

2015 NCI Cancer Clinical Investigator Team Leadership Award (CCITLA) Recipients

Leora Horn, M.D., M.Sc.	Vanderbilt-Ingram Cancer Center Focus area: small cell lung cancer
David Hyman, M.D.	Memorial Sloan Kettering Cancer Center Focus area: gynecologic cancers
Matthew Katz, M.D.	MD Anderson Cancer Center, University of Texas Focus area: pancreatic ductal adenocarcinoma
Edward Kim, M.D., Ph.D.	UC Davis Comprehensive Cancer Center, University of California, Davis Focus area: pancreatic ductal adenocarcinoma
Frederick Lansigan, M.D.	Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center Focus areas: leukemia and lymphoma
Charles Leath, III, M.D., M.S.P.H.	UAB Comprehensive Cancer Center, University of Alabama at Birmingham Focus area: gynecologic cancers
Elizabeth Plimack, M.D., M.S.	Fox Chase Cancer Center Focus areas: bladder and kidney cancers
Andrew Poklepovic, M.D.	Massey Cancer Center, Virginia Commonwealth University Focus areas: breast cancer, sarcoma, melanoma and hepatobiliary cancers
Yvonne Saenger, M.D.	Herbert Irving Comprehensive Cancer Center, College of Physicians & Surgeons Columbia University Focus areas: pancreatic ductal adenocarcinoma, melanoma and immunotherapy
Emma Scott, M.D.	OHSU Knight Cancer Institute, Oregon Health & Science University Focus areas: multiple myeloma and plasma cell malignancy
Liza Villaruz, M.D.	University of Pittsburgh Cancer Institute Focus area: small cell lung cancer



Leora Horn, M.D., M.Sc.

Associate Professor of Medicine

**Clinical Director, Thoracic Oncology Research Program
Assistant Vice Chancellor for Faculty Development**

Vanderbilt-Ingram Cancer Center

Dr. Leora Horn is an associate professor of medicine and the clinical director of the thoracic oncology research program at Vanderbilt-Ingram Cancer Center (VICC) in Nashville, TN. She is also the assistant vice chancellor for faculty development at Vanderbilt Medical Center. Her clinical practice focuses on the care of patients with lung cancer. She is the principal investigator (PI) of several investigator-initiated and industry-sponsored clinical trials and an active member of the Eastern Cooperative Oncology Group, International Association for the Study of Lung Cancer and the American Society of Clinical Oncology. In the last year, she was the highest in accrual to clinical trials at VICC where she has a focus on clinical trials with targeted therapies and immunotherapy as well as small cell lung cancer. Dr. Horn works closely with many collaborators at VICC translating laboratory findings into clinical trials for patients with lung cancer and proposes evaluating pre-treatment biopsies and biopsies on progression to further understand mechanisms of response as well as de novo and acquired mechanisms of drug resistance for patients treated with targeted therapy and immunotherapy.



David Hyman, M.D.

**Assistant Professor, Gynecologic Medical Oncology
Acting Director, Developmental Therapeutics
Memorial Sloan Kettering Cancer Center**

Dr. David Hyman completed medical school at Weill Cornell Medical College, medicine residency at New York Presbyterian Cornell, and fellowship in Hematology/Oncology at Memorial Sloan Kettering Cancer Center (MSK). Following completion of his training, Dr. Hyman joined the Department of Medicine at MSK as an Assistant Professor with a dual appointment to the Gynecologic Medical Oncology service and Developmental Therapeutics Clinic in 2012. He currently serves as Acting Director of the Developmental Therapeutics Clinic. In this capacity, Dr. Hyman leads large multidisciplinary group of physicians, nurses, and research coordinators to conduct a variety of early phase clinical studies including first-in-human studies, novel combinations of investigational therapy, and histology-independent, molecularly selected “basket” studies. Dr. Hyman’s primary research interest is the application of precision medicine techniques to early phase (I/Ib) clinical trials with a focus on molecular targets of therapeutic relevance to gynecologic cancers. To accomplish these goals, Dr. Hyman has been heavily involved in NCI-sponsored work as exemplified by four NCI-sponsored studies for which he currently leading at MSK. For three of these protocols, Dr. Hyman also serves Study Chair or Co-Chair.

Dr. Hyman’s current proposal stems from his work on two studies: 1) A Phase II Trial of DCTD-Sponsored Dasatinib (NSC #732517 IND #120636) In Recurrent/Persistent Ovary, Fallopian Tube, Primary Peritoneal, and Endometrial Clear Cell Carcinoma Characterized for the Retention or Loss of BAF250a Expression (GOG-0283), and 2) An Open-Label, Phase 2 Study Of the Pan-HER Kinase Inhibitor, Neratinib, In Patients With Solid Tumors With Activating Somatic ERBB2 (HER2) Mutations. Through the support of this grant, Dr. Hyman will focus on correlative studies associated with these protocols. In addition, Dr. Hyman plans to work closely as part of a multidisciplinary group of physicians and scientists to facilitate the conduct of precision medicine studies at his institution.



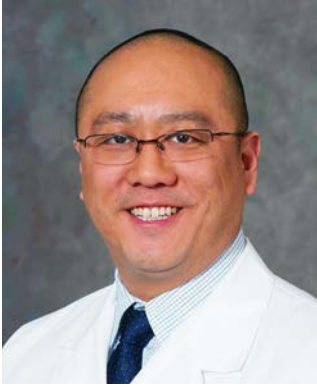
Matthew Katz, M.D.

Associate Professor, Surgical Oncology

**MD Anderson Cancer Center
University of Texas**

Dr. Matthew Katz is an associate professor in the Department of Surgical Oncology at The University of Texas MD Anderson Cancer Center (MDACC). He has extensive experience in developing, conducting, and participating in clinical research trials. He is currently the national PI of an intergroup cooperative group study of the effects of preoperative therapy in patients with advanced pancreatic cancer, run by the Alliance for Clinical Trials in Oncology and is the chairman of the American College of Surgeons Clinical Research Program Cancer Care Standards Development Committee. He has published over 90 original articles that have described the multimodality treatment of patients with this disease and has been an exemplary mentor to young surgical oncology trainees interested in clinical research.

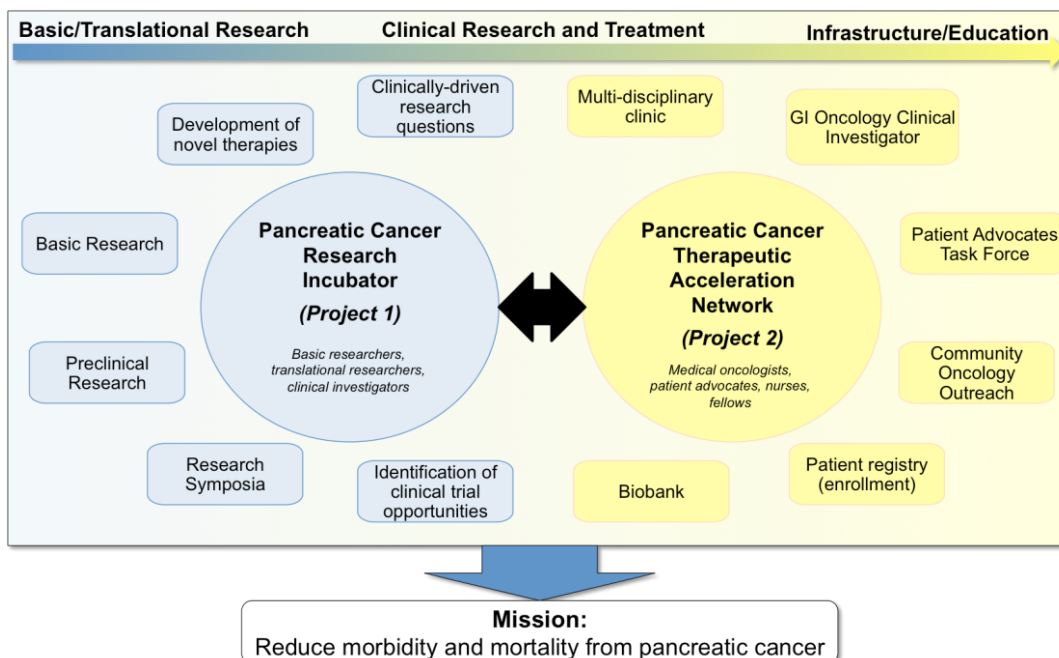
As a recipient of the Cancer Clinical Investigator Team Leadership Award (CCITLA), Dr. Katz will increase awareness of and accrual to open National Clinical Trials Network (NCTN) trials at MDACC by developing programs to increase enrollment at affiliated regional sites, and will enhance an educational clinical trials program. He will also develop and enhance educational programs aimed at trainees and faculty who have not had formal training in clinical research.



Edward Kim, M.D., Ph.D.
Assistant Professor of Medicine
UC Davis Comprehensive Cancer Center
University of California, Davis

Dr. Edward Kim is an Assistant Professor of Medicine in the Division of Hematology Oncology at UC Davis Comprehensive Cancer Center. He received his BA in chemistry at Harvard University and subsequently received his MD and PhD in genetics at Stony Brook University. He completed residency and fellowship training at University of Michigan in a Physician Scientist Training Program. After completing fellowship, he stayed at Michigan joining the faculty as a Clinical Lecturer prior to moving to UC Davis in the fall of 2012. Dr. Kim is a gastrointestinal oncologist who specializes in the management of pancreatic, hepatobiliary, gastric, colorectal cancers, and clinical trials for these malignancies. Dr. Kim's research focus is on novel developmental therapeutics for gastrointestinal malignancies with a special focus on translational research on pancreatic cancer.

Planned activities with the CCITLA fall under 2 main projects. Project 1 involves establishment of a Pancreatic Cancer Research Incubator at UC Davis to foster collaborative pancreatic cancer research and bridge the gap between the medical campus in Sacramento and the basic science campus in Davis. This will be accomplished through regularly scheduled teleconferenced meetings, virtual project management discussion boards, and an annual UC Davis Comprehensive Cancer Center Pancreatic Research Symposium. Project 2 is focused on optimizing clinical trial participation through formation of a Pancreatic Cancer Therapeutic Acceleration Network consisting of physicians, nurses, social workers, patients and patient advocates and will draw from their respective experiences and expertise. Planned initiatives to be addressed by this group include the formation of a UC Davis Pancreatic Cancer Registry with an associated Pancreatic Cancer Biobank and streamlining patient experience navigating the multidisciplinary team of physicians and support staff.





Frederick Lansigan, M.D.
Assistant Professor of Medicine, Hematology/Oncology
Inpatient Medical Director of Cancer Services
Norris Cotton Cancer Center
Dartmouth-Hitchcock Medical Center

Dr. Frederick Lansigan is a rising Associate Professor of Medicine at the Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center where he has been working for 6 years. He is the principal investigator of at least 33 clinical research projects including cooperative group trials, investigator-initiated clinical trials, and pharmacy-sponsored trials, and correlative studies. He is an active member of the Lymphoma Committee of Alliance for Clinical Trials in Oncology, and was recently appointed the Norris Cotton Cancer Center (NCCC) Deputy Director of the Lead Academic Participating Site (LAPS) initiative to help expanding involvement in National Clinical Trials Network (NCTN) studies involving hematologic malignancies.

His planned activities to promote the research culture at NCCC, and institutional commitment include:

1. Extending Norris Cotton Cancer Center at Dartmouth engagement in NCTN hematologic studies.
2. Obtaining a Master's degree at The Dartmouth Institute (TDI), a world-renowned program in public health and outcomes research. Dr. Lansigan is applying for the Master of Science in Health Care Research.
3. Developing a proof-of-principle clinical trial in the treatment of Chronic Lymphocytic Leukemia (CLL) using ibrutinib combined with a novel inhibitor of JNK in collaboration with basic science researcher Alan Eastman, PhD.
4. Developing an investigator-initiated Phase II clinical trial for Follicular lymphoma using immune checkpoint inhibition.
5. Developing a novel treatment for cutaneous T-cell lymphoma using a new form of skin directed therapy.
6. Using social media to help advertise and promote clinical trial recruitment.



Charles Leath, III, M.D., M.S.P.H.

Associate Professor of Obstetrics and Gynecology

University of Alabama School of Medicine

UAB Comprehensive Cancer Center

University of Alabama at Birmingham

Dr. Charles Leath is a 1994 graduate of The Citadel, The Military College of South Carolina and a 1998 graduate of the Medical University of South Carolina. Following completion of medical school, Dr. Leath completed a residency in Obstetrics and Gynecology at the University of Alabama at Birmingham. Following residency, Dr. Leath remained in Birmingham where he completed his fellowship in Gynecologic Oncology. During fellowship he performed gene therapy research focusing on novel treatment options for epithelial ovarian carcinoma. Following fellowship, Dr. Leath served in the United States Air Force from 2005-2012 and was stationed in San Antonio, Texas. During his active duty commitment, he became the Division Director of Gynecologic Oncology at Brooke Army Medical Center and served as the Chairman of the IRB for three years at the same institution. Currently Dr. Leath is an Associate Professor at the University of Alabama at Birmingham and is a member of the Gynecologic Oncology Group's Cervical & Vulvar Cancer and Safety Committees. Dr. Leath is board certified in both Obstetrics & Gynecology as well as Gynecologic Oncology and holds a Masters of Science in Public Health (MSPH) degree from the University of Alabama School of Public Health. In addition to his clinical responsibilities as a Gynecologic Oncologist, Dr. Leath is the Co-Director of the Lynne Cohen and Norma Livingston Preventive Care Program for Women's Cancer. Additionally, Dr. Leath is actively involved in clinical research in the management of cervical and ovarian cancers, as well as clinical trials for all aspects of gynecologic cancer, and he is an author or co-author of 80 peer reviewed publications.

Selection as a CCITLA recipient will allow Dr. Leath to spend, on average, a dedicated one-half day a week working at the UAB Comprehensive Cancer Center on all aspects of clinical trials including protocol review, monitoring of clinical trial data and safety as well as feasibility determinations including budgetary concerns. In addition, during this time Dr. Leath plans to develop an early phase clinical trial for patients with platinum resistant ovarian cancer based on collaborative work with basic science investigators at UAB.



Elizabeth Plimack, M.D., M.S.
Director, Genitourinary Clinical Research
Associate Professor, Department of
Hematology/Oncology
Fox Chase Cancer Center

Dr. Elizabeth Plimack is an Associate Professor of Medical Oncology and Director of Genitourinary Clinical Research at Fox Chase Cancer Center (FCCC) where she oversees clinical research within the genitourinary group. She is a clinical expert on the treatment of genitourinary malignancies with a focus on bladder and kidney cancers. Her research effort is focused on the discovery of novel therapeutic approaches and predictive biomarkers for patients with these diseases. Dr. Plimack is an active clinical trialist completing several investigator-initiated trials investigating novel combination therapies in kidney cancer, and neoadjuvant chemotherapy in bladder cancer. Additionally she serves on the National Comprehensive Cancer Network guidelines panels for Kidney and Bladder Cancer, and on the American Joint Committee on Cancer (AJCC) Kidney/Urinary Tract Expert Panel. Dr. Plimack received her undergraduate degree from Yale University majoring in American Studies. She received her M.D. and completed her residency in Internal Medicine at the New York University School of Medicine. She went on to complete a Medical Oncology Fellowship at the MD Anderson Cancer Center, concurrently working towards and receiving a Master's in Patient Based Biologic Research from the University of Texas Graduate School of Biomedical Science.

With the CCITLA, Dr. Plimack plans to expand the clinical trial program in GU malignancies at Fox Chase through the mentorship of junior faculty and trainees and the development of rational investigator-initiated trials based on innovative scientific discoveries in the lab. To support these efforts, Dr. Plimack has instituted a "Pod" concept for clinical trial management within the GU group at Fox Chase and plans to use the support afforded by the CCITLA to streamline and innovate the way clinical trials are processed and staffed.



Andrew Poklepovic, M.D.

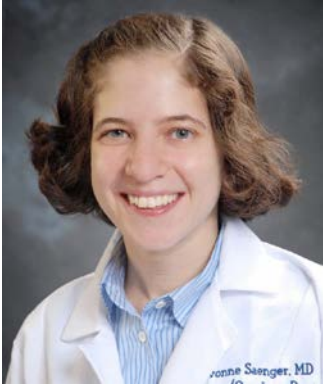
Assistant Professor of Hematology, Oncology and Palliative Care, VCU

Associate Member, Developmental Therapeutics Program

**Massey Cancer Center
Virginia Commonwealth University**

Dr. Andrew Poklepovic is a medical oncologist who treats patients with a wide variety of hematologic and solid tumor malignancies. Dr. Poklepovic treats patients with breast cancer, sarcoma, melanoma and hepatobiliary cancers. He is an associate member of the Developmental Therapeutics Program at the Massey Cancer Center, and an active member in the Massey Cancer Center phase I program. Dr. Poklepovic has been in cancer related clinical trial design for the past 5 years, and has developed therapeutic trials for diseases including hepatocellular carcinoma, breast cancer, lymphoma, prostate cancer, pancreatic cancer, colon cancer and glioblastoma, along with a wide variety of solid tumors as part of phase I studies. He has been the PI on the successfully completed phase I trial of pemetrexed with sorafenib in advanced malignancies (NCT 01450384), and will serve as the PI as this concept is developed further in breast cancer as part of a phase II study. In addition to this clinical trial, Dr. Poklepovic is the PI on several other locally initiated clinical trials, including a general solid tumor phase I dose escalation study (NCT02466802), along with disease specific phase I studies in hepatocellular carcinoma (NCT01075113) and pancreatic cancer (NCT02349867). In addition to running locally initiated clinical trials, Dr. Poklepovic is also the institutional PI on multiple cooperative group and NCI trials. He is the study co-PI on one of the NCI-MATCH trial arms, (arm V, sunitinib in cKIT mutated cancers), an arm which is open to accrual at this time. His currently open clinical trials include active collaborations with radiation oncology, cardiology, hepatology, basic scientists and industry. He continues to develop new translational research protocols in conjunction with basic scientists and clinicians at the Massey Cancer Center, with additional projects undergoing regulatory review.

Dr. Poklepovic's planned activities include further development of pemetrexed and sorafenib in triple negative breast cancer as part of a phase II study, development and initiation of a neoadjuvant protocol in breast cancer, which incorporates immune therapy in addition to chemotherapy. He is also developing a disease specific phase I study in sarcoma and kidney cancer. In addition to protocol development and management of these clinical trials, Dr. Poklepovic will also serve on the local scientific review committee for cancer related clinical trials and serve as a mentor to young investigators and fellows in training.



Yvonne Saenger, M.D.

Director, Melanoma Immunotherapy

**Assistant Professor, Department of Medicine,
Division of Hematology Oncology**

**Herbert Irving Comprehensive Cancer Center
College of Physicians & Surgeons Columbia
University**

Dr. Yvonne Saenger completed her undergraduate training at Harvard University, attended both medical school and residency in internal medicine at Columbia University, as well as a medical oncology fellowship at Memorial Sloan-Kettering and a fellowship in pancreas immunotherapy at Johns Hopkins Medical Center. Her clinical focus is on melanoma, pancreatic cancer and immunotherapy and her research focus is on immunotherapy and immune biomarkers. Dr. Saenger has spoken at meetings at the Society for the Immunotherapy of Cancer and the American Association for Cancer Research. She is the recipient of a Cancer Immunology Innovator Grant from the American Association for Cancer Research Innovator Award as well as awards from Melanoma Research Alliance. She has developed a novel immune biomarker to predict survival in patients with resected stage II and stage III melanoma and is currently working with the Eastern Collaborative Oncology Group to validate this signature using samples from the E1697 adjuvant interferon study. In her laboratory, Dr. Saenger is researching immune biomarkers in blood and cancer tissues as well as studying combination of oncolytic viro-therapy with other therapeutic modalities.

As a recipient of the Cancer Clinical Investigator Team Leadership Award, Dr. Saenger will develop tools to bank patient samples and characterize the immune microenvironment in patients undergoing immunotherapy for the purpose of understanding gene networks implicated in successful immune-mediated eradication of tumors.



Emma Scott, M.D.

Assistant Professor of Medicine, OHSU

Director, Myeloma and Amyloid Program

OHSU Knight Cancer Institute

Oregon Health & Science University

Dr. Emma Scott's passion and interest is leading clinical research, focused on making an impact on the dismal outcomes for patients with relapsed and high risk multiple myeloma, by designing clinical translational trials. Her experience as a junior faculty member at the Center for Hematologic Malignancies at the Knight Cancer Institute, Oregon Health & Science University (OHSU) is to develop the plasma cell malignancy clinical and research program. Dr. Scott has opened multiple NIH, industry and myeloma consortia clinical trials and recently completed an investigator-initiated clinical-translational study addressing how the mTOR and autophagy pathways affect chemo-resistance in relapsed myeloma.

Dr. Scott's goals for the next 2 years are firstly, to expand the OHSU clinical translational laboratory to facilitate innovative and clinically relevant approaches to identification of drug sensitivities in individual patients, to develop personalized, novel treatment strategies for patients suffering from this incurable disease. Secondly, she will be addressing the role of stem cell transplantation for high risk patients by i) performing the Center for International Blood and Marrow Transplantation (CIBMTR) analysis of post-transplant outcomes of patients with high risk genomic abnormalities, ii) opening her investigator-initiated allogeneic stem cell transplant (allo HCT) study with novel agent maintenance. Lastly, she is committed to discovering ways to improve patient care and will be co-leading a SWOG study using novel direct thrombin inhibition to prevent thromboembolism in patients on immunomodulatory therapy and she is the PI of the cardiotoxicity evaluation of patients on proteasome inhibitor induction therapy (ECOG) study that is currently underway.

The support provided by the Cancer Clinical Investigator Team Leadership Award will be critical for Dr. Scott to protect the time needed to devote to these projects while continuing to lead and accrue to plasma cell malignancy clinical trials. Her ultimate goal is to make an impact on relapsed refractory and high risk myeloma through clinical – translational research and to lead a nationally recognized plasma cell malignancy program.



Liza Villaruz, M.D.

Assistant Professor of Medicine

Director of Small Cell Lung Cancer Clinical Investigation

University of Pittsburgh Cancer Institute

Dr. Liza Villaruz is an Assistant Professor of Medicine at the University of Pittsburgh Cancer Institute (UPCI), where she was recently appointed the Director of Small Cell Lung Cancer Clinical Investigation. As a clinical and translational investigator with a disease specific focus in lung cancer, she actively develops institutional clinical trials in both the UPCI Lung Cancer Program and the UM1 NCI ET-CTN with Phase I Emphasis at the UPCI, and facilitates the interactions between the Lung Cancer Program and the Phase I Program. She has a strong track record of successful development of clinical trials through NCI-CTEP and industry and works in close collaboration with the basic and translational scientists at UPCI to development the correlative science of novel drug combinations in early phase clinical trials.

Over the course of the award period, Dr. Villaruz will work at the multidisciplinary level to develop a dedicated small cell lung cancer referral clinic with tissue banking protocols for translational studies. Dr. Villaruz will work to build a robust small cell lung cancer clinical trial portfolio through the incorporation of NCTN Group, industry sponsored and institutional clinical trials, which Dr. Villaruz will develop over the course of the grant period. Dr. Villaruz will work on the prioritization of small cell lung cancer clinical trials across oncology disciplines, organization of tissue collection efforts, and planning of retrospective studies. A priority over the course of the grant period will be the selection of small cell lung cancer trials for initiation at the VA Pittsburgh Healthcare System, where there are currently no small cell lung cancer clinical trials. Dr. Villaruz will work to implement a multidisciplinary Thoracic Oncology Tumor Board to review the diagnosis and management of challenging lung cancer cases, including small cell lung cancer cases, with the goal of education of thoracic oncology trainees.