Americans, African-Americans, and cancer survivors of different races and ethnicities.

Future Plans

Center plans by aim are as follows:

Aim 1: Research

- Conduct new pilot tests, for example, developing a physical activity smart phone app for cancer survivors.
- Test energy balance measures in the Cancer Prevention Center, the high-risk breast cohort, the lung cancer screening study, and the gynecological oncology cancer survivor clinic.
- Submit proposals in response to PAR 12-228/229, IRG and DFI seed money opportunities.

Aim 2: Collaboration

- Recruit members and create a member directory.
- Develop and disseminate a newsletter.
- Convene a research retreat in February 2014.
- Launch accelerometer work group and investigate a chemoprevention and energy balance work group.

Figure 2. Initial Focus Areas of the Center for Energy Balance in Cancer Prevention and Survivorship

- Trials in cancer survivors on the effects of physical activity and weight control interventions on biomarkers of prognosis and survival, as well as symptom management.
- Trials in people at risk of cancer (particularly high risk populations) to test the effect of physical activity/exercise, diet, and weight on biomarkers related to cancer initiation, alone or in combination with chemopreventive agents.
- Studies of the biological mechanisms underlying the relationships between physical activity, diet, weight status and cancer initiation, promotion, progression, and recurrence.
- Dissemination and implementation research on energy balance interventions for cancer survivors and at risk populations, including technology-based interventions delivered in health care settings.
- 5. Research on biobehavioral mechanisms underlying weight changes (gain, loss, and maintenance of loss), eating behavior, and physical activity.

Aim 3: Infrastructure

- · Hire a midlevel provider.
- Enhance infrastructure for study recruitment.

Aim 4: Education and Outreach

 Co-sponsor two Cancer Prevention and Control Grand Rounds and two Integrative Health Grand Rounds speakers.

Publications — Study Results for Research Supported by the Center for Energy Balance in Cancer Prevention and Survivorship.

As the Center just completed its first year of operation, there have been no energy balance peer-reviewed journal articles published in FY13 acknowledging the Center. However, we consider the number of energy balance-related publications from all MD Anderson faculty to be an important metric for the Center, as it represents the strength of MD Anderson in energy balance research. We inventoried the energy balance-related publications authored by MD Anderson faculty during this review period to establish a baseline and have identified 29 publications, and provide a selection of these here.

- 1. McNeill LH. Stoddard A. Bennett GG. Wolin KY. Sorensen GG. Sep-12. Influence of individual and social contextual factors on changes in leisure-time physical activity in working-class populations: results of the Healthy Directions-Small Businesses Study. Cancer Causes Control. 23(9). 1475-87.
- 2. Palmer NR. Bartholomew LK. McCurdy SA. Basen-Engquist KM. Naik AD. Oct-12. Transitioning from active treatment: colorectal cancer survivors' health promotion goals. Palliat Support Care. Epub.
- 3. Lin J. Forman MR. Wang J. Grossman HB. Chen M. Dinney CP. Hawk ET. Wu X. Oct-12. Intake of red meat and heterocyclic amines. metabolic pathway genes and bladder cancer risk. Int J Cancer. 131(8). 1892-903.
- 4. Rhondali W. Chisholm GB. Daneshmand M. Allo J. Kang DH. Filbet M. Hui D. Fingeret MC. Bruera E. Oct-12. Association Between Body Image Dissatisfaction and Weight Loss Among Patients With Advanced Cancer and Their Caregivers: A Preliminary Report. J Pain Symptom Manage. S0885-3924(12). 00364-8.
- 5. Treviño RA. Vallejo L. Hughes DC. Gonzalez V. Tirado-Gomez M. Basen-Engquist K.Dec-12. Mexican-American and Puerto Rican breast cancer survivors' perspectives on exercise: similarities and differences. J Immigr Minor Health. 14(6). 1082-9.
- 6. Basen-Engquist K. Carmack CL. Li Y. Brown J. Jhingran A. Hughes DC. Perkins HY. Scruggs S. Harrison C. Baum G. Bodurka DC. Waters A.Feb-13. Social-Cognitive Theory Predictors of Exercise Behavior in Endometrial Cancer Survivors Health. Psychol. Epub.
- 7. Strong LL. Reitzel LR. Wetter DW. McNeill LH.Feb-13. Associations of Perceived Neighborhood Physical and Social Environments With Physical Activity and Television Viewing in African-American Men and Women. Am J Health Promot. Epub.
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- 9. Daniel CR, Park Y, Chow WH, Graubard BI, Hollenbeck AR, Sinha R. May-13 Intake of fiber and fiber-rich plant foods is associated with a lower risk of renal cell carcinoma in a large US cohort. Am J Clinical Nutrition. 97(5). 1036-1043.
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The Premalignant Genome Atlas

Co-Directors:

Xifeng Wu, M.D., Ph.D., chair, Department of Epidemiology

Ernest Hawk, M.D., M.P.H., vice president for Cancer Prevention and division head, Cancer Prevention and Population Sciences

Lopa Mishra, M.D., chair, Department of Gastroenterology, Hepatology and Nutrition

Background

The Mission of the Premalignant Genome Atlas Program is to assess the spectrum of risk factors contributing to the progression from healthy individuals to those with precancerous lesions to cancer patients, and to determine molecular differences among these patients. The goal is to identify markers of progression risk, targets for prevention, and markers of prevention response.

The Premalignant Genome Atlas program brings together faculty with expertise in the study of premalignant lesions to create a well-organized infrastructure for patient recruitment and data analysis (Figure 3). The three specific aims are:

1. Establish a biobank for patients coming to the Cancer Prevention Center (CPC) and MD Anderson clinics for the purpose of cancer screening. The biobank collects peripheral blood, premalignant tissues, tumor tissues, epidemiologic data, clinical variables, and demographic information. The initial focus is colorectal polyps due to their high prevalence, well-established premalignant tissue type and screening protocols, and relative ease of tissue collection.

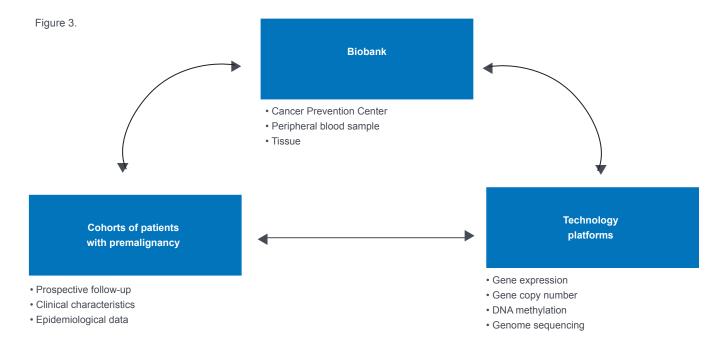


Figure 3. Schematic of the infrastructure of the Premalignant Genome Atlas Strategic Research Initiative.

- 2. Build a cohort of patients with premalignant lesions to prospectively follow. In addition to collecting biospecimens for storage in the biobank, epidemiologic and exposure data for core risk factors will be collected by way of in-person interviews using structured questionnaires or the patient history database. Regular follow-up will be conducted over an extensive period of time.
- 3. Perform genome-wide analysis of genetic variations in germline DNA and genome-wide molecular profiling (genetic, epigenetic, and expression) of normal, premalignant, and cancer tissues. Genetic and molecular profiles of healthy individuals, patients with premalignant lesions, and cancer patients will be compared to identify those markers that have the best predictive value of malignant progression.

Scientific Progress

Infrastructure

The PGA team has expanded patient recruitment and biobank collections and forged collaborations with clinical investigators across MD Anderson. Moreover, they have successfully completed and initiated several important whole-genome projects to identify molecular markers that are predictive of premalignant lesions and their progression in both esophageal and colorectal cancers. These efforts will provide the resources and foundation for further translation of these findings to benefit patients in cancer treatment and prevention.

Table 1 outlines the progress with patient recruitment, data collection and biospecimen banking for the PGA polyp program as of June 2013. The program currently draws on the services of 12 clinicians from Gastroenterology, Hepatology, and Nutrition. Current participant recruitment includes 1460 patients.

Table 1. Patient Recruitment and Biospecimen **Banking: Progress from Study Onset**

Cases recruited	1460
Non-Hispanic white	1115
Hispanic	113
Black	158
Other	74
Inquire questionnaires	629
Blood samples	1365
Tissue samples*	1405
Normal	1393
Abnormal / polyp	430

*In some instances more than 1 sample of normal or polyp tissue per patient collected

To enable data collection and analysis of the above samples, a web-based Oracle database, the PGA POLYP INQUIRE, has been created to allow for rapid and secure query of epidemiologic, demographic, clinical, and Patient History Databases questionnaire information. The benefits of the web-based database include a lower cost for data collection; direct capture of data in electronic format providing for faster analysis; and streamlined access for faster data verification and validation.

Research Highlights

Several genome-wide and molecular profiling studies were performed in the last year to identify markers predictive of premalignant lesions and progression in both colorectal adenoma/cancer patients and Barrett's Esophagus/esophageal cancer patients. Below are findings from two such studies:

- Serum microRNA (miRNA) expression profiling in patients with colorectal adenomas or colorectal cancer identified a miRNA, miR-376a, showing significant differential expression among controls, those with adenomas and those with cancer, suggesting this miRNA plays a role in the progression of cancer.
- Serum global metabolomic profiling in patients with Barrett's Esophagus (BE) and Esophageal Adenocarcinoma (EAC) revealed hundreds of metabolites differing between controls and those with BE, and between controls and those with EAC, suggesting these metabolites may serve as biomarkers of esophageal adenocarcinoma progression.

Future Plans

The PGA team will continue to establish and recruit participants to premalignant patient cohorts, and expand and maintain efforts in molecular and phenotypic profiling. Areas of interest for future studies include:

- Evaluating the gut microbiome in colorectal neoplasia, with correlation of markers of energy balance with risk of cancer and progression.
- Whole-exome sequencing in additional adenoma-normal tissue pairs.
- Developing a personalized oral cancer risk classification system in patients with oral premalignant lesions.

Building on the success in establishing and expanding the infrastructure and resources in colorectal and esophageal cancers, the PGA investigators are exploring collaborations with internal and/or external investigators to expand the scope of the PGA to other cancers to identify unique markers for premalignant lesions at these disease sites. A research team submitted a letter of intent for the institutional Multidisciplinary Research Program (MRP) to develop transdepartmental and transdisciplinary collaborations to characterize the mechanisms of neoplastic development and progression in tissues commonly affected by cancer (oral, colorectal, breast, and skin), while identifying promising avenues for identification and development of markers of risk and preventive response, leading to insights for preventive interventions. Funding of the PGA through the MRP mechanism provides an opportunity to establish the infrastructure, generate preliminary data, and develop a cohesive research program that will provide a strong foundation for a future program grant submission to an extramural funding agency, such as the National Cancer Institute or the Cancer Prevention Research Institute of Texas. The PGA team will remain engaged in Moon Shots initiatives with regard to colorectal and melanoma studies.

Publications — Study Results for Research Supported by the PGA

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- 2. Gu J. Wang Y. Wu X. *MicroRNA in the pathogenesis and prognosis of esophageal cancer*. Curr Pharm Des. 19(7):1292-300. 2013. PMID:23092349
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Integrative Health

Co-Directors:

Ernest Hawk, M.D., M.P.H., vice president for Cancer Prevention and division head, Cancer Prevention and Population Sciences

Therese Bevers, M.D., F.A.A.F.P., professor, Clinical Cancer Prevention; Medical Director, Cancer Prevention Center **Richard T. Lee, M.D.,** assistant professor, General Oncology; clinical director, Integrative Medicine Program **Lorenzo Cohen, Ph.D.,** professor, General Oncology and Behavioral Science; director, Integrative Medicine Program

Background

The Integrative Health (IH) initiative expands MD Anderson's multidisciplinary care model and recognized leadership in medical, radiation and surgical oncology treatment to include additional evidence-based behavioral and complementary clinical services for cancer prevention and survivorship patients and those undergoing active treatment. New and expanded clinical services are provided to meet patient needs in five domains: nutrition, physical activity, psychosocial, complementary therapies, and tobacco cessation (Figure 4). By providing personalized services tailored to individual patient needs, the IH initiative aims to achieve better patient health outcomes.

The IH initiative is distinct from the other five Strategic Initiatives of the Duncan Family Institute, as its primary focus is on clinical service delivery. Implementation of the IH initiative in the clinical setting is being done in four phases:

- **Phase 1:** Develop a plan to establish and/or expand Integrative Health services in the five modalities defined within this initiative.
- Phase 2: Develop, implement and expand Integrative Health services in three patient populations: healthy/at-risk patients seen in the Cancer Prevention Center (CPC), patients in treatment, and breast cancer survivors seen in the CPC. The Integrative Health initiative is currently in Phase 2.
- **Phase 3:** Expand services to additional clinical care centers as well as all prevention and survivorship patients seen in the CPC.
- **Phase 4:** Make Integrative Health services the standard of care.



Figure 4. Schematic illustrating the five domains of care in the Integrative Health Initiative. The Health Navigator is shown in the center, navigating patients to the appropriate domain(s) according to patient needs. Within each domain, interventions are tailored to a patient's individual needs and include counseling, follow-up, and educational resources.

Clinical Operations Progress

Cancer Prevention Center

The aim of the IH initiative in the Cancer Prevention Center is to reduce cancer incidence rates among at-risk patients and reduce recurrence rates in cancer survivors by providing supportive, patient-centered care. The following multidisciplinary team has been assembled to develop the initiative in the CPC:

- Integrative Health Navigator
- Exercise Physiology Technologist
- Dietitian
- Social Worker
- Manager of Health Education
- Program Manager

This team is working closing with CPC-based providers to navigate patients to Integrative Health services based on their health needs.

Under the leadership of the Clinical Program Manager, IH staff began evaluating prevention patients and cancer survivors in the CPC in January 2013. Patients are referred by a CPC provider based on nutrition or physical activity needs. Each intervention is tailored to a patient's individual needs and includes counseling, follow-up, and educational resources for the domain identified for intervention. The clinic is currently offering services for nutrition and physical activity, with referrals made to social work, tobacco treatment, and complementary therapies, as needed. In the coming year, the team will hire a Patient Service Coordinator to help schedule patients proactively. The goal is that all new CPC survivorship patients and consults will be seen by the Integrative Health Navigator, who will then make appropriate referrals based on patient needs.

During the five-month period of January through May FY13, the clinic provided a total of 1,862 patient interventions (Figure 5). Nearly 60% of these interventions were initial in-person consults, with the remainder of the interventions being patient follow-ups delivered either through the secure on-line portal myMDAnderson, or through telephone or in-person follow-up appointments.

In order to expand knowledge and understanding of the IH initiative at MD Anderson, a poster describing the CPC IH model was presented at MD Anderson's Annual Education Week in 2013. The poster was positively received and was awarded second place out of 28 posters.

Integrative Medicine Center

The Integrative Medicine Center (IMC) provides integrative health services to cancer patients in active treatment. The IMC saw a total of 3,636 outpatient visits, which include the following specific areas supported by the Duncan Family Institute: physical activity/exercise (215), meditation (66), and nutrition (203) through May 2013. Prior to Duncan Family Institute support, these services did not exist or were very limited. Outpatient group activity in these areas includes nutrition classes (160) and meditation (404). With support from the Duncan Family Institute IH Initiative, the IMC was able to expand its clinical team to include:

- Sr. Clinical Dietitian
- Sr. Physical Therapist
- Behavioral Psychologist
- Physician Assistant (inpatient services)

These professionals have provided resources needed to address two key areas – physical health (obesity) and inpatient



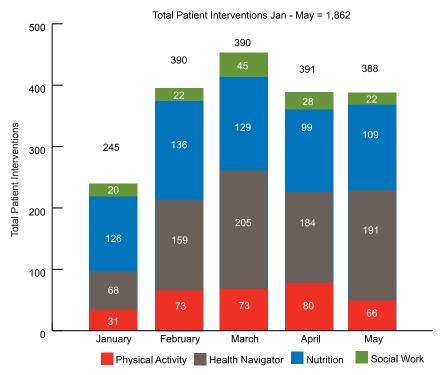


Figure 5. Total patient interventions provided as part of the Integrative Health Strategic Research Initiative for the period January-May, 2013. A total of 1,862 interventions were provided.

integrated medicine services. A major focus continues to be a comprehensive program for patients focusing on physical health and weight management to control obesity, with plans in place to provide a multidisciplinary approach that includes nutrition and exercise services and psychological support.

The Sr. Clinical Dietitian was instrumental in creating a nutrition screening tool used for IMC patients in an effort to target specific concerns to the appropriate practitioner: dietitian, mid-level provider, or physician. Numerous patient education materials addressing nutrition education, nutrition references, and recipes have also been created focusing on patients in active treatment. Two classes have been developed: a monthly cooking class to teach patients a variety of healthy recipes and a monthly nutrition lecture open to all patients and caregivers, instructing them on the plant-based, whole foods diet guidelines.

The Sr. Physical Therapist worked to develop the physical activity/exercise component of the IMC by providing comprehensive evaluations for patients identified through the Integrative Medicine physician consultation service. This individual provides patients with expert advice on exercise and physical therapy and does it in coordination with the Sr. Clinical Dietitian to facilitate change to promote patient health and build strength and endurance as they prepare for upcoming surgery, chemotherapy regimen, or other interventions. Patients who require more traditional physical therapy are referred to Rehabilitation Medicine while those for exercise prescription remain within the IMC plan of care.

With regard to inpatient services, the center has for many years received requests for inpatient services and has not been able to meet these requests in a coordinated manner. In an effort to establish timely and efficient communication and triage all inpatient requests for Integrative Medicine services, a formal inpatient consultation pilot was initiated. Led by the IMC Physician Assistant and on referral by the patient's primary medical team, the service provides a comprehensive assessment resulting in a more effective and efficient triage of appropriate inpatient clinical services that assure patients with the greatest medical need are treated first.

Research Progress

In collaboration with the Office of Cancer Survivorship, the IH team within the CPC launched a Breast Cancer Survivorship Pilot in January 2013. The aim of this three month pilot was to prospectively identify supportive care needs across six domains of care in breast cancer survivors before the date of their breast cancer follow-up appointment. These domains were: 1) energy-balance (diet and exercise), 2) tobacco, 3) psychosocial, 4) integrative medicine, 5) lymphedema and 6) sexual health. The goal was to find the best means of identifying supportive care needs within each of the six domains in order to coordinate appropriate care on the same day as the patient's clinical breast cancer survivor follow-up visit. A survey addressing potential supportive care needs was administered to breast cancer survivors with a BMI \geq 30 approximately 90 days prior to their survivorship appointment. A total of 136 women who were scheduled for an appointment in the CPC between January 1 and March 31 met the defined criteria and were approached for participation in the pilot via mail, phone, or myMDAnderson. Of the 136 patients identified, 93 agreed to participate. The team achieved an 85% survey completion rate over three months of the pilot study. Analysis of data from the pilot demonstrated that prospectively contacting breast survivorship patients for referral services increases overall identification of needs, allows for time to coordinate referral appointments and increases adherence to referrals. The team is currently working on Phase II of this pilot to determine more efficient ways to prospectively ascertain needs and provide access to appropriate services. Abstracts for this pilot were accepted for presentation at the 2013 Cancer Patient Education Network (CPEN) conference and the International Conference of the Society for Integrative Oncology (see Publications section).

A major innovative research study is occurring in the IMC. With a large team of experts from across the institution, including faculty from the Departments of General Oncology, Behavioral Science, Breast Medical Oncology, Breast Radiation Oncology, Internal Medicine, Cancer Biology, and Hematopathology, the Comprehensive Lifestyle Change Study consists of a patient intervention addressing physical activity, diet/nutrition, mind-body practice, social support/social network, and smoking cessation, as appropriate. Stage III breast cancer patients randomized to the intervention group will receive the intervention during their radiotherapy treatment at MD Anderson and will also remain active in the intervention via an interactive website and video/telephonic counseling providing guidance on all aspects of the overall intervention. In collaboration with various partners, including the Duncan Family Institute-supported e-Health research resource, tools have been created for the study, including educational and interactive websites for assessment and at-home tracking of behaviors as well as customized mobile applications with community resources.

Future Plans

The IH initiative, under the leadership of Drs. Hawk, Bevers, Lee, and Cohen, with guidance from the multidisciplinary Integrative Health Working Group (IHWG), will continue to implement its work plan, focusing on fully implementing Phase 2 pilot activities and initiating Phase 3 based on evaluation of Phase 2 pilot data. The focus over the coming year will be on continued implementation of IH services in the CPC, assessing readiness for expansion of the IH model into one of the multidisciplinary clinical centers for patients undergoing active treatment, and evaluation of pilot programs using a number of process and outcome metrics.

For prevention and survivorship patients, the CPC will hire a Patient Services Coordinator (PSC), a Research Assistant, and an additional Exercise Physiology Technician (part-time) in 2014 in response to patient demand. Investments will be made to strengthen and populate the clinical and research data infrastructure to understand the patterns of uptake of integrative health services and, long-term, the impact of Integrative Health services on patient outcomes. It is anticipated that the IH initiative will provide insights into the CPC's expansion plans now in discussion and will also serve as a model for other centers within MD Anderson.

Integrative Health professionals are planning to develop patient education materials, including creating short, YouTube-style videos to reinforce the information provided during consults. A pilot study is planned to explore the advantages and disadvantages of pedometers vs. Wi-Fi devices for tracking activity and motivating individuals to adopt healthy behaviors.

For patients undergoing active cancer treatment, the IMC plans to continue development of its multidisciplinary weight management program, an intensive comprehensive program to include both individual and group services for approximately eight weeks along with long-term follow-up. It plans to expand Mind-Body/Behavioral Counseling services and its inpatient consultation service. A priority will be to develop and populate a clinical outcomes database to evaluate the clinical impact of IMC services, with a preference for web-based data collection supported by mobility tools, such as tablet devices for use by patients in the clinic.

A high priority is the financial sustainability of Integrative Health services. The Integrative Medicine Center will review its visit and fee structure with a goal of expanding opportunities for patient access and overall patient satisfaction as well as providing additional revenue sources to sustain services. Similarly the Cancer Prevention Center will explore opportunities for reimbursement. With the American Medical Association's recognition of obesity as a disease and the growing understanding of the relationship of diet and exercise to cancer risk and recurrence, the environment for reimbursement for Integrative Health preventive services could become more favorable.

Abstracts — to Disseminate the Work of Investigators and Practitioners of the Integrated Health Initiative

- 1. Abstract for MD Anderson's Education Week 2013
 - Title: Integrative Health Program at MD Anderson's Cancer Prevention Center
 - Sally Scroggs, M.S., R.D., L.D., Bonnie Nelson, M.ED., C.H.E.S., Rachel M. King, M.P.H., Allica Austin, B.S., Haley Hollas, B.S., and Therese B. Bevers, M.D.
- 2. Abstract #1 for CPEN, accepted for CPC Staff. The CPEN conference is a joint meeting of CPEN, American Association for Cancer Education (AACE), and The European Association for Cancer Education (EACE).

Title: Needs Identification Process of the Breast Cancer Survivorship Services Pilot at The University of Texas MD Anderson Cancer Center (MDACC)

Bonnie Nelson, M.E.D., C.H.E.S., Sally Scroggs, M.S., Katherine Gilmore, M.P.H., Rachel M. King, M.P.H., Allica Austin, B.S., and Therese B. Bevers, M.D.

3. Abstract #2 for CPEN, accepted for CPC Staff.

Title: Integrative Health Breast Cancer Survivorship Services Pilot at The University of Texas MD Anderson Cancer Center (MDACC)

Rachel M. King, M.P.H., Sally Scroggs, M.S., Katherine Gilmore, M.P.H., Bonnie Nelson, M.Ed., Allica Austin, B.S., and Therese B. Bevers, M.D.

Tobacco Transdisciplinary Research Program

Director: David Wetter, Ph.D., chair, Department of Health Disparities Research

Background

The Tobacco Transdisciplinary Research Program (TTRP) unites investigators with complementary expertise related to tobacco use and prevention from across MD Anderson in the common goal of designing innovative research studies that seek to better understand and address tobacco use as a risk factor for cancer. Over the past year, the TTRP has focused on addressing tobacco cessation through a health systems approach. This work is highly translational in nature and includes implementing, disseminating and evaluating evidence-based cessation strategies in clinical and community settings.

Scientific Progress

During FY13, the TTRP submitted two very large tobacco-related federal grant proposals and was awarded an important Medicaid Delivery Service Reform Incentive Payment (DSRIP) project. These proposals are described below:

- 'Tobacco TIPS: Translation Into Practice Systems'. David Wetter, Ph.D., chair and professor, Health Disparities Research; P01, National Cancer Institute; \$12,399,279. Submitted, Under Review: This proposal aims to develop and test innovative approaches to implement and disseminate evidence-based tobacco cessation treatments in primary care practices that serve disadvantaged populations. Tobacco TIPS has tremendous potential to improve public health and reduce tobacco-related health disparities by increasing and accelerating the use of evidence based tobacco cessation treatments. The results from this research will advance the emerging field of dissemination and implementation science and will have implications for the broad scale-up and use of cancer preventive services throughout the nation.
- 'MD Anderson-Geisel (MG) Tobacco Centers of Regulatory Science (TCORS)' David Wetter, Ph.D., chair and professor, Health Disparities Research; James D. Sargent, M.D., professor, Geisel School of Medicine, Dartmouth

University; P50, U.S. Food and Drug Administration; \$19,976,197. Submitted, Not Funded. This proposal sought to address the impact of tobacco marketing at point of sale (POS) on tobacco use behaviors among young adults and adults attempting to quit, with a special emphasis on vulnerable populations (i.e., racial/ethnic minorities: low socioeconomic status individuals). This multi-project research program aimed to link investigators with expertise in the full spectrum of tobacco use and quitting behaviors, tobacco marketing, tobacco policy, mobile technology, geospatial analysis, and health disparities with the goal of improving the evidence base regarding the impact of POS marketing



among legal users of tobacco. Although this proposal was not funded, it brought together investigators at a national level whose interactions are leading to new collaborations, one of which is engaging with the National Institutes of Health Big Data to Knowledge (BD2K) Centers, which seeks to enable biomedical scientists to capitalize more fully on the Big Data being generated by numerous different research communities. In addition, MG TCORS researchers are seeking support for their individual projects and designing new research studies that build on the collaboration.

"Extend "Ask-Advise-Connect" to 4 FQHC systems (12 clinics). Jennifer Irvin Vidrine, Ph.D., associate professor, Health Disparities Research; Delivery Service Reform Incentive Program1115 Waiver project, Center for Medicare and Medicaid Services; \$1,000,000. Submitted, Funded. In this recently funded project, Ask-Advise-Connect (AAC), a successful smoking cessation intervention, will be delivered in four Federally Qualified Health Centers (FQHCs) in Harris County by implementing clinical practice guidelines and promoting health system supports in electronic health records. In AAC, licensed vocational nurses and medical assistants are trained to ask all adult patients at every visit about their smoking status at the time that vital signs are assessed, provide brief advice to all smokers to quit, offer cessation assistance via the Quitline, and directly connect patients willing to accept assistance with the Quitline. Connections to the Quitline are made by clicking an automated link in the electronic health record (EHR) that sends smokers' names and phone numbers to the Quitline within 24 hours. Patients are contacted by the Quitline within 48 hours of receipt of their contact information. This proposal represents the translation of earlier successful research on AAC into a real-world setting.

Future Plans

The TTRP will continue to bring together interested investigators with expertise in tobacco prevention, use and cessation from across MD Anderson and will continue to partner with nationally and internationally renowned experts in tobacco research and control to develop innovative proposals addressing the pressing questions in tobacco-related research. Plans for FY14 include a focus on the successful implementation of the AAC Medicaid DSRIP project as well as the continued development of innovative research directions, including the two individual investigator-initiated study proposals emerging from the MG TCORS collaboration.

Publications — Study Results for Research Associated with the Tobacco Transdisciplinary Research Program Vidrine JI, Shete S, Cao Y, Greisinger A, Harmonson P, Sharp B, Miles L, Zbikowski SM, Wetter DW. Ask-Advise-Connect: a new approach to smoking treatment delivery in health care settings. JAMA Intern Med. 2013 Mar 25;173(6):458-64.

Center for Translational and Public Health Genomics

Co-Directors:

Xifeng Wu, M.D., Ph.D., chair, Department of Epidemiology

Alma Rodriguez, M.D., professor, Department of Lymphoma/Myeloma, and Vice President for Medical Affairs

Background

The Center for Translational and Public Health Genomics (CTPHG) brings together the resources available through MD Anderson's large patient population and its well established foundation of epidemiologic and genomic research to facilitate and support translational and public health genomics research. The Center serves as an institutional hub for research and scientific exchange among investigators in translational epidemiology, public health genomics, pharmacogenomics, clinical outcomes, and survivorship research with an emphasis on inherited genetic and phenotypic variations.

Scientific Progress

The Center has three components that contribute to its overall research goals:

- Infrastructure building and utilization.
- Blood-based biomarker discovery, development, and validation.
- Personalized risk model development and implementation.

Each of these components is an active area of research with faculty from across the institution contributing. Highlights from these three components are described below.

1. Infrastructure: The Infrastructure component consists of the following vital research resources that support a range of investigations.

MD Anderson Cancer Patient Cohort (MDACPC): This is a cohort of MD Anderson cancer patients that serves as a resource for studies to define and integrate determinants of cancer-related risks and outcomes across the continuum of care (Figure 6). The strength of this unique cohort is the ability to couple biospecimens collected from MD Anderson's population of patients and healthy controls with comprehensive epidemiologic and clinical data. Investigators can then use high-throughput "-omic" technologies to ask and answer scientific questions about cancer risk, progression and response

Figure 6.

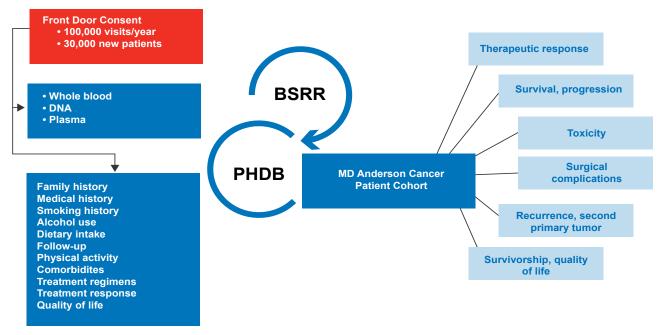


Figure 6. Schematic of the components of the MD Anderson Cancer Patient Cohort.

to treatment. Biospecimens are collected and banked through our highly successful Blood Specimen Research Resource (BSRR). The BSRR has continued to systematically collect residual blood samples from all newly diagnosed patients seen at MD Anderson who sign the front door consent. To date, the BSRR has collected and banked 53,799 blood samples from 52,925 unique patients. The largest collections are in breast (10.9%) and colorectal (7.7%) cancers, followed by lymphoma (6.9%), prostate (6.8%) and lung (6.4%) cancers. Data and Biospecimen Access Committees have been established to ensure appropriate investigator access to biospecimens and associated data. These committees review and prioritize requests, provide oversight and insure adherence to all institutional and federal compliance and policies.

Survivorship Cohort: There is an urgent need for research focusing on this growing patient population. To address the gap in the collection of biospecimens and patient data from long-term cancer survivors that visit our survivorship clinics, a Survivorship Cohort has been developed that parallels the efforts of the MDACPC to build a significant research resource for investigators who are interested in survivorship research. To date, we have recruited and banked biospecimens from a total of 2,476 survivors.

Collaborative Biospecimen Banks: The Center has rapidly become recognized as a leader in biorepository development, and this has yielded a number of collaborative biospecimen banking efforts associated with various research projects from across the institution. More than 3,400 samples have been banked to provide resources for diverse projects. The Center also oversees and provides support for TexGen, a biorepository established prior to the Center's startup. TexGen is a collection of blood samples from patients with gastrointestinal and genitourinary cancers developed in collaboration with colleagues in the Gastrointestinal and Genitourinary Care Centers, with an estimated 16,000 samples. These collaborations have already yielded several impactful publications.

- **2.** Blood-based Biomarker Discovery, Development, and Validation: The CTPHG is an active platform for use by faculty across the institution to identify blood-based biomarkers from samples obtained from one of the above-described infrastructure resources. Projects focus on end-points across the cancer continuum, including risk assessment, pre-malignancy, early detection, treatment response, clinical outcomes, quality of life, and survivorship. Examples include studies in sarcoma investigating mitochondria copy number and telomere length as risk factors; and genome-wide association analysis of clinical outcomes for lung cancer (in both ever and never smokers) and bladder cancer to discover novel loci associated with survival. It is anticipated that this Center component will see substantial activity in the coming years with the expansion and growth of the resources described above.
- 3. Personalized Risk Prediction Models: As a step towards translation and implementation of our research findings, faculty members of the Center develop personalized risk prediction models for not only risk of developing cancer, but also for other clinically-relevant endpoints across the cancer continuum. This process requires an integrative approach that incorporates patient variables (demographics, epidemiology, and clinical information) with biomarkers and other predictive factors. A significant effort has been put into the identification of modifiable risk factors that can inform the risk model while also demonstrating reduction in risk with corresponding lifestyle changes. Energy balance, adiposity, and the gut microbiome are all subjects of ongoing investigation. The Center is also bolstered by strength in computational epidemiology research focusing on development of next-generation sequencing pipelines and analytic tools. These tools are needed as investigators begin to incorporate rare variants and other products of sequencing analyses into the risk prediction models. Risk prediction models for colorectal cancer risk, lung cancer risk and lung cancer survival are in various stages of development.

Other Center Activities

International Training Program: Over the last year we have envisioned development of an international training program operated under the auspices of the Center in order to promote global collaboration and interactions and help build resources in low-to-middle income countries (Figure 7). Less developed countries often lack the expertise in development of cohorts and biorepositories and international fellows would greatly benefit from receiving such training within the environment of the Center. In July 2013, a memorandum of agreement was signed with the Instituto Nacional de Canerologia in Mexico and the first trainees arrived this Fall at MD Anderson.

Distinguished Seminar Series: The Center continues its efforts in scientific and public health education through its Distinguished Seminar Series. Center support has enabled 19 high-profile scientists in the fields of translational science and public health to visit our institution to deliver their research highlights, meet with faculty colleagues to discuss interactions, and provide guidance and insight on future directions. Planning for the FY14 series is well underway with five speakers currently confirmed.

Future Plans

The Center has developed near-term and midrange to long-term plans to continue to build the infrastructure while fostering the design and conduct of studies relevant to its research directions. Highlights of these plans are as follows:

Near term

- Implement effective recruitment of patients to enable rapid procurement of fresh blood sample collections focusing on key malignancies.
- Finalize development of colorectal cancer personalized risk prediction model.
- Complete development of personalized risk model for lung cancer survival.
- Complete refinement of lung cancer personalized risk prediction model.

Figure 7.

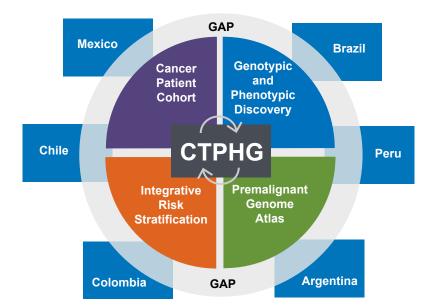


Figure 7. Schematic illustrating the Center's International Training Program, a joint effort with MD Anderson's Global Academic Programs (GAP).

• Formalize Center membership and develop a database to track relevant research activities, including publications and presentations.

Mid to Long-term

- Expand infrastructure to enable collection and banking of fresh blood from all patients newly registering at MD Anderson.
- Expand and build upon our biorepository collection and biobanking collaborations, both within the Division of Cancer Prevention and Population Sciences and across the institution, to support the research initiatives of investigators at MD Anderson.
- Develop and submit a program project/CPRIT grant using the MD Anderson Cancer Patient Cohort as one of the key cores supporting the project, an activity that will contribute to sustaining the resource.
- Optimize a long-term plan to prioritize building, refinement and implementation of personalized risk prediction models across the cancer continuum with development of web-based tools for patients and clinicians to better assess individual risk to facilitate appropriate health management and screening decisions.
- Design biomarker-based intervention trials to help reduce cancer risk and risk behavior.

Publications — Study Results for Research Associated with the Center for Translational and Public Health Genomics

Considering only Center members from the Department of Epidemiology, a total of 112 manuscripts were published in FY13. This includes manuscripts published in high-impact journals such as Science, Journal of the National Cancer Institute, Nature Genetics, Genome Research, Journal of Clinical Oncology, Cancer Research, Human Molecular Genetics and Carcinogenesis. If we were to consider all Center members, this number would be dramatically increased. A list of papers that specifically reference the Center in FY13 is provided below.

- 1. Xu E., Gong Y., Gu J., Jie L., Ajani J.A., Wu X. Risk assessment of esophageal adenocarcinoma using g-H2AX assay. Cancer Epidemiol Biomarkers Prev. 2013 Jul 31. Epub.
- 2. Xu E., Sun W, Gu J., Chow WH., Ajani JA., Wu X. Association of mitochondrial DNA copy number in peripheral blood leukocytes with risk of esophageal adenocarcinoma. Carcinogenesis. 2013 Jul 20. Epub.

- 3. Wu X, Wang L, Ye Y, Aakre JA, Pu X, Chang GC, Yang PC, Roth JA, Marks RS, Lippman SM, Chang JY, Lu C, Deschamps C, Su WC, Wang WC, Huang MS, Chang DW, Li Y, Pankratz VS, Minna JD, Hong WK, Hildebrandt MA, Hsiung C.A., Yang P., Genome-Wide Association Study of Genetic Predictors of Overall Survival for Non-Small Cell Lung Cancer in Never Smokers. Cancer Res. 2013 Jul 1;73(13):4028-4038.
- 4. Wang Y, Gu J, Roth JA, Hildebrandt MA, Lippman SM, Ye Y, Minna JD, Wu X. Pathway-Based Serum microRNA Profiling and Survival in Patients with Advanced Stage Non-Small Cell Lung Cancer. Cancer Res. 2013 Aug 1;73(15):4801-9.
- 5. Xie H, Wu X, Wang S, Chang D, Pollock RE, Lev D, Gu J. Long telomeres in peripheral blood leukocytes are associated with an increased risk of soft tissue sarcoma. Cancer. 2013 May 15;119(10):1885-91.
- 6. Xie H, Lev D, Gong Y, Wang S, Pollock RE, Wu X, Gu J. Reduced mitochondrial DNA copy number in peripheral blood leukocytes increases the risk of soft tissue sarcoma. Carcinogenesis. 2013 May;34(5):1039-43.
- 7. Wen CP, Lin J, Yang YC, Tsai MK, Tsao CK, Etzel C, Huang M, Hsu CY, Ye Y, Mishra L, Hawk E, Wu X. Hepatocellular carcinoma risk prediction model for the general population: the predictive power of transaminases. J Natl Cancer Inst. 2012 Oct 17;104(20):1599-611.
- 8. Ye Y, Madison B, Wu X, Rustgi AK. A LIN28B polymorphism predicts for colon cancer survival. Cancer Biol Ther. 2012 Dec 1;13(14):1390-5.
- 9. Hildebrandt MA, Tan W, Tamboli P, Huang M, Ye Y, Lin J, Lee JS, Wood CG, Wu X. Kinome expression profiling identifies IKBKE as a predictor of overall survival in clear cell renal cell carcinoma patients. Carcinogenesis. 2012 Apr;33(4):799-803.
- 10. Chung CC, Kanetsky PA, Wang Z, Hildebrandt MA, Koster R, Skotheim RI, Kratz CP, Turnbull C, Cortessis VK, Bakken AC, Bishop DT, Cook MB, Erickson RL, Fosså SD, Jacobs KB, Korde LA, Kraggerud SM, Lothe RA, Loud JT, Rahman N, Skinner EC, Thomas DC, Wu X, Yeager M, Schumacher FR, Greene MH, Schwartz SM, McGlynn KA, Chanock SJ, Nathanson KL. Meta-analysis identifies four new loci associated with testicular germ cell tumor. Nat Genet. 2013 Jun;45(6):680-5. doi:10.1038/ng.2634. Epub 2013 May 12.
- 11. Schumacher FR, Wang Z, Skotheim RI, Koster R, Chung CC, Hildebrandt MA, Kratz CP, Bakken AC, Bishop DT, Cook MB, Erickson RL, Fosså SD, Greene MH, Jacobs KB, Kanetsky PA, Kolonel LN, Loud JT, Korde LA, Le Marchand L, Lewinger JP, Lothe RA, Pike MC, Rahman N, Rubertone MV, Schwartz SM, Siegmund KD, Skinner EC, Turnbull C, Van Den Berg DJ, Wu X, Yeager M, Nathanson KL, Chanock SJ, Cortessis VK, McGlynn KA. Testicular germ cell tumor susceptibility associated with the UCK2 locus on chromosome 1q23. Hum Mol Genet. 2013 Jul 1;22(13):2748-53. doi:10.1093/hmg/ddt109. Epub 2013 Mar 5.



The Duncan Family Institute supports five research resources, including a new resource established this year, the Health Services Research Core Data Resource. Other resources include e-Health Technologies, the Mexican-American Cohort, the Center for Community-Engaged Translational Research, and the Clinical Cancer Prevention Research Core.

Over the past year, the Institute's research resources contributed to 58 newly submitted grant proposals totaling more than \$101 million in support for research studies. The DFI Resources provided core services essential to conducting 37 actively funded research studies with total costs exceeding \$21 million, resulting in 26 peer reviewed publications.

Health Services Research Core Data Resource

Co-Directors:

Sharon Giordano, M.D., M.P.H., chair, Department of Health Services Research Linda Elting, Dr.P.H., professor, Department of Health Services Research (retired, Nov 2013) Benjamin Smith, M.D., associate professor, Department of Radiation Oncology George Chang, M.D., associate professor, Department of Surgical Oncology Maria Suarez-Almazor, M.D., Ph.D., professor, Department of Internal Medicine

Background

The field of Health Services Research (HSR) examines "how people get access to health care, how much care costs, and what happens to patients as a result of this care" (Agency for Healthcare Research and Quality, 2002). This field of research is increasingly important given that the U.S. health care system is the most costly in the world, the cost of care is growing on an unsustainable trajectory, and significant gaps exist in health care quality and care coordination. Large

population-based datasets are one of the most important resources for studying health care delivery, economics of care, cost-effectiveness, quality of care, and outcomes. Yet acquiring, maintaining and managing these can be expensive and timeconsuming, requiring specialized expertise. A core data resource will contribute greatly to advancing health services research by providing a critical resource so investigators can concentrate efforts on asking and answering important health services questions.

The goal of the HSR Core Data Resource (HSRCDR) is to acquire, maintain and make available large datasets to promote HSR studies at MD Anderson. Specifically, the HSRCDR leaders plan to:

- 1. Purchase, maintain, and update large databases and make these available to MD Anderson researchers.
- 2. Maintain licenses, data use agreements, and confidentiality agreements to ensure regulatory compliance with the use of such databases.
- 3. Provide guidance and analytic support on studies using these databases.

Progress/Future Plans

A multidisciplinary investigative team of faculty across four divisions, all of whom have expertise in using national datasets, has been assembled. The team consists of investigators in Health Services Research, Radiation Oncology, Surgical Oncology, and Internal Medicine. In the coming year, the group will meet to make a collective decision regarding which databases would be of highest utility to faculty across MD Anderson. The databases proposed for discussion include the following:

- 1. **SEER-Medicare:** This database is a linkage between the Surveillance, Epidemiology, and End Results (SEER) cancer registry and Medicare data. It includes patients who were diagnosed in a SEER region and whose registry records could be linked to Medicare claims. This linked dataset provides information on cancer staging, patterns of care, use of resources, prescription drug use, costs of care, and outcomes.
- 2. Marketscan: This database is comprised of medical claims from patients with private health insurance, and it can be licensed for use on a yearly basis. The data provide information on patterns of care, costs, toxicities, and prescription drug use for both younger and older patients and includes information on more than 170 million unique patients.
- 5% Medicare: The 5% Medicare database is a random 5% sample of Medicare beneficiaries and includes medical claims for patients 65 years and older across the entire United States. This database also includes prescription drug information starting in 2007.
- 4. **AMA Masterfile:** This dataset contains current and historical data on physicians who practice in the United States, including variables such as age, gender, years in practice, practice setting, and board certification. These data can be linked with Medicare and SEER-Medicare to obtain information about the characteristics of the treating physician.
- 5. AHA Database: This database includes information on hospital demographics, utilization, expenses, and staffing across the United States.
- 6. Other databases of interest would include the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample, the Texas Healthcare Information Collection Inpatient discharge and outpatient datasets, the KIDS (pediatric inpatient) database, and Geolytics (US Census). The datasets would be available for use by any MD Anderson investigator and would be a valuable institutional resource. The group has proposed to create a link on the MD Anderson internal website with information about the available datasets and instructions for access.

The near-term (1-2 year) expected outcomes include:

- 1. Finalizing the selection of datasets to purchase and/or license the selected datasets.
- 2. Conducting analyses to generate preliminary data using this resource.
- 3. Submitting grant proposals for ongoing funding.

Mid-term (3-5 years) and long-term expected outcomes include:

- 1. Securing grants to sustain the data resource;
- 2. Publishing multiple manuscripts describing results of studies using these data.
- 3. Expanding the resource to include additional data resources supporting HSR projects.
- Expanding sources of funding for ongoing multidisciplinary HSR projects using this resource.

e-Health Technology

Co-Directors:

Alexander Prokhorov, M.D., Ph.D., professor, Department of Behavioral Science Ludmila Cofta-Woerpel, Ph.D., assistant professor, Department of Behavioral Science

Background

The e-Health Technology Research Resource is dedicated to the advancement of data collection and interactive interventions for research, patient care and professional, patient or public education using cutting-edge technology. The resource supports the development and implementation of multimedia intervention and data capture tools for cancer prevention and control research in the areas of behavior change, cancer symptoms management, quality of life issues, patient and professional education, and patient care. The availability of e-Health Technology as a resource serves to bring together colleagues from across MD Anderson with an interest in employing cutting-edge technology in their work.

e-Health Technology research services include:

- · Designing and maintaining web-based applications.
- Developing mobile applications, including applications for Ecological Momentary Assessment (EMA).
- Developing Content Management Systems.
- Designing SMS/MMS texting systems for interventions.
- Consulting on initial project and idea development.
- Faculty-to-faculty consulting for preliminary idea development.

Progress

e-Health Technology invested in strengthening the resource, both in terms of expertise as well as sustainability. During this past year, e-Health continued to focus on building its expertise and engaging in training opportunities. Efforts of e-Health supported its goal of having an extensive offering of programming and development capabilities across multiple platforms. Additionally, the resource developed enhanced expertise with complex project scopes. Key accomplishments during this past year include:

- 1. Received Cancer Center Support Grant (CCSG) designation as a Developing Shared Resource, the first Duncan Family Institute Research Resource to receive peer review funding.
- 2. Provided 33 consultations and submitted 15 service proposals in FY13.
- 3. Expanded capability to include native app and hybrid app development, real-time calorie counter, and exercise tracking tools for multiple platforms.
- 4. Developed expertise with social media software developer kits to connect customer websites with their corresponding Facebook pages for collection and storage of social media metrics.
- 5. Standardized Content Management System (CMS) for re-use and greater efficiency in future projects; purchased Zend Studio software suite, which provides cross-platform development capability through an extension of existing mobile device programming languages.
- 6. Coordinated collaboration between the Department of General Oncology, Institute for Personalized Cancer Therapy and an external vendor for eConsent user interface.
- 7. Disseminated information about e-Health to scientists across the campus through:
 - Cancer Prevention and Control Grand Rounds and Advances in Oncology Institutional Grand Rounds presentations by the Co-Directors.
 - Orthopedic Oncology, Epidemiology, Clinical Cancer Prevention, and Leukemia Department faculty meeting presentations, resulting in three new service proposals.

- Faculty Resource Fair exhibit, resulting in two new service proposals.
- External facing e-Health Technology website launched.
- 8. Advised institutional IT leadership on project approval process to include proposing process improvements to reduce the time to deployment for technology infrastructure for research projects, while maintaining data security and compliance with regulatory requirements.
- 9. Participated in conferences, training workshops, and other educational events related to e-Health to build the expertise of the resource technical team and staff.

Science Supported by the Resouce

The e-Health core resource contributed expertise to seven active projects (\$5.4 million total costs) and completed another four projects (\$4.5 million total costs) during FY13. In addition, it provided maintenance and support to five additional projects (\$3.2 million total cost). Sixteen projects (\$5.2 million total costs) have been submitted to the core requesting support in FY14. Below are selected examples of supported projects:

Educational website for bone health in cancer survivors

Maria A. Lopez-Olivo, M.D., Ph.D, instructor, General Internal Medicine (active)

- This study will help to increase awareness of the importance of bone health issues in cancer survivors. Patient education and strategies to improve patient's self-efficacy can help sustain healthy behaviors and ultimately improve outcomes.
- e-Health Contribution: Develop public facing website to display learning modules with assessments. Design a tracking tool for tailored messages and web usage for data collection and analysis.

eCookbook for pediatric patients and survivors

Joya Chandra, Ph.D., associate professor, Pediatrics (completed)

- The purpose of building this interactive website was to provide pediatric cancer patients and survivors with a resource that met their unique nutritional needs. The development of a collection of healthy recipes targeted toward pediatric cancer patients and survivor populations was an important preventive health measure that could be used as part of a nutritional/healthy living counseling-based intervention in future research studies.
- e-Health Contribution: Designed and developed user interface to support keyword searchable recipes (ingredients, type of food, etc.). Embedded interactive images, photos, and videos of cooking demonstrations for recipes. Inserted survey functionality to capture recipe rating and comments, chefs' bios as well as a link to their respective restaurants. Designed prototype of eCookbook mobile app.

Strategies to Increase Fitness (Xtend)

Raheem Paxton, Ph.D., assistant professor, Cancer Prevention and Population Sciences

- This study involves a randomized controlled trial of physical activity and sedentary behavior intervention in a racially and ethnically diverse sample of breast cancer survivors.
- e-Health Contribution: Design a website and database. Create tracking tools for participant goal setting. Install software, and provide training and support.

Future Plans

For FY14, e-Health will expand its collaborations and build capacity in several crucial areas. A high priority, driven by the need to keep pace with technology trends, is a focus on the development of new data collection and intervention tools. Specifically, e-Health plans to:

- 1. Expanding mobile application program capabilities to include:
 - Automating phone data acquisition and application upgrades.
 - Developing new Ecological Momentary Interventions (EMI) utilizing mobile app technology.
 - Integrating sensor technology.

- Supporting social media integration.
- Defining mobile app standards
- 2. Developing cross-platform multimedia graphic design competency.
- 3. Building e-Health app to include services and assessment vehicle for customer project needs.
- 4. Strengthening resource delivery capability by enhancing technical and management systems and staff training opportunities and continuing implementation of the marketing plan.

Mexican-American Cohort Study

Co-Directors:

Sara Strom, Ph.D., associate professor, Department of Epidemiology **Hua Zhao, Ph.D.,** associate professor, Department of Epidemiology

Background

Mexican Americans are an understudied population, yet comprise 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 Cohort (MAC), also known as The Mano a Mano Cohort Study, was launched in 2001 by the Department of Epidemiology at MD Anderson with resources from the Texas Tobacco Settlement fund, philanthropy, and later, from the Duncan Family Institute. To the best of our knowledge, this research forms the first longitudinal population-based cohort study of Mexican Americans (MAs). Through personal interviews, data are



collected on characteristics, such as, socio-demographics, lifestyle, acculturation, health, and family history of disease. Biological specimens are collected and banked for future use.

The goals of this resource are to:

- Understand cancer and other chronic diseases and their related risk and protective factors as they emerge in a population undergoing social changes.
- Utilize epidemiological, behavioral and genetic risk factors to develop cancer prevention strategies and reduce morbidity and mortality among Mexican Americans residing in the Houston area.
- Serve as an infrastructure to advance the mission of MD Anderson Cancer Center to eliminate cancer by supporting institutional and inter-institutional collaborations.

This unique resource provides interested investigators with a well-characterized population with data and biological specimens available to facilitate health-related research. In the future, studies integrating acculturation, socio-demographic and epidemiologic/behavioral information, along with biomarkers, will allow the identification of individuals at high risk of developing specific types of cancer and other chronic diseases. This will allow the development of tailored cancer prevention programs and their implementation.

Progress

As of June 30, 2012 there were 24,125 participants from 16,381 households enrolled in the MAC Study. During FY13, the MAC group focused on recruiting new patients and following-up with those already enrolled, implementing new data collection tools, community support, and enhancing the utility of the MAC database by linking it to the Texas Cancer Registry. More details are provided below for each of these focus areas.

Recruiting New Participants: During FY13, the MAC received approval from the Institutional Review Board of Harris Health System to begin recruiting new participants at three of the Harris Health Clinics and to obtain copies of medical records from participants who received medical care within the Harris Health System.

Follow-up of Study Participants: For participants enrolled as of 2012, the overall current follow-up rate (participants) pants contacted in the last 18 months) is 82%, representing more than 16,000 individuals for whom there is updated contact information. During this past year, the MAC group focused on increasing follow-up rates using new approaches, including a web-based search engine that uses real-time information to obtain new addresses and phone numbers, which resulted in an increase of over 900 households with current follow-up information (Figure 8).

Implementation of New Data Collection Tools: The MAC implemented a new baseline questionnaire during FY13, as well as launching an electronic wireless data collection system. This new configuration allows the interviewers to transmit data remotely from the field directly into the MAC database. The group enrolled 1284 study participants using this new method. In addition, the MAC implemented navigation forms and a cancer questionnaire. Participants who indicate they have had a cancer diagnosis are asked specific questions regarding their diagnosis, type, treatment, location of treatment, and/ or name of doctor. This information is collected in an electronic form and facilitates timely collection of a participant's medical records related to the cancer diagnosis.

Community Support: A community health worker from the MAC staff is available full-time to answer questions from the study participants and to provide information on available resources and how to access these. The community health worker also provides help in navigating the participants to cancer screenings and appointments at MD Anderson or other locations. MAC staff publishes an annual newsletter that contains health information, updates on the study status, and information on ongoing studies that could be of interest to MAC participants. In collaboration with outside nonprofit and private organizations, Cohort staff contribute holiday baskets and support for Cohort families in need.

Link to the Texas Cancer Registry: In order to verify cancer-related information collected from MAC participants, the MAC established a link between its database and the Texas Cancer Registry (TCR), which collects information on all cancer cases diagnosed in the state of Texas. Among 24,125 enrolled participants, 1,062 reported at baseline and/or follow-up having being diagnosed with cancer. A linkage of MAC participants' information with the TCR database identified 638 matches. Participants who self-reported cancers that were not available in the TCR are currently being contacted to obtain authorization to request copies of their medical records to verify diagnosis. Preliminary epidemiological analyses were also begun using SEER and TCR data.

Science Supported by the Resource

The MAC contributed to 13 submitted proposals (\$20.1 million total costs) and contributed samples and epidemiological expertise to five active studies during FY13 (\$2.6 million total costs). The MAC contribution to current studies is highlighted below:

Hypertension in Mexican Americans: assessing disparities in air pollutant risks

Elaine Symanski, Ph.D., assistant professor, Division of Epidemiology, Human Genetics and Environmental Science, University of Texas School of Public Health

The aim of this study is to test the hypothesis that individual- and neighborhood-level psychosocial stressors exacerbate risks for hypertension associated with air pollution among Mexican Americans. Several studies have shown an association between air pollutants and hypertension via oxidative stress and inflammatory pathways. Yet, little is known about the modifying effects of nonchemical stressors on air pollutant risks for hypertension.

MAC Contribution: MAC staff has identified focus group participants for the first part of this study and has developed pre-screening forms. The MAC is currently contacting potential participants to obtain their verbal consent for providing

Cohort Follow-up Summary

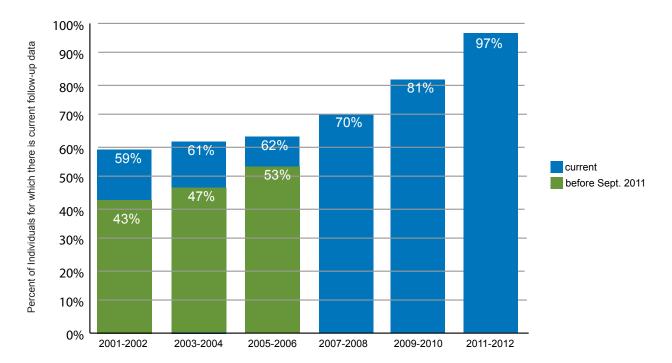


Figure 8. A summary of the Mexican-American Cohort follow-up efforts. The percent of individuals for which there is current follow-up data is shown by year of enrollment. The overall follow-up rate is approximately 82%, representing more than 16,000 individuals that have updated contact information.

their contact information to the coordinators of the pilot study. After the pilot is completed and data evaluated, the MAC staff will be responsible for conducting interviews for the next phase of the research.

Reducing cancer disparities among Latinos in Texas (research core)

David Wetter, Ph.D., chair, Health Disparities Research

- The study evaluates the efficacy of a theoretically- and empirically-based, culturally-tailored Motivation And Problem Solving (MAPS) intervention, conducted within a community-based participatory research (CBPR) framework for reducing cancer risk related to smoking, poor diet, and physical inactivity. High-risk Mexican-American individuals (i.e., smokers who are also overweight/obese; N = 400) will be recruited from the MAC or from the community, will be followed for a period of 18 months, and will be randomly assigned to one of two groups: Health Education (HE) or MAPS.
- MAC Contribution: The cohort staff has been providing support to Dr. Wetter's group by identifying and pre-screening potential participants.

Socio-demographic, acculturation, and psychosocial factors influence Mexican-Americans to provide biologic specimens for bio-banking in Houston, El Paso and Brownsville, TX

David Lopez, Dr.P.H., assistant professor, Division of Epidemiology, Human Genetics and Environmental Science, University of Texas School of Public Health

- The purpose of this research study is to investigate the factors that motivate Mexican Americans to participate in blood donation for biobanking. The information gained from this study is important because it may help to increase the participation of Mexican Americans in studies that require biobanking for cancer research.
- MAC Contribution: The cohort staff role is to identify and pre-screen potential participants.

Data Analysis related to physical activity from the Mexican American cohort study

Larkin Strong, Ph.D., M.P.H., assistant professor, Health Disparities Research (former Duncan Family Institute Fellow)

- Dr. Strong is analyzing data for longitudinal associations of physical activity, television viewing and BMI among adolescents from the Mexican American Cohort Study. The aim of this study is to identify the barriers and facilitators to healthy eating and physical activity. She is also analyzing data collected from the MAC members who were participants in the overweight smokers focus group. Both analyses will inform development of interventions to reduce obesity, a risk factor for cancer and other chronic diseases.
- MAC Contribution: The MAC staff provided the data for analysis and screened potential participants for the focus groups.

Acculturation and its association with tobacco use in the Mexican American cohort

Irene Tami-Maury, Dr.P.H., instructor, Behavioral Science

- Dr. Tami-Maury is currently analyzing data on acculturation and tobacco use among Mexican Americans to inform interventions to prevent initiation of smoking.
- **MAC Contribution:** The staff provided the data for analysis.

Student and Post-Doctoral Support: There are several post-doctoral trainees and graduate students who are working on data sets provided by the Mexican-American cohort. In addition to the data, the Cohort staff assisted with the writing and processing of IRB protocols and the use of large relational databases, which are important foundational skills for scientists to obtain early in their training.

Future Plans

In FY14, the MAC will:

- 1. Develop new research initiatives and continue/expand intra- and inter-institutional collaborations (e.g., continue planning a large P01 proposal to address environmental and genetic factors associated with energy balance).
- 2. Integrate results from the genetic admixture analysis into the cohort database.
- 3. Continue to expand participant accrual to replace those lost to follow-up, increase the accrual of men and older participants to the Cohort to better reflect the demographics of the Mexican-American population in the greater Houston Metropolitan area; and invite MD Anderson employees of Mexican origin to participate in the study.
- 4. Work with the Mexican-American community to develop health awareness programs for cancer and other relevant diseases.
- 5. Strengthen the Cohort infrastructure to include: streamlining the follow-up procedure using new technology and specialized staff and establishing management systems to recover costs from investigators accessing this resource.
- 6. Enhance the Cohort data by exploring feasibility of adding dietary assessments and adding occupational and industry data codes to participant records.
- 7. Seek input from the scientific and community advisory boards and reach out to scientists conducting studies of Mexican Americans in Texas, engaging them in a retreat or similar format to explore collaborative opportunities.

Publications — Study Results for Research Supported by the Mexican-American Cohort

- Strong LL, Anderson CB, Miranda PY, Bondy ML, Zhou R, Etzel C, Spitz M, Wilkinson AV. Gender differences in sociodemographic and behavioral influences of physical activity in Mexican-origin adolescents. J Phys Act Health, 9:829-39, 2012.
- 2. Palmquist AE, Wilkinson AV, Sandoval JM, Koehly LM. Age-related differences in biomedical and folk beliefs as causes for diabetes and heart disease among Mexican origin adults. J Immigr Minor Health 14:596-601, 2012.

- 3. Hernandez-Valero MA, Bustamante-Montes LP, Hernandez M, Halley-Castillo E, Wilkinson AV, Bondy ML, Olvera N. Higher risk for obesity among Mexican-American and Mexican immigrant children and adolescents than among peers in Mexico. J Immigr Minor Health. 14:517-22, 2012.
- 4. Wilkinson AV, Okeke NL, Springer AE, Stigler MH, Gabriel KP, Bondy ML, Prokhorov AV, Spitz MR. Experimenting with cigarettes and physical activity among Mexican origin youth: A cross sectional analysis of the interdependent associations among sensation seeking, acculturation, and gender. BMC Public Health. 12(1):332, 2012.
- 5. Ashida S, Wilkinson AV, Koehly LM. Encouragement from social network members and Intention to screen among Mexican origin Americans: A cross-generational perspective. Am J Prev Med (In press).
- 6. de Heer HD, Wilkinson AV, Strong LL, Bondy ML, Koehly LM. Sitting time and health outcomes among Mexican origin adults: obesity as a mediator, 2012 BMC Public Health 12:896, 2012.
- 7. Prokhorov AV, Hudmon KS, Marani SK, Bondy ML, Gatus LA, Spitz MR, Wilkinson AV, Hammond K, Koehly LM. Eliminating second-hand smoke from Mexican American households: outcomes from Project Clean Air-Safe Air (CASA). Addict Behav 38:1485-1492, 2012.
- 8. Wilkinson AV, Swartz M.D., Yu X, Spitz MR, Shete S. Cigarette experimentation and the population attributable fraction for associated genetic and non-genetic risk factors. Epub, 2013 (in press).
- 9. de la Haye K, de Heer HD, Wilkinson AV, Koehly LM. Predictors of parent-child relationships that support physical activity in Mexican-American families. J Behav Med, 2012. Epub.
- 10. Wilkinson AV, Gabriel KP, Wang J, Bondy ML, Dong Q, Wu X, Shete S, Spitz MR. Sensation-seeking genes and physical activity in youth. Genes Brain Behav 12 (2) 181-8, 2013.
- 11. Oluyomi AO, Whitehead LW, Burau KD, Symanski E, Kohl HW, Bondy M. Physical activity guideline in Mexican-Americans: Does the built environment play a role? J Immigr Minor Health. 2012 Oct 7. Epub.
- 12. Wilkinson AV, Vandewater EA, Carey FR and Spitz MR. Exposure to pro-tobacco messages and smoking status among Mexican origin youth. J Immigr Minor Health 2013 Apr 13. Epub.
- 13. Okeke NL, Spitz MR, Forman MR, Wilkinson AV. The associations of body image, anxiety and smoking among Mexican-origin youth. J Adolesc Health 2013 May 10. Epub.
- 14. Bangia, Komal. A cross-sectional analysis of the association between polycyclic aromatic hydrocarbons and diesel particulate matter exposures and hypertension among individuals of Mexican origin residing in Houston, TX. (January 1, 2011). Texas Medical Center Dissertations (not previously reported).

Center for Community-Engaged Translational Research

Co-Directors:

David Wetter, Ph.D., chair, Department of Health Disparities Research Lorna McNeill, Ph.D., M.P.H., associate professor, Department of Health Disparities Research

Background

The Center for Community-Engaged Translational Research (CCETR) was created in 2010 with support from the Duncan Family Institute. CCETR's mission is to bring communities and researchers together to create long-term solutions to prevent cancer and improve health. CCETR's overarching goals are to:

- 1. Facilitate research development and implementation between MD Anderson investigators and diverse communities.
- 2. Enhance the capacity of investigators to recruit and retain diverse patients to clinical studies.
- 3. Increase community capacity to engage in beneficial research through collaborative relationships with MD Anderson investigators.

CCETR offers researchers a broad range of services to accomplish these goals, including assistance with developing community-engaged research, identifying community research partners, facilitating research collaboration agreements with community partners, developing clinical trial recruitment plans for minorities and women, developing grant narratives for



study populations, 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 on minority and women clinical trial recruitment progress to studies at MD Anderson, helping researchers to ensure equitable access and participation in interventional clinical trials for all patients with cancer.

Progress

In its three years of operation, CCETR has demonstrated successful facilitation and leadership in community-academic research collaborations that advance cancer prevention, control and treatment in real-world public health and clinical practice settings. CCETR is supporting research that addresses multiple cancer risk behaviors, with projects aiming to expand smoking cessation treatment to underserved populations, promote physical activity in sedentary individuals, and encourage healthful eating and engagement in cancer screening behaviors. Key accomplishments in FY13 include:

- 1. Led MD Anderson's Patient Demographic Initiative (PDI).
- Prepared the Healthy Family Project proposal on tobacco and obesity for medically underserved Hispanics in Texas (one of three proposals submitted to the Development Office for funding).
- Assisted an MD Anderson investigative team on creating a dissemination plan for communicating the risks and benefits of contralateral prophylactic mastectomy for breast cancer patients and clinicians, which resulted in the awarding of a large grant.
- Increased the capacity of MD Anderson research teams to recruit and retain diverse patients to therapeutic clinical trials.

Science Supported by the Resource

CCETR has played an instrumental role in 25 submitted grants totalling over \$75 million over the past reporting year. CCETR staff provided administrative and scientific support as well as assumed responsibility for submission of three major research grants (two pending, one not funded), which totaled just over \$33 million.

- FDA Tobacco Centers of Regulatory Science (TCORS; P50) proposed a program of research that will address the impact of tobacco marketing at the point of sale on tobacco use behaviors among both young adults and adults with an emphasis on vulnerable populations.
- National Cancer Institute Program Project Grant (P01) proposed a program of research to increase the reach, efficacy, adoption, implementation, and sustainability of evidence-based tobacco cessation treatment, with a focus on community health centers.
- Investigator-Initiated Resource-Related Research Projects Applications (R24) proposed the use of a community-based participatory approach to expand the existing Project CHURCH partnership to engage additional Houston area churches and community-based organizations to develop ecological, multilevel community-wide strategies to address cancer-related health disparities.

In addition to these grants, four projects are highlighted for which CCETR played a prominent role:

Project CONNECT (CPRIT)

Jennifer Irvin Vidrine, Ph.D., associate professor, Health Disparities Research

- This study aims to increase dissemination of the state smoking Quitline among medically underserved and racially/
 ethnically diverse smokers, a population with limited access to smoking cessation resources using an enhanced dissemination approach (Ask-Advise-Connect (AAC)). Harris Health system is the community partner. This project extends
 previous successful Quitline dissemination projects in diverse clinic settings.
- CCETR Contribution: CCETR has been involved with AAC since its inception. AAC was first developed and tested in 10 Harris Health system clinics. Subsequent funding allowed expansion of AAC to 10 Kelsey-Seybold clinics and the Good Neighbor Health Center (a Federally Qualified Health Center). These projects have demonstrated the program's ability to significantly increase smoking cessation treatment uptake, leading the investigators to seek funding for statewide dissemination of AAC with an emphasis on low resource clinic settings (i.e., P01 grant application listed above). CCETR facilitated the relationship with Harris Health system, assists with budget development and justification, grant submission, contract negotiation with the smoking cessation treatment provider, IRB submission, and development of training for Harris Health personnel involved in recruitment and education of patients.

Reducing tobacco related health disparities (Project Health) (NCI R0I)

David Wetter, Ph.D., chair, Health Disparities Research

- Project Health evaluates the efficacy of a theoretically and empirically-based "Motivation and Problem Solving"
 (MAPS) intervention and proactive provision of nicotine replacement therapy (NRT) for promoting and facilitating
 smoking cessation among low income smokers who are not ready to quit. Harris Health System is the community partner. Project Health has recruited 2878 potential participants, enrolled 603 participants and has randomized 401
 individuals to the counseling intervention (goal: n= 600).
- CCETR Contribution: CCETR's established relationship with Harris Health System facilitated the development and
 implementation of this study. CCETR assists with recruitment from the clinics, design of the recruitment materials,
 submission of progress reports, IRB reporting, and payment and contract negotiations with Harris Health. In addition,
 CCETR's informatics analyst has provided information technology expertise, including Questionnaire Development
 System (QDS) software management, database management, and the creation of participant status and follow-up
 reports.

Reducing cancer disparities among Latinos in Texas (CNPC) (NCI U54)

David Wetter, Ph.D., chair, Health Disparities Research **Lovell Jones, Ph.D,** professor emeritus, Health Disparities Research

Maria Fernandez, Ph.D., associate professor, Health Promotion and Behavioral Sciences, University of Texas School of Public Health

- The goal of the Texas regional Community Networks Program Center, Latinos Contra El Cancer, is to reduce cancer-related health disparities among Latinos in three regions in Texas (Houston, El Paso, Lower Rio Grande Valley). Key accomplishments/activities of the last year include the publication of research results including eight articles in peer-reviewed journals, three poster presentations at the CNPC meeting, and initiation of a research study "Motivation and Problem Solving Intervention for Spanish Speaking Mexican Americans", which began recruiting participants. In addition, mini grants (\$8,000 each) were awarded to five community-based organizations to deliver cancer control programs.
- *CCETR contribution:* CCETR supported the work of the administrative core of this project to manage communications among all cores and to lead research teams on progress toward research aims including study launch and publications. Major activities included communications and meetings with the Houston Community Advisory Group; the monthly trainee seminar series on CBPR and health disparities research; the NCI Site Visit and Steering Committee meeting; and review and selection of the mini grants.

African American cancer prevention project and Project **CHURCH**

Lorna McNeill, Ph.D., M.P.H., associate professor, Health Disparities Research

• Project CHURCH is an ongoing prospective, longitudinal, community based cohort study designed to investigate the role of behavioral, social, environmental and genetic factors on health and cancer-related disparities among African Americans in Houston. Windsor Village United Methodist Church is the original community partner, with a community advisory board and 1,501 participants in the study. Project CHURCH, now in its fourth year, has expanded to include



two additional churches (Cross Roads Community Church and New Faith Church) to increase the sample to approximately 2500 participants. Within the reporting year, major accomplishments include maintaining high retention rates (90% or higher), five publications describing results of studies conducted in the Project CHURCH setting and seven submitted grants (1 funded).

CCETR Contribution: CCETR assisted with various tasks for Project CHURCH, including leading recruitment of the newest church to join the cohort. In addition, CCETR facilitates the Community Advisory Board meetings, coordinates cancer prevention programming for the churches and surrounding communities, and has worked collaboratively to implement programs on smoking cessation, physical activity, healthy eating and survivorship. CCETR's resources have also been used to provide database design support, lead database synchronization efforts between sites, provide onsite data quality monitoring, and create reports. Finally, CCETR has developed training programs for faith leaders, to ensure sustainability of cancer risk reduction programs in the church settings.

Future Plans

Plans to strengthen CCETR

CCETR plans to develop expertise in conducting qualitative research so that service offerings can be expanded. CCETR's research scientist will attend the 10th Annual Qualitative Research Summer Intensive workshop at University of North Carolina-Chapel Hill for coursework in qualitative grant writing and varied data analytic methods. In addition, CCETR has added staff with expertise in Global Positioning Systems/Geographic Information Systems (GPS/GIS) so that GPS/GIS data analysis and management services can be offered to researchers. Finally, CCETR staff will continue to attend conferences and network with similar Community-Academic Resource Centers.

Future Projects

Plans for FY14 include:

- Partnering with the MD Anderson/University of Texas Health Science Center Clinical and Translational Science Award (CTSA) Community-Engaged Research Unit, specifically through the establishment of a Clinical Research Unit at Harris Health's LBJ Hospital, which is serviced by MD Anderson faculty.
- Continuing engagement with the Community Clinical Oncology Program (CCOP), including support for the program's transition to the National Cancer Institute Community Oncology Research Program (NCORP).
- Seeking extramural funds through opportunities such as the NIH/NICHD R13 Academic-Community Partnership Conference Series, NIDA Research "Center of Excellence" Grant Program (P50), and resubmission of a National Cancer Institute Program Project Grant (P01).

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- 12. Vidrine JI, Shete S, Li Y, Cao Y, Alford MH, Galindo-Talton M, Rabius V, Sharp B, Harmonson P, Zbikowski SM, Miles L, Wetter DW. *Ask Advise Connect: A New Approach to Link Smokers in a Safety Net* Healthcare System with Treatment. (Revise & Resubmit).
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Clinical Cancer Prevention Research Core

Co-Directors:

Powel Brown, M.D., Ph.D., chair, Department of Clinical Cancer Prevention

Therese Bevers, M.D., professor, Clinical Cancer Prevention; medical director, Cancer Prevention Center

Background

The Clinical Cancer Prevention Research Core (CCPRC) was established to provide an infrastructure for prevention research conducted within the Department of Clinical Cancer Prevention (CCP) and through collaboration within the

institution supporting a goal to establish and conduct the highest quality collaborative translational and clinical research investigating risk assessment, risk reduction interventions, cancer risk and early detection markers, and cancer screening.

CCPRC serves the dual purpose of supporting the chemoprevention protocols conducted in collaboration with Clinical Cancer Prevention faculty through the CCPRC Clinical Trials Support component as well as the High Risk Breast Cancer Cohort and Biorepository. The High Risk Breast Cancer Cohort is a subset of cancer-free patients at high-risk of developing invasive breast cancer who participate in the Clinical Cancer Prevention Biorepository.

Progress

Clinical Trials Support Component

In an environment of declining federal funding for clinical research, the CCPRC Clinical Trials Support group has become essential to the success and existence of new prevention research initiatives. Accomplishing the plans stated in the previous year's report, CCPRC staff opened three new prevention protocols during this reporting period while continuing to actively support ongoing clinical trials. During FY13, the CCPRC Clinical Trials Support group provided research infrastructure for:

- Protocol submission
- Planning, activation and initiation of studies
- Participant screening, recruitment, enrollment, and management
- Protocol-specific data management
- Audit preparation and response

Protocols supported by the CCPRC Clinical Trials Support group represent National Cancer Institute (NCI) multicenter chemoprevention trials and innovative investigator initiated protocols. The types of protocols range from laboratory to clinical trials (currently Phase II).

Table 2. Description of High Risk Breast Cancer Cohort		
	Number of Participants (Total number = 1021)	Baseline Tissue Available at MD Anderson
Ductal Carcinoma In Situ	219 (21%)	183 (84%)
Lobular Carcinoma In Situ	49 (5%)	29 (59%)
Proliferative Disease	224 (22%)	138 (62%)
Elevated Risk*	521 (51%)	
BRCA1/2	7 (<1%)	
Mantle Radiation	2 (<1%)	

^{*}Defined as ≥ 1.66% 5 year risk or ≥ 20% lifetime risk

High Risk Breast Cancer Cohort and Biorepository

The development of the High Risk Breast Cancer Cohort database was completed in early FY13. The database provides participant and specimen tracking along with data capture and retrieval; therefore, the major objective for this past year was to enter and verify collected epidemiologic and clinical outcome data. This objective has been met while diligently maintaining a balance between follow-up appointments, new subject recruitment and data quality. Although the High Risk Breast Cancer Cohort remains in its infancy, descriptive data can be compiled for interested researchers planning epidemiologic and descriptive studies. To date, more than 1000 high-risk individuals have been enrolled into the High Risk Breast Cancer Cohort (Table 2).

Science Supported by the Resource

Clinical Trial Support component

CCPRC provides pre-funding support or additional funding for underfunded research protocols. The Clinical Trials Support group includes research nurses, data coordinators and a statistical analyst to provide varying levels of research

infrastructure that would otherwise not be available. CCPRC staff opened three new prevention protocols during this reporting period. Access to staff is determined by the Clinical Cancer Prevention Research Core Steering Committee. Active projects that received support in varying degrees from the CCPRC Clinical Trials Support group during FY13 include:

Neoadjuvant trial of Lapatinib for the treatment of women with DCIS breast cancer (LAPIS)

Powel Brown, M.D., Ph.D., (PI), professor and chair, Clinical Cancer Prevention **Henry Kuerer, M.D., Ph.D.,** (Co-PI), professor, Surgical Oncology

LAPIS is a multi-institutional project, funded by the Breast Cancer Research Foundation. It is a two-arm, randomized, double-blinded, placebo-controlled biomarker modulation trial of lapatinib. The primary goal is to compare the effect of women taking lapatinib at 1000 mg for 2-6 weeks as compared to women taking placebo to determine whether lapatinib therapy substantially reduces proliferation of DCIS breast cancer cells in patients who are have positive biomarker EGFR or Her2 Neu testing. The results of this clinical trial will provide critical information to develop tyrosine kinase inhibitors as agents for the treatment and prevention of women with breast cancer in future clinical trials.

CCPRC Clinical Trials Support Group Contribution: The CCPCRC supported the intensive screening process required to enroll study participants within a limited timeframe with stringent eligibility criteria. The CCPRC has supported the registration of 27 patients with 4 eligible patients randomized.

Double blind placebo-controlled trial of effornithine and sulindac to prevent recurrence of high risk adenomas and second primary colorectal cancers in patients with stage 0-III colon cancer, phase III

Elise Cook, M.D., (PI), associate professor, Clinical Cancer Prevention George Chang, M.D., (Co-PI), associate professor, Surgical Oncology Imad Shureiqi, M.D., (Collaborator), associate professor, Gastrointestinal Medical Oncology

This cooperative group project, sponsored by the Southwest Oncology Group, is a four-arm evaluation to assess whether effornithine, sulindac, or the combination are effective in increasing the three-year survival rate in patients with previously treated Stage 0-Stage III colon cancer. Primary endpoints for this trial will be the occurrence of high-risk adenomas and second primary colorectal cancers.

CCPRC Clinical Trials Support group Contribution: Newly open to patient accrual in April 2013, this protocol has been under development for several months. During this reporting period, CCPRC provided support for regulatory and financial ground work required prior to protocol activation. An extensive pre-activation amendment was submitted during this reporting period. MDACC investigators and collaborators have conducted protocol planning and initiation meetings focused on participant accrual and management. A comprehensive tracking of colon cancer patients has been maintained to provide a resource for potential participants. This study also includes optional pharmacokinetic sampling.

Discovering new targets for chemoprevention in hereditary colorectal cancer syndromes;

Eduardo Vilar-Sanchez, M.D., (PI), assistant professor, Clinical Cancer Prevention Patrick Lynch, M.D., (Co-PI), professor, Gastroenterology, Hepatology and Nutrition Miguel Rodriguez-Bigas, M.D., (Collaborator), professor, Surgical Oncology Y Nancy You, M.D., (Collaborator), assistant professor, Surgical Oncology Melissa Taggart, M.D., (Collaborator), assistant professor, Pathology

This investigator-initiated protocol seeks to study the genomic and epigenetic profile of adenomatous polyps and normal mucosa in patients diagnosed with Hereditary Colorectal Cancer Syndromes. The overarching goal of this proposal is to identify new targets that are amenable to drug intervention.

CCPRC Clinical Trials Support group Contribution: During FY13, the CCPRC staff submitted the protocol for approval and activation. The staff actively participated in the planning protocol logistics, including participant identification, specimen collection and tracking, staff training, and data retrieval management. This protocol is an excellent example of interdepartmental collaboration between the Departments of Clinical Cancer Prevention, Gastroenterology, Hepatology and Nutrition, Surgical Oncology, and Pathology. Activated in March 2013, three patients have been registered to this protocol thus far.

A multicenter phase II study of docosahexaenoic acid (DHA) in triple-negative breast cancer (TNBC) survivors

Powel Brown, M.D., Ph.D., (PI), chair, Clinical Cancer Prevention Elise Cook, M.D., (Co-PI), associate professor, Clinical Cancer Prevention Banu Arun, M.D., (Collaborator), professor, Breast Medical Oncology.

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) administered for 24 weeks at 1000mg twice daily as compared to placebo reduces normal breast tissue levels of inflammatory biomarkers in overweight triple negative breast cancer survivors. Previous studies demonstrate subclinical breast inflammation can increase the risk of breast cancer. The severity of breast inflammation correlates to a woman's body mass index. Therefore, this study is being conducted only in women with a body mass index greater than or equal to 25.

CCPRC Clinical Trials Support group Contribution: During this reporting period, the CCPRC researchers have laid steps toward recruitment by presenting the protocol to the clinical providers in the Cancer Prevention Center. In collaboration with Breast Medical Oncology, a database search has yielded a list of more than 1,700 MD Anderson patients with a history of TNBC to identify potential participants providing a resource for recruitment. Identified as a high priority cancer by the MD Anderson Breast and Ovarian Moon Shots program, the DHA study aligns with institutional priorities in developing new understanding and risk reduction strategies for TNBC.

High Risk Breast Cancer Cohort and Biorepository

The High Risk Breast Cancer Cohort and Biorespository is 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. Participants enrolled in the cohort are women seen in the Cancer Prevention Center who have a diagnosis of proliferative breast disease (atypical ductal hyperplasia or atypical lobular hyperplasia), lobular carcinoma in situ, ductal carcinoma in situ, or who are at elevated risk of developing breast cancer ($\geq 1.66\%$ 5 year risk or $\geq 20\%$ lifetime risk) or known deleterious mutation in BRCA1 or BRCA2. The High Risk Breast Cancer Cohort and Biorepository will provide a ready-access resource for both institutional and outside researchers interested in the investigation of biomarkers and lifestyle risk factors that can be used to predict risk of invasive breast cancer. Access to the archived biologic material and data will require a protocol approved by the MD Anderson IRB and approval by an oversight committee. In addition to the distribution of eligibility, Table 2 shows the percentage of participants with tissue available at the institution. A majority of participants are individuals with elevated risk (51%) followed by those with diagnoses of DCIS (21%) and Proliferative Disease (22%). A priority for future recruitment is individuals with proliferative breast disease and elevated lifetime risk.

Future Plans

In FY14, the CCPRC plans to:

- Increase utilization of the High Risk Breast Cohort and Biorepository through the conduct of the following planned epidemiological studies:
 - o "Molecular profiling of DCIS/ADH lesions for breast cancer risk stratification": Powel Brown, M.D., Ph.D. (PI), Abenaa Brewster, M.D., Clinical Cancer Prevention; Amy Zhang, M.D., Miriam Rogers Fund.
 - o "Characterize the epidemiological and demographic characteristics of the cohort participants and describe the use of chemoprevention among high risk patients with ADH": Abenaa Brewster, M.D. (PI), Clinical Cancer Prevention; Powel Brown, M.D., Ph.D., Clinical Cancer Prevention; Therese B. Bevers, M.D., Clinical Cancer Prevention. IRB submission pending.
 - o "Association of Breast Stem Cells with High-Risk Lesions and Epidemiology Factors": Abenaa Brewster, M.D. (PI), Clinical Cancer Prevention and Rachel Adkinson, Ph.D., Postdoctoral fellow.
- Promote availability of the CCPRC and Cancer Prevention Center (CPC) to site-specific Moon Shot Program teams.
- Identify other future resources to further leverage Duncan Family Institute Funding for the CCPRC.
- Issue a Request for Information on behalf of the High Risk Breast Cancer Cohort to potential researchers within the

institution describing the resource and outlining the application process for utilization.

- Increase utilization of CCPRC Clinical Trials Support statistical resource through the following studies:
 - o "Role of genetic counseling in managing microsatellite-low colorectal cancers". Eduardo Vilar Sanchez, M.D., Ph.D. (PI), Clinical Cancer Prevention.
 - o "Analysis of ADH data from the clinical management conference of benign breast lesions" Therese Bevers, M.D. (PI), Clinical Cancer Prevention.



The Duncan Family Institute invests in the next generation of cancer prevention researchers through its Mentored Junior Faculty Fellowship. These 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.

Mentored Junior Faculty Fellowship

We are pleased to report that Diana Stewart, Ph.D., instructor in Health Disparities Research, is this year's fellowship recipient. Previously supported fellows have advanced to tenure track positions or are established in the early phase of their

careers. Their progress is reported here as well.



Reducing Tobacco-Related Cancer Disparities in the Underserved Diana Stewart, Ph.D., instructor, Department of Health Disparities Research

Dr. Stewart's research focuses primarily on promoting health behavior change, particularly smoking cessation, to eliminate cancer-related health disparities in underserved populations. She has a specific interest in gaining a better understanding of tobacco use and cessation in low socioeconomic racial and ethnic minority populations by studying the impact of factors such as health literacy, social support, and depression on smoking cessation outcomes in underserved smokers. Her research is translational in nature, as she seeks to use this knowledge to develop and test interventions for smokers with low health literacy and to ultimately implement and disseminate these interventions in the real world to reduce tobacco-related cancer disparities.

Dr. Stewart's fellowship work will focus on evaluating a conceptual mediation model throughout the process of quitting using data from three large cessation trials with low-socioeconomic, racially/ethnically diverse samples. The conceptual mediation model posits that the level of an individual's health literacy is related to smoking cessation outcomes through mechanisms possibly involving depression and social support. The significance of this research is that it will be the first to investigate mechanisms of health literacy and cessation.

Dr. Stewart was recently honored with the FY13 Postdoctoral Outstanding Trainee in Cancer Prevention award.

Progress of Previously Funded Fellows



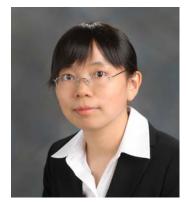
Claire Adams, Ph.D., instructor, Department of Health Disparities Research

Dr. Claire Adams was an FY12 Mentored Junior Faculty Fellow. The title of her fellowship project was "Mindfulness-based strategies for improving cancer risk behaviors." We are pleased to report that Dr. Adams recently accepted an Assistant Professor faculty position at the Catholic University of America. Her research seeks to inform behavioral interventions to reduce unhealthy behaviors (i.e., smoking, at-risk alcohol use, and unhealthy eating) linked to cancer risk and cancer-related mortality. Such research may eventually help to identify shared mechanisms and causal pathways underlying effects of mindfulness on health behaviors relevant to cancer prevention.



Meng Chen, Ph.D., instructor, Department of Epidemiology

Dr. Meng Chen was an FY12 Mentored Junior Faculty Fellow. The title of her fellowship project was "Identification of pathway associated with bladder cancer risk using gene set enrichment analysis". Dr. Chen is in the process of publishing the results from this study and applying for additional early career support. She recently accepted a highly competitive (1 of 42 applicants) twoyear fellowship in laboratory medicine at MD Anderson that will complement the epidemiological and statistical training she received as part of her DFI fellowship. At the end of this training, she plans to seek an independent career that combines clinical service and consultation, education, research, and laboratory management in an academic medical center.



Jian Wang, Ph.D., instructor, Department of Biostatistics

Dr. Jian Wang was a FY12 Mentored Junior Faculty Fellow. Her fellowship project was entitled "Risk modeling using mediation analysis and Bayesian Network Recovery with application to smoking cessation study". Dr. Wang has published numerous papers on her work and is in the process of publishing additional results from her fellowship project. She has been highly productive, with six first author publications during her fellowship, unusually productive for someone junior in her field. She is currently applying for tenure-track assistant professorship positions while continuing her research at MD Anderson.

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 Research Training Program Grand Rounds lecture series.

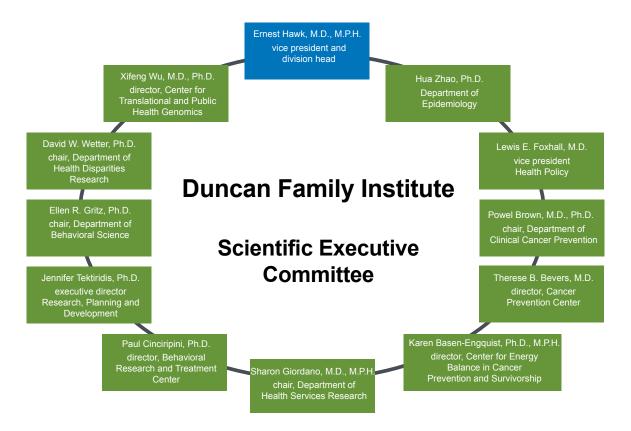
Topics of the DFI-supported seminars addressed a range of real-world issues relevant to cancer prevention by internationally renowned experts. The six lectures in FY13 were:

- "Highlights from the Health of Houston 2010 Survey" by Stephen Linder, Ph.D., UT School of Public Health Institute for Health Policy and McGovern Center for Humanities and Ethics, The UT Health Science Center at Houston
- "Cancer Prevention and Early Detection: Time for a New **Synthesis**" by Brian Reid, M.D., Ph.D., Full Member, Divisions of Human Biology and Public Health Sciences, Fred Hutchinson Cancer Research Center; professor of Medicine, adjunct professor of Genome Sciences, University of Washington; PI, Seattle Barrett's Esophagus Center
- "Interactive Health Communications Interventions for Cancer **Prevention**" by Vic Strecher, Ph.D., M.P.H., professor and director for Innovation and Social Entrepreneurship, University of Michigan School of Public Health



- "Cancer Prevention and Control Outreach with Hispanics" by Elmer Huerta, M.D., M.P.H., director, Cancer Preventorium, Washington Cancer Institute, MedStar, Washington Hospital Center
- "INFORMED melanoma early detection: Check It Out" by Martin A. Weinstock, M.D., Ph.D., professor of Dermatology and Epidemiology, Brown University
- "eHealth science: CTRL-ALT-DEL" by Gary Bennett, Ph.D., associate professor of Psychology, Global Health and Medicine, Duke University

Scientific Leaders



In FY13, the Duncan Family Institute focused on continuing to make investments in research and infrastucture, sustaining programs and reviewing progress to ensure the excellence of the Institute's work and to maximize the productivity of the Institute's investments.

The Insititute experienced two leadership changes in FY13 with the launch of the department of Health Services Research, Sharon Giordano, M.D., M.P.H., joined the Duncan Family Institute Scientific Executive Committee (EC). Lovell Jones, Ph.D., professor emeritus, retired this past year and will no longer be serving on the EC. We wish him all the best in his retirement.

Finally, the EC expanded its scope by linking the Institute's work more directly to real-world settings through its engagement with the Moon Shots Cancer Prevention and Control Platform. The Platform seeks to develop and deliver comprehensive evidence-based strategies in prevention, screening, early detection, and survivorship to achieve a measurable reduction in the cancer burden, especially among the underserved. Association with MD Anderson's cancer control mission leadership and infrastructure provides a pathway to accelerate translation of discovery and practice from the lab and clinic to the community, with the potential for the greatest impact.

Ernest Hawk. M.D., M.P.H.

Ernest T. Hawk, M.D., M.P.H., is vice president and head of the Division of Cancer Prevention and Population Sciences at the University of Texas MD Anderson Cancer Center and holds the Boone Pickens Distinguished Chair for Early Prevention of Cancer. Prior to his appointment at MD Anderson in December 2007, Dr. Hawk held several positions at the National Cancer Institute (NCI) in Bethesda, MD, most recently director of the Office of Centers, Training and Resources.

Dr. Hawk leads one of the largest and most developed programs dedicated to cancer prevention in the nation. With nearly 500 full-time employees, over 80 faculty and 200 trainees, the work of the division focuses the identification of factors that contribute to the risk, incidence and mortality of cancer as well as mitigation of their effects through laboratory, clinical and population research; provision of clinical screening and preventive services; education of trainees, patients, health care professionals and the public; and cancer control efforts.



He is the executive leader of the Duncan Family Institute. Additionally, he is a member of the Cancer Center Support Grant Executive Committee and provides strategic and tactical direction to the center's work in cancer prevention research, education, and clinical services; with Dr. Lewis Foxhall he co-leads the institution's Comprehensive Cancer Control Program with the aim of employing a community-based, integrated, coordinated, prioritized and rigorous strategic approach to deliver a measurable impact on the cancer burden in the Houston metro area over a 10-year period and serves on numerous intramural and extramural committees.

Dr. Hawk has been involved in a wide range of preclinical and clinical chemoprevention research, including studies of nonsteroidal anti-inflammatory drugs, COX-2 inhibitors, and agent combinations in high-risk cohorts. In addition, he is interested in improving the participation of minority and underserved populations in clinical research, and in the integration of risk assessment, behavioral science, and preventive strategies in clinical trials.

He has published more than 140 articles, abstracts and book chapters, is the senior deputy editor for Cancer Prevention Research, serves on the editorial board of Cancer Medicine, and an ad hoc reviewer for numerous peer-reviewed journals, including JNCI, NEJM, Lancet and Lancet Oncology. He has earned numerous awards for his work, including the NCI Research Award for Distinguished Achievement in Cancer Prevention.

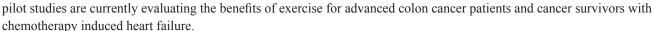
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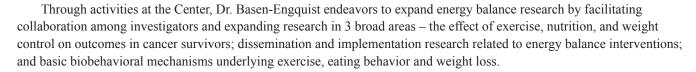
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Karen Basen-Engquist, Ph.D.

Karen Basen-Engquist, Ph.D., M.P.H., is a professor of Behavioral Science and the director of the Center for Energy Balance in Cancer Prevention and Survivorship at The University of Texas M. D. Anderson Cancer Center. Dr. Basen-Engquist's research focuses on cancer survivors and the role of health behavior interventions in decreasing the severity of late effects, improving physical functioning, optimizing quality of life and reducing risk of chronic diseases. In addition, she studies intervention methods for behavior change and innovative real-time methods for assessing symptoms and behavior in cancer patients and survivors.

Dr. Basen-Engquist recently completed an R01 study funded by the National Cancer Institute (NCI) to investigate the mechanisms of exercise adoption and maintenance in endometrial cancer survivors, using a social cognitive theory model that tests the social, physiological and behavioral predictors of exercise adherence. Additionally, 2 NCI-funded







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Therese B. Bevers, M.D.

Therese B. Bevers, M.D., is professor of Clinical Cancer Prevention and the medical director of the Cancer Prevention Center and prevention outreach programs at MD Anderson Cancer Center.

In her role as medical director, Dr. Bevers has overseen the growth and program development of the Cancer Prevention Center—the first comprehensive clinical cancer prevention service program in the country—since its opening in 1996.

Her clinical and research interests are in the area of breast cancer prevention, screening, diagnosis and survivorship. She was the MD Anderson co-principal investigator (PI) on the groundbreaking Breast Cancer Prevention Trial which demonstrated that tamoxifen reduced the risk of developing breast cancer by one half and the PI on the STAR trial which showed that raloxifene had similar benefits but fewer risks. She was the principal investigator at



MD Anderson for a study investigating whether polyphenon E, an active substance of green tea, benefits women at increased risk for breast cancer. She is currently investigating the potential role of Vitamin D in breast cancer prevention. Dr. Bevers chairs the National Comprehensive Cancer Network's guideline panels on Breast Cancer Screening and Diagnosis and Breast Cancer Risk Reduction.

She is the recipient of many awards including the Julie and Ben Rogers Award for Excellence in Prevention in 2006, the Kathryn S. Stream Award for Excellence in Women's Health in 2011 and the Faculty Achievement Award in Prevention in 2011.

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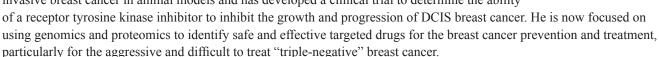
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Powel Brown, M.D., Ph.D.

Powel H. Brown, M.D., Ph.D., is a professor of Medicine and breast medical oncologist and chair in the Department of Clinical Cancer Prevention at The University of Texas MD Anderson Cancer Center.

Dr. Brown has been caring for women with breast cancer for over 25 years and has focused his research on identifying critical signaling pathways in breast cancers that might be targeted for the prevention and treatment of breast cancer.

Dr. Brown has demonstrated that drugs related to vitamin A prevent ER-negative breast cancer in animal models and has conducted a human clinical trial testing the synthetic Vitamin A analog bexarotene for its ability to prevent cancer in women at high risk of breast cancer. He has also demonstrated that signal transduction inhibitors suppress the progression of noninvasive breast cancer in animal models and has developed a clinical trial to determine the ability



Dr. Brown earned his bachelor's degree at the University of North Carolina and his medical degree and Ph.D. from New York University. He completed an internal medicine internship and residency at Duke University, a medical oncology clinical fellowship at the National Cancer Institute (NCI) and a Research Fellowship, at the Navy Medical Oncology Branch, National Cancer Institute. Prior to his appointment at MD Anderson in September, 2009, Dr. Brown was the associate director for cancer prevention at the Dan L. Duncan Cancer Center at Baylor College of Medicine.

Clinical Trials:

- Principal investigator for the LAPIS DCIS breast cancer trial testing the dual kinase inhibitor lapatinib in women with HER-2 positive DCIS breast cancer
- Principal investigator for a colon cancer prevention trial through the SWOG cooperative group (S0820)
- Co-principal investigator for DHA breast chemoprevention trial

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Paul Cinciripini, Ph.D.

Paul M. Cinciripini, Ph.D., is professor and deputy chair of the Department of Behavioral Science, and director of the Tobacco Treatment Program, at the University of Texas MD Anderson Cancer Center. He has over 30 years' experience conducting basic and clinical research in the area of smoking cessation and nicotine psychopharmacology.

Dr. Cinciripini's major research areas have included:

- Studies developing novel behavioral and pharmacological treatments for nicotine dependence
- Studies of nicotine titration and compensation
- Psychophysiological effects of nicotine during stress
- Individual differences in the effects of nicotine on EEG and cardiovascular activity
- Genetic factors treatment outcome
- Pharmacogenetic effects of antidepressants during smoking cessation
- Recent studies using startle probe and EEG/ERP methodology to examine the relations between genetics, emotional reactivity, nicotine exposure and nicotine withdrawal
- Studies of the effects of depression, coping behavior and self-efficacy as well as genetic factors related to nicotine dependence and in response to both behavioral and pharmacological interventions

In addition to his sponsored research Dr. Cinciripini also serves as the director of a large clinical service — the Tobacco Treatment Program, which offers in-person behavioral counseling and tobacco-cessation pharmacological treatment to all MD Anderson patients and employees.

Dr. Cinciripini has been the recipient of several NIH, extramural and industry sponsored research grants and is the author of over 165 articles and book chapters. Dr. Cinciripini is currently the PI/site PI on 4 NIH sponsored clinical trials, 2 subcontracts and other sponsored research evaluating smoking cessation medications, treatment of psychiatric co-morbid disorders, pharmacogenetics, and differences between smokers and nonsmokers in specific brain area associated with reward sensitivity, neural modulation of craving, and attentional bias. Over the last 10 years, Dr. Cinciripini has served as the PI, for 18 clinical trials, both NIH and industry sponsored, and he has participated as Co-Investigator in an additional 13 clinical trials for smoking cessation as well as studies of behavioral and neuropsychopharmacology of nicotine.

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- 4. Versace F, Lam CY, Engelmann JM, Robinson JD, Minnix JA, Brown VL, Cinciripini PM. Beyond cue reactivity: blunted brain responses to pleasant stimuli predict long-term smoking abstinence. Addict Biol 17(6):991-1000, 11/2012. e-Pub 10/2011.
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- 8. Blalock JA, Minnix JA, Mathew AR, Wetter DW, McCullough Jr JP, Cinciripini PM. *Relationship of childhood trauma to depression and smoking outcomes in pregnant smokers.* J Consult Clin Psychol 81(5):821-830, 10/2013. e-Pub 6/2013.
- 9. Versace FV, Engelmann JM, Cinciripini PM, Robinson JD, Jackson E, Green C, Lam C, Minnix JA, Karam MH, Brown V, Wetter DW. *Pre-quit fMRI Responses to Pleasant and Cigarette Cues Predict Smoking Cessation Outcome. Nicotine and Tobacco Research.* In Press.
- 10. Robinson JD, Engelmann JM, Cui Y, Versace F, Waters AJ, Gilbert DG, Gritz ER, Cinciripini PM. *The effects of nicotine dose expectancy and motivationally relevant distracters on vigilance. Psychology of Addictive Behaviors.* In Press.



Lewis E. Foxhall, M.D.

Lewis E. Foxhall, M.D. is MD Anderson's vice president for health policy and professor in the Department of Clinical Cancer Prevention. His work focuses on community-based cancer prevention and early detection, access and quality of care for low-income populations. He received his medical degree from Baylor College of Medicine and his clinical background is in family medicine.

Dr. Foxhall is responsible for coordination of MD Anderson's charity care program as well as administrative coordination of the MD Anderson/Harris County Hospital District oncology program. He is board member and founding chair of the Harris County Healthcare Alliance, an umbrella organization for safety-net medical provider organizations in Houston and Harris County.

He currently co-leads the Institution's comprehensive cancer control program and is a member of the Cancer Prevention and Control Moonshot Platform leadership team. He directs the institution's cancer survivorship efforts in policy outreach and education. He led efforts to secure and coordinates community cancer prevention and control programs through the Texas Medicaid Waiver. He supported an effort to update the Texas Cancer Plan and served as chair of the Texas Comprehensive Cancer Control Coalition. He is director of the Texas Cancer Information website project and chaired the Texas Medical Association's Physician Oncology Education Program. He is serving his second term on the Texas Department of State Health Services Advisory Council.

Dr. Foxhall supports policy development and outreach programs in collaboration with government agencies, voluntary health organizations and organized medical groups, including:

- Liaison to community physicians and is medical director of the Office of Physician Relations
- Past-president of the Harris County Medical Society
- Member of the Board of Trustees of the Texas Medical Association
- Officer of the Texas Medical Center Library, JP McGovern Museum of Medical Science and the American Cancer Society High Plains Division

Awards:

- St. George National Award, American Cancer Society 2011
- Presidential Award of Merit, Texas Academy of Family Physicians 2012

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- 3. Foxhall L, Von Eschenbach AC. Counseling Patients About Prostate Cancer Screening. American Family Physician 65(9), 2002.
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Sharon Giordano, M.D., M.P.H.

Sharon Giordano is chair with tenure at The University of Texas MD Anderson Cancer Center in the Department of Health Services Research. Dr. Giordano received her undergraduate degree from Yale University and graduated Summa Cum Laude and With Distinction in Biology. Dr. Giordano received her M.D. degree from The Johns Hopkins School of Medicine in 1996. She is a board certified Medical Oncologist. In 2004, Dr. Giordano received a Master of Public Health degree in Disease Control from The University of Texas School of Public Health.

Dr. Giordano's research interests include breast cancer outcomes research, late effects of treatment, and male breast cancer. She is currently funded through the American Cancer Society, CPRIT, and BCRF. Dr. Giordano is on the editorial boards for Cancer and the Journal of Clinical Oncology. Dr. Giordano has received numerous awards including the Faculty Educator of the Month (2009), the Distinguished Alumnus Award (2010), Mentor



of the Year Award (2011), Teaching Department of the Year (2011), and Faculty Scholar Award (2012). Dr. Giordano is the chair-elect of the ASCO Clinical Practice Guideline Committee and serves on the National Comprehensive Cancer Network Breast Cancer Guideline Committee.

- 1. Giordano SH, Kuo YF, Freeman JL, Buchholz TA, Hortobagyi GN, Goodwin JS. *Risk of cardiac death after adjuvant radiotherapy for breast cancer.* J Natl Cancer Inst 97(6):419-24, 2005. PMCID: PMC1853253.
- 2. Giordano SH, Duan Z, Kuo YF, Hortobagyi GN, Freeman J, Goodwin JS. *Impact of a scientific presentation on community treatment patterns for primary breast cancer.* J Natl Cancer Inst 98(6):382-8, 2006. PMCID: PMC1853252.
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Ellen R. Gritz, Ph.D.

Ellen R. Gritz, Ph.D., is chair of the Department of Behavioral Science and holds the Olla S. Stribling Distinguished Chair for Cancer Research at MD Anderson. She is an established leader in cancer prevention and control research and internationally known investigator. Dr. Gritz has published extensively on cigarette smoking behavior: prevention, cessation, pharmacologic mechanisms, and special issues of concern to women and high-risk groups, including ethnic minorities, youth, cancer patients and persons living with HIV/AIDS. Other research includes skin cancer prevention in children and high-risk individuals, genetic testing and counseling for hereditary cancers, and cancer survivorship.

Dr. Gritz has served on several cancer center and other advisory boards, including:

- Institute of Medicine (IOM), currently serving as Chair, Section 11 (Social Sciences, Humanities and Law)
- The Academy of Medicine, Engineering and Science of Texas (TAMEST) and sits on the Board of Directors
- Board of Directors of the American Legacy Foundation, the large, non-profit public health foundation established in 1998 as part of the Master Settlement Agreement, and was vice-chair of the board (2005-2008).
- President of the Society for Research on Nicotine and Tobacco (2006-2007)
- President of the American Society of Preventive Oncology (ASPO) (1993-1995)

Dr. Gritz has received numerous honors, including:

- American Society of Preventive Oncology's (ASPO) Joseph W. Cullen Memorial Award for outstanding research in smoking
- ASPO's Distinguished Achievement Award
- MD Anderson's Margaret and James A. Elkins, Jr. Faculty Achievement Award in Cancer Prevention
- The Alma Dea Morani Renaissance Woman Award and the Society of Behavioral Medicine, Cancer Special Interest Group's Outstanding Biobehavioral Oncology Award
- Distinguished Professional Woman's Award, presented by UT Health Science Center at Houston
- Angel Award, from the Be An Angel Fund
- 2013 Greater Houston Women's Chamber of Commerce Hall of Fame

Dr. Gritz is a fellow of the Society of Behavioral Medicine and the American Psychological Association, and is senior editor for Behavioral Sciences of the journal, *Cancer Epidemiology, Biomarkers, and Prevention*. She has more than 291 publications to her credit, including numerous journal articles, as well as books, book chapters and teaching aids. Dr. Gritz holds a Ph.D. in psychology from the University of California at San Diego.

- 1. Gritz ER, Lam CY, Vidrine DJ, Fingeret MC. Cancer Prevention: Tobacco Dependence and Its Treatment. In: Cancer: Principles and Practice of Oncology. 2, Part 3, Chapter 51, 9th edition. (Eds) V DeVita, T Lawrence, S Rosenberg. Lippincott Williams and Wilkins: Philadelphia, PA, pp. 529-542, 2011.
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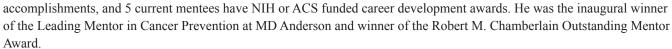
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David W. Wetter, Ph.D.

David W. Wetter, Ph.D. is the Cullen Trust for Health Care Chair in the Department of Health Disparities Research at MD Anderson Cancer Center. His work is targeted at eliminating disparities in health-related behavior through translational research. Specific research foci include: theoretical models of addictive and cancer risk behaviors; the development and evaluation of theoretically-based interventions; and, translational research to implement and disseminate those interventions in real world settings. His research spans the continuum from cells to society, and focuses on high-risk and underserved populations, with a major focus on low socioeconomic status individuals, minorities, and women.

He is a passionate advocate for students and education. In the last 5 years alone, Dr. Wetter has mentored 10 postdoctoral fellows, 8 of whom are now faculty members. During that same time period, his fellows won 3 institution-wide awards and 2 divisional awards for outstanding research



In addition to leading the Department of Health Disparities Research, his leadership responsibilities at MD Anderson include serving as:

- Director of the Center for Community-Engaged Translational Research
- Director of the Minority and Women Clinical Trials Recruitment Program
- Director of the Tobacco Disparities Training Program
- Associate director for Health Disparities Research for the Cancer Center Support Grant

His professional service includes serving as:

- Chair of the Community Level Health Promotion study section at the National Institutes of Health
- Contributing to the 2000 Report of the Surgeon General on Reducing Tobacco Use
- Scientific consultant for two U.S. Public Health Service tobacco treatment guidelines
- Invited participant in numerous NIH workgroups

He has an extensive NIH-funded grant portfolio and over 150 peer-reviewed publications. Dr. Wetter earned his Ph.D. in Clinical Psychology and a M.S. in Epidemiology from the University of Wisconsin – Madison. He has a joint appointment in the Department of Behavioral Science and an adjunct appointment at The University of Texas School of Public Health.

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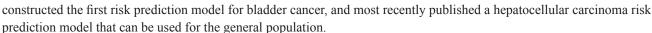
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Xifeng Wu., M.D., Ph.D.

Xifeng Wu, M.D., Ph.D., is chair of the Department of Epidemiology, Director of the Center of Translational and Public Health Genomics, and Epidemiology program leader for the Cancer Center Support Grant at MD Anderson. She also holds the endowed Betty B. Marcus Chair in Cancer Prevention. She earned her medical degree from Fudan University in 1984 and her Ph.D. from The University of Texas School of Public Health in 1994.

Dr. Wu's multifaceted, highly interactive and multidisciplinary molecular epidemiology program bridges field epidemiology, laboratory study and clinical research. Her team has developed or adapted an array of phenotypic and genotypic assays to identify, study, and validate inherited susceptibility biomarkers for cancer risk assessment and clinical outcome prediction. Her vision is to incorporate epidemiological, clinical and genetic information to develop personalized risk prediction models for cancer etiology, prevention, clinical outcomes, and survivorship. She



Dr. Wu is a highly productive cancer epidemiologist with more than 331 publications, many in highly acclaimed journals. She consistently maintains a high level of funding from the NCI, holds a CPRIT grant, is co-director of or leads projects on four SPORES, and is contributing to four moonshot programs. Dr. Wu supervises a 55-member research team and serves as mentor or advisor for several junior faculty, pre-and post-doctoral trainees, and clinical fellows, many of whom have received prestigious awards from both inside and outside of the institution.

Dr. Wu has received many awards, including MD Anderson's Faculty Scholar Award, The University of Texas Ashbel Smith Professorship, the Margaret and James A. Elkins Jr. Faculty Achievement Award in Cancer Prevention, the Julie and Ben Rogers Award for Excellence in Research, and the Robert M. Chamberlain Distinguished Mentor Award. She is frequently invited to present at workshops, deliver lectures and seminars, and chair conference sessions. She serves on study sections including NCI and the American Cancer Society, and is the current chair of the International Bladder Cancer Consortium.

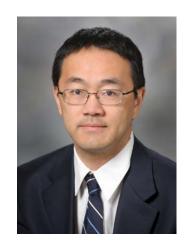
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Hua Zhao, Ph.D.

Hua Zhao, Ph.D., is an associate professor of the Department of Epidemiology and codirector of Mexican American Cohort in MD Anderson Cancer Center. He earned his Ph.D. from The University of Texas School of Public Health in 2003.

Dr. Zhao's research focuses on the influence of genetic factors as well as gene, environment, and behavior interactions in the context of human cancers and other chronic diseases. He is particularly interested in carrying out the research in minority populations, such as Mexican Americans and African Americans, because they have a disproportionally higher cancer burden but are much less studied than Caucasian Americans. Obesity and overweight affect 3 out of 4 Mexican Americans. As the co-director of Mexican American Cohort, Dr. Zhao is interested in studying obesity, physical inactivity, and cancer outcomes in Mexican Americans. He is particularly interested in conducting exercise and dietary based interventions



to reduce cancer risk and improve cancer outcomes. He is also interested in studying obesity and energy balance related biomarkers which can not only assess the intervention efficacy, but also provide targets for future molecular-tailored interventions. Another part of his research interest is the psychological stress and how the stress might affect the health of Mexican Americans.

Dr. Zhao is a very productive cancer epidemiologist with more than 40 publications in highly acclaimed journals. He is the principal investigator of several NIH and DOD funded studies and a collaborator on many other projects.

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- 8. Shen J, Yan L, Liu S, Ambrosone CB, and Zhao H. Plasma metabolomic profiles in breast cancer patients and healthy controls: by race and tumor receptor subtypes. Translational Oncology 6(6): 757-765, 12/2013

Jennifer H. Tektiridis, Ph.D., C.P.A.

Jenny Tektiridis, Ph.D., C.P.A., is the executive director, research planning and development in the Division of Cancer Prevention and Population Sciences. She directs the scientific business operations of the Duncan Family Institute for Cancer Prevention and Risk Assessment and serves as the chief of operations for the Cancer Prevention and Control Platform. In both roles, she facilitates start-up and change initiatives, gaining consensus on new strategic directions and collaborating with colleagues at all levels to achieve program results. Her work to establish the management systems, financial reporting and communications infrastructure supports lifecycle (concept to closeout) operations of the diversity of initiatives that are funded through the Institute and the Platform. In addition to her role with the Institute and Platform, Jenny provided planning and startup operations leadership for the Integrative Health clinical services initiative, establishing a foundation for moving this new venture to its current status as an integral component of the Cancer Prevention Center's patient services.



Prior to her role with the Duncan Family Institute, Jenny was the administrative leader for the NCI-funded Cancer Center Support Grant (CCSG), which supports 19 research programs and 24 core laboratory resources. Following an "outstanding" peer review rating, the grant was renewed with a 15% increase in funding (the maximum available), for a five-year total of more than \$52.7 million. She was recognized as a Rogers Award for Research finalist for her contributions.

Jenny joined MD Anderson in 2002 as the first Executive Director for the Gulf Coast Consortia (GCC), responsible for start-up operations for this six-academic institution collaborative's interdisciplinary bioscience research and training programs. She led the development, submission and post-award implementation of 5 extramurally peer-reviewed training grants (over \$12 million total costs) and raised \$4 million in philanthropic support for the organization. In 2005, the State of Texas Higher Education Coordinating Board recognized the GCC with its Texas Star Award.

Before joining MD Anderson, Jenny held executive leadership positions with a laboratory supplies distributor and retail energy start-up, and served in a senior position with a national consulting firm.

Jenny is a member of the UH – Victoria School of Business Administration Dean's Advisory Council, the GHP Health Policy Committee, the APHA and the AACR. She has served on institutional committees, including as co-chair of the Comprehensive Cancer Control Energy Balance Workgroup, and on grant review panels. Jenny has a B.S. degree in Geology and Spanish from Dickinson College, an M.S.M. degree in Business with a concentration in Accounting from Rollins College and is a State of Texas licensed C.P.A. She has been admitted to candidacy in the PhD program in Health Management at The UT School of Public Health and anticipates completing her degree in spring 2014.

Publications and Abstracts

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- 2. Denton, KA., Smith, CR, Scroggs, S, and Tektiridis, JH, "A Lean Survivorship Program" Abstract, UT System Building Bridges Clinical Safety and Effectiveness Conference, October 26, 2011.
- 3. Denton, KA., Smith, CR, Scroggs, S, and Tektiridis, JH, "A Lean Survivorship Program" UT MD Anderson Cancer Center Clinical Safety & Effectiveness Program, July 2011 (recognized with a Gold award).
- 4. "Cancer Prevention and Health Services Research Future Directions," (co-author), poster for the American Society of Preventive Oncology Annual Meeting, Washington, DC, 2010.
- 5. "Collaboration Challenges and Opportunities," (copresenter), Research Centers in Minority Institutions Annual Conference, Houston, TX, 2005.

- 6. "The Gulf Coast Consortia," poster for the National Academies Convocation on Facilitating Interdisciplinary Research, Washington, D.C., 2004.
- 7. "Total Quality Management Tools and Techniques," Workshop Co-facilitator, Pre-conference Workshop, Clinical Laboratory Management Association National Conference, 1993.
- 8. "The Team Approach to Quality Improvement" Tech Sample Management and Education No. MGM-4, American Society of Clinical Pathologists (co-author), 1993.
- 9. Total Quality Management in Environmental Laboratories Module 1 and 2 (Curtin Matheson Scientific, Inc., internal publication), 1991.
- 10. Total Quality Management in Healthcare Module 1 and 2 (Curtin Matheson Scientific, Inc., internal publication), 1990.



Location

The Duncan Family Institute for Cancer Prevention and Risk Assessment is located within the Division of Cancer Prevention and Population Sciences in the Dan L. Duncan Building, 1155 Herman P. Pressler, Houston, TX 77030-3721

If you would like more information on supporting the Duncan Family Institute, please contact Ernest Hawk, M.D., M.P.H., vice president and division head, Cancer Prevention and Population Sciences, 713-792-3900, or visit the Duncan Family Institute Internet site at www.mdanderson.org/duncanfamilyinstitute

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