**2016 NCI Cancer Clinical Investigator Team Leadership Award (CCITLA) Recipients**

**Rahul Aggarwal, M.D.** UCSF Helen Diller Family Comprehensive Cancer Center
University of California, San Francisco
**Focus: genitourinary cancers, early phase clinical trials**

**Jamie N. Bakkum-Gamez, M.D.** Mayo Clinic Cancer Center
**Focus: gynecologic cancers, surgical oncology**

**Catherine S. M. Diefenbach, M.D.** Perlmutter Cancer Center
New York University Langone Medical Center
**Focus: lymphoma (Hodgkin and non-Hodgkin)**

**Noah M. Hahn, M.D.** Sidney Kimmel Cancer Center, Johns Hopkins University
**Focus: bladder cancer, genitourinary malignancies**

**Erin W. Hofstatter, M.D.** Yale Cancer Center, Yale University School of Medicine
**Focus: breast cancer, clinical breast cancer genetics and prevention**

**Kevin R. Kelly, M.D., Ph.D.** USC Norris Comprehensive Cancer Center
University of Southern California
**Focus: acute myeloid leukemia, multiple myeloma**

**Sarah E. S. Leary, M.D., M.S.** Fred Hutchinson/University of Washington Cancer Consortium
Fred Hutchinson Cancer Research Center
**Focus: pediatric brain cancers**

**Frederick L. Locke, M.D.** Moffitt Cancer Center
**Focus: lymphoma, multiple myeloma, immune and cellular therapies**

**Rachel Miller, M.D.** Markey Cancer Center, University of Kentucky
**Focus: ovarian cancer, gynecologic cancers, chemotherapy-induced cognitive impairments**

**Taofeek K. Owonikoko, M.D., Ph.D.** Winship Cancer Institute of Emory University
**Focus: small cell lung cancer, aerodigestive cancer, early phase clinical trials**

**Geoffrey R. Oxnard, M.D.** Dana-Farber/Harvard Cancer Center, Dana-Farber Cancer Institute
**Focus: lung cancers, noninvasive plasma genotyping technologies**

**Dale R. Shepard, M.D., Ph.D.** Case Comprehensive Cancer Center, Case Western Reserve University
**Focus: sarcomas, early phase clinical trials**

**Theresa L. Werner, M.D.** Huntsman Cancer Institute, University of Utah
**Focus: ovarian cancer, gynecologic cancers, early phase clinical trials**

For a list of past CCITLA awardees and the 2016 CCITLA Program Announcement, visit:
http://www.cancer.gov/about-nci/organization/ccct/funding/ccitla

**Rahul Aggarwal, M.D.**

**Assistant Clinical Professor of Medicine**

**UCSF Helen Diller Family Comprehensive Cancer Center (HDFCC), University of California, San Francisco**

**Focus: genitourinary cancers, early phase clinical trials**

Dr. Aggarwal is an Assistant Clinical Professor at the University of California San Francisco. He received his medical degree from Northwestern University and completed his residency and fellowship training in Hematology/Oncology at UCSF. His current translational and clinical research is focused on the early phase development of novel targeted therapies for patients with advanced solid tumor malignancies. By means of his dual appointment in the Genitourinary Oncology and Phase 1 programs, Dr. Aggarwal has successfully developed a robust early phase clinical trials portfolio that has helped to establish a strong bridge between the two programs. Dr. Aggarwal will lead the efforts to expand upon the paradigm of linking the Phase 1 program with other disease groups in order to facilitate opening Phase 1 studies spanning multiple tumor types.

With the receipt of the NCI CCITLA grant, Dr. Aggarwal's goal is to leverage his new role as Director of the UCSF Phase 1 Scientific Oversight Committee, a group comprised of early phase clinical investigators and translational scientists, to establish the infrastructure necessary to facilitate cross-cutting research across disease-specific groups in the conduct of early phase clinical trials. He will develop a cadre of basic and translational scientists and clinical investigators that will specialize in the development of investigator-initiated phase 1 trials across tumor types, and expand the integration of molecular oncology and molecular imaging research within the Phase 1 program. He will be the principal Phase 1 representative on the Protocol Review Committee, the scientific review committee that approves new clinical protocols at the HDFCCC, and the lead early phase clinical investigator on the UCSF molecular tumor board.

**Jamie N. Bakkum-Gamez, M.D.**

**Associate Professor of Obstetrics and Gynecology**

**Consultant in Gynecologic Surgery**

**Mayo Clinic Cancer Center**

**Focus: gynecologic cancers, surgical oncology**

Dr. Bakkum-Gamez is an Associate Professor of Obstetrics and Gynecology and has been on staff at Mayo Clinic as a gynecologic oncologist since 2009. She completed both residency in Obstetrics and Gynecology and fellowship in Gynecologic Oncology at Mayo Clinic. She has been the GOG/NRG site principal investigator at Mayo since 2011, principal investigator of 3 investigator-initiated clinical trials, represents Mayo on the NCCN Ovarian Cancer Guidelines Committee, and was recently appointed as co-leader of the Mayo Clinic Cancer Center's Women's Cancer Program.

Dr. Bakkum-Gamez has been actively leading 2 investigator-initiated research programs that will continue under the Cancer Clinical Investigator Team Leadership Award (CCITLA). One is designed to develop the first screening test for endometrial cancer and the other is to investigate the impact of a systemic oncolytic virus for the treatment of metastatic, incurable endometrial cancer. During the CCITLA, she plans to establish a putative multi-target molecular test for endometrial cancer and its precursors that can be performed on fluid obtained through self-sampled tampons (NCT01793545). Additionally, she just resubmitted an R01 application to support a phase I trial of vesicular stomatitis virus (VSV) genetically engineered to express thyroidal sodium iodide symporter (NIS) and human interferon beta (hIFNB) and correlative studies in women with metastatic endometrial cancer (IND#016811). Dr. Bakkum-Gamez is also the Mayo principal investigator of The Women Choosing Surgical Prevention (WISP) Trial, a prospective observational trial of interval salpingectomy with delayed oophorectomy (ISDO) v risk reducing bilateral salpingo-oophorectomy (RRSO) in women at increased risk of ovarian cancer (NCT02760849). This trial will open to accrual at Mayo in July 2016.

**Catherine S. M. Diefenbach, M.D.**

**Assistant Professor of Medicine**

**Perlmutter Cancer Center**
**New York University Langone Medical Center**

**Focus: lymphoma (Hodgkin and non-Hodgkin)**

Dr. Diefenbach is an Assistant Professor of Medicine in the Department of Hematology/Oncology at the NYU Langone Medical Center and a member of its Laura and Isaac Perlmutter Cancer Center. She is a translational physician-scientist specializing in the care of patients with lymphoma (both Hodgkin and non-Hodgkin lymphoma).

An alumna of the University of Pennsylvania School of Medicine, Dr. Diefenbach completed her internship and residency at the Johns Hopkins Hospital and her oncology fellowship at Memorial Sloan-Kettering Cancer Center, where she spent an additional year focusing on translational immunology. Her scientific research focuses on the relationship between lymphoma and immunity; on developing novel and immune based treatment strategies for patients with relapsed lymphoma; and on biomarker discovery. Dr. Diefenbach serves as the Study Chair of the cooperative group trial E4412 (NCT01896999) combing immunotherapy with antibody-drug conjugate for patients with relapsed Hodgkin lymphoma, as well as the CTEP sponsored trial P9086 (NCT01695941) for patients with relapsed low grade and mantle cell lymphoma. She has developed a refined risk prognostic tool (the IPS-3) for newly diagnosed Hodgkin lymphoma. Within her institution Dr. Diefenbach directs the lymphoma clinical research within the Hematology Division of the Perlmutter Cancer Center, where she serves as the Principle Investigator on multiple investigator initiated and industry sponsored clinical trials.

Dr. Diefenbach is a member of the Conquer Cancer Foundation of ASCO Grants Selection Committee (GSC), the ECOG-ACRIN Lymphoma Committee, the Lymphoma Research Foundation Clinical Research Mentoring Program, and the Editorial Board of Clinical Cancer Research. Her research support includes: the National Cancer Institute, the Doris Duke Foundation, the Lymphoma Research Foundation, he and the American Cancer Society. She was selected as a member of the ASCO Leadership Development Program for 2015-2016.

As a recipient of the Cancer Clinical Investigator Team Leadership Award Dr. Diefenbach will continue her translational lymphoma research, analyzing the clinical and correlative data associated with E4412, and developing a large scale national follow-up study within the cooperative group. In addition, Dr. Diefenbach plans to continue to develop novel and immune focused clinical trials against multiple relapsed lymphoma subtypes, and on biomarker discovery.

**Noah M. Hahn, M.D.**

**Associate Professor of Oncology and Urology**

**Director, Bladder Cancer Medical Oncology Program**

**The James Buchanan Brady Urological Institute**
**Johns Hopkins Greenberg Bladder Cancer Institute**
**Sidney Kimmel Cancer Center, Johns Hopkins University**

**Focus: bladder cancer, genitourinary malignancies**

Dr. Hahn attended the University of Notre Dame where he graduated with a degree in mechanical engineering. He finished his medical school training at the Indiana University School of Medicine. He completed a transitional year internship at Emory University, his internal medicine residency at Duke University, and his hematology and oncology fellowship at the Indiana University Simon Cancer Center (IUSCC). Upon completion of his fellowship training, he was appointed to the IUSCC oncology faculty and served as the leader of their prostate and bladder cancer programs. In addition, he served as the chief scientific officer of the Hoosier Cancer Research Group (formerly the Hoosier Oncology Group) and the executive officer of the Big Ten Cancer Research Consortium. In April 2014, Dr. Hahn joined the Johns Hopkins University School of Medicine faculty as the director of the medical oncology bladder cancer program with the academic rank of associate professor of oncology and urology.

Dr. Hahn is an internationally recognized authority in the conduct of bladder cancer novel therapeutic clinical trials and translational investigations. He maintains an active clinical practice and sees patients with urothelial cancers of all locations and stages including non-muscle invasive bladder cancer. He is one of the few oncologists in the world to have led a clinical trial in non-muscle invasive bladder cancer. In addition, Dr. Hahn continues to care for patients with non-urothelial genitourinary malignancies including prostate, testicular, and other rare tumors. Dr. Hahn's clinical and translational research interests focus on improving outcomes for patients with urothelial cancers through: 1) The identification and validation of predictive biomarkers relevant to urothelial cancers, and 2) The identification of novel therapeutic and preventative targets for urothelial cancer patients.

In addition to his efforts at Johns Hopkins, Dr. Hahn serves as the bladder cancer chairman of the Eastern Cooperative Oncology Group (ECOG), co-chairs the Hoosier Cancer Research Network genitourinary oncology clinical trials working group, participates on the NCI Bladder Cancer Task Force, and serves on the scientific advisory board of the Bladder Cancer Advocacy Network.

**Erin W. Hofstatter, M.D.**

**Associate Professor of Medicine, Section of Medical Oncology**

**Co-Director, Smilow Cancer Genetics and Prevention Program**

**Yale Cancer Center, Yale School of Medicine**

**Focus: breast cancer, clinical breast cancer genetics and prevention**

Dr. Hofstatter is an Associate Professor of Medicine in the section of Medical Oncology at Yale School of Medicine, where she serves as a breast cancer medical oncologist with a clinical specialty and research interest in breast cancer risk and prevention. Dr. Hofstatter received her BA in Biology from Amherst College. Following completion of medical school at University of Connecticut, she went on to internal medicine residency at Mount Auburn Hospital/Harvard Medical School and completed her fellowship in Hematology/Oncology at Beth Israel Deaconess Medical Center. Dr. Hofstatter then joined the faculty at Yale Cancer Center, where she specializes in breast oncology and clinical breast cancer genetics and prevention.

Dr. Hofstatter serves as Principal Investigator on several investigator-initiated, industry-sponsored, and national cooperative group breast cancer trials supported by the National Cancer Institute. She also serves as a member of the SWOG Cancer Prevention Committee. Recently, Dr. Hofstatter was appointed in July 2014 as Co-Director of the Smilow Cancer Genetics and Prevention Program, a new clinical and research initiative to provide multidisciplinary care to patients at increased risk of cancer. Dr. Hofstatter's goal is to develop a comprehensive, integrated program unifying cancer genetic counseling services with clinical cancer high-risk/prevention initiatives. Dr. Hofstatter has given over 40 academic lectures on breast cancer genetics and prevention on the local, regional and national levels, and provides practice-based education and clinical research mentorship to oncology fellows, residents and medical students.

As a recipient of the Cancer Clinical Investigator Team Leadership Award, Dr. Hofstatter's planned activities include the ongoing development of a robust clinical genetics database and biorepository to include both clinical data and matched specimens for broad use by Yale Cancer Center's basic and clinical investigators. In addition, Dr. Hofstatter will continue work on her investigator-initiated clinical/translational research project examining the role of epigenetics and the process of aging in breast cancer risk. She will pursue ongoing career and professional development in clinical research through formal coursework and training, and plans to develop an investigator-initiated clinical trial examining the role of PARP inhibition in the treatment of BRCA-related breast cancer.

**Kevin R. Kelly, M.D., Ph.D.**

**Associate Professor of Clinical Medicine**

**USC Norris Comprehensive Cancer Center**
**University of Southern California**

**Focus: acute myeloid leukemia, multiple myeloma**

Dr. Kelly completed a fellowship in hematology in Dublin, Ireland and subsequently completed an Advanced Drug Development fellowship in the Institute for Drug Development (IDD) in San Antonio. He is currently an Associate Professor of clinical Medicine at the University of Southern California. His career focuses on the development of novel therapeutics for Acute Myeloid Leukemia and Multiple Myeloma. In his role as the assistant medical director of the Clinical Investigations Support Office he manages the hematology research team, serves on the scientific review committee and co-chairs the data monitoring committee. He is site principal investigator on several NCI sponsored clinical trials involving the Southwest Oncology Group and the California Cancer Consortium. His research laboratory focuses on the development of novel methods to target endoplasmic reticulum stress pathways to overcome drug resistance in hematological malignancies.

The CCITL award will allow Dr. Kelly to enhance the existing clinical trials infrastructure at the Norris Comprehensive Cancer Center. In particular, he will implement a clinical trial navigator program to enhance access to clinical trials for ethnic minorities in the Southern California area, oversee the implementation of a clinical trials management system to improve study activation timelines and monitor accrual and develop clinical trial pathways for hematological malignancies. In addition, the award will permit Dr. Kelly to increase his time in direct involvement in clinical research. As a project team member in the Cancer Therapy Evaluation Program, he plans to develop and activate an early phase protocol for Acute Myeloid Leukemia. He will lead several investigator-initiated studies that will investigate the use of an oncolytic virus to induce immune priming in Myeloma (NCT02514382) and the use of a small molecule, pevonedistat, to target protein homeostasis in high risk Acute Myeloid Leukemia.

**Sarah E. S. Leary, M.D., M.S.**

**Associate Professor of Pediatrics**
**University of Washington School of Medicine**

**Attending Physician, Cancer and Blood Disorders Center Seattle Children's Hospital**

**Fred Hutchinson/University of Washington Cancer Consortium Fred Hutchinson Cancer Research Center**

**Focus: pediatric brain cancers**

Dr. Leary is an attending physician in the Cancer and Blood Disorders Center at Seattle Children's Hospital and Associate Professor of Pediatrics at the University of Washington School of Medicine. Her clinical and research focus is in the area of pediatric brain tumors.

Locally, she serves on the Tumor Tissue Subcommittee and the Research Review Committee; Nationally, she is leading several clinical trials to study new medications for children with brain tumors at Seattle Children's Hospital, through the Children's Oncology Group, the Pacific Pediatric Neuro-Oncology Consortium (PNOC) and the Pediatric Brain Tumor Consortium (PBTC). Dr. Leary works with laboratory investigators at the Fred Hutchinson Cancer Research Center and the Seattle Children's Research Institute as well as the Pathology Department at Seattle Children's Hospital to identify novel therapeutic targets and tests. The goal of her clinical and translational research is to improve outcomes for brain tumor patients by developing biologically targeted therapeutics.

With the CCITLA award, Dr. Leary will continue with and develop multidisciplinary collaborative clinical research efforts related to pediatric brain tumor patients, including development of cellular immunotherapy for pediatric brain tumor patients. She will serve as the Children's Oncology Group (COG) study co-chair of the first NCI-funded US study to molecularly stratify medulloblastoma, the most common malignant pediatric brain tumor, patients at diagnosis. Additionally, during the course of the CCITLA, Dr. Leary will work with a focused international group of pre-clinical and clinical investigators to develop a clinical trial protocol for the first US clinical trial for CNS-PNET (supratentorial primitive neuroectodermal tumor).

**Frederick L. Locke, M.D.**

**Assistant Member, Department of Blood and Marrow Transplantation**

**Assistant Professor, Department of Oncologic Sciences**

**Moffitt Cancer Center, University of South Florida**

**Focus: lymphoma, multiple myeloma, immune and cellular therapies**

Dr. Locke is a physician and translational investigator in the Department of Blood and Marrow Transplantation at Moffitt Cancer Center. Recently, Dr. Locke has emerged as an institutional and national leader in clinical investigations utilizing adoptive cellular therapies for lymphoma and multiple myeloma. Dr. Locke is Chair of the Moffitt Cellular Therapy Advisory Committee and Chair of the Moffitt Immunotherapy Working Group. Dr. Locke led the creation of an innovative initiative at Moffitt: the **Immune and Cellular Therapy (ICE-T) Program**. He is the Chief for the ICE-T clinical service and the Research Director for the ICE-T clinical trials group. It is anticipated that in FY2017 the ICE-T group will enroll and treat patients on over a dozen cellular therapy clinical trials for diverse cancers such as diffuse large B cell lymphoma, acute lymphoblastic leukemia, non-small cell lung carcinoma, sarcoma, gastric cancer, melanoma, and multiple myeloma.

As a recipient of this award Dr. Locke will centralize clinical care, trial coordination, data support, and regulatory processes for cellular therapy trials at Moffitt which will ultimately promote a successful research culture at Moffitt Cancer Center. To accomplish this goal Dr. Locke will perform the following specific activities:

1. **Chair the Immunotherapy Working Group, which oversees the ICE-T initiative**
   - Define the group's responsibilities and structure
   - Develop a process for the review of proposed cellular therapy trials at Moffitt, with a specific focus on feasibility, safety, and priority of proposed projects

2. **Lead and administer the ICE-T clinical service**
   - Author a set of standard operating procedures including clinical operations and internal review of treatment safety
   - Create a cellular therapy education program for faculty, fellows, nurses, clinical trial coordinators, and pharmacists

3. **Cultivate the ICE-T clinical trial group**
   - Construct an independent cost center and budget for FY2017
   - Act as liaison to PIs from diverse departments to open additional ICE-T trials

4. **Develop the lymphoma and multiple myeloma cellular therapy clinical trials program**
   - Oversee cellular immunotherapy trials as PI including: CAR T cell, DC vaccine, Marrow Infiltrating Lymphocyte, and autologous transplant + checkpoint blockade trials.

- Conduct a first-in-human clinical trial utilizing a Moffitt created dendritic cell vaccine

**Rachel Miller, M.D.**

**Associate Professor of Obstetrics and Gynecology**

**Associate Director, Clinical Research Office**

**Markey Cancer Center, University of Kentucky**

**Focus: ovarian cancer, gynecologic cancers, chemotherapy-induced cognitive impairments**

Dr. Miller is a Kentucky native and an alumna of the University of Kentucky, where she completed her undergraduate and medical degrees. She completed medical residency in Obstetrics and Gynecology at Dartmouth-Hitchcock Medical Center, and fellowship training in Gynecologic Oncology at the University of Kentucky Markey Cancer Center (MCC). Dr. Miller is board certified in both Obstetrics and Gynecology and Gynecologic Oncology. She is an Associate Professor of Obstetrics and Gynecology in the University of Kentucky Division of Gynecologic Oncology. Dr. Miller's interests include ovarian cancer research, including chemotherapy-induced cognitive impairments; early detection of ovarian cancer; novel strategies in the treatment of advanced ovarian, fallopian tube, and peritoneal cancers; and population-based ovarian cancer research. She has experience with investigator-initiated clinical trial development and has participated in numerous cooperative group trials and played a key role in a longstanding ovarian screening study. She is the principal investigator of two investigator-initiated clinical trials, one evaluating neoadjuvant chemotherapy in ovarian cancer patients, and the other evaluating the cognitive effects of chemotherapy in ovarian cancer patients. Dr. Miller is actively involved in clinical research oversight activities in the MCC through the Protocol Review and Monitoring Committee, the Gynecologic Oncology Clinical Care and Research Team (CCART), and the Early Therapeutics CCART. She also serves as Associate Director of the MCC Clinical Research Office (CRO). These experiences and positions have helped Dr. Miller identify critical aspects of maintaining and enhancing a culture of successful clinical research at MCC.

Support from the CCITLA will allow Dr. Miller to continue her current activities while having additional protected time to move forward with new initiatives for the MCC. Through her current activities, she is in a position to monitor the research portfolio for each respective group, prioritize research efforts and approve proposed clinical trials accordingly, monitor clinical trial accrual and resolve any issues with accrual. Dr. Miller has identified four areas to focus her efforts under this award, which she feels are particularly critical for creating a culture of successful research at the MCC:

1. Ensuring a diverse clinical trials portfolio for each disease site with optimized scientific outcomes and a high likelihood of patient accrual.

2. Encouraging junior faculty to develop IITs and pursue NCI funding for such efforts.
3. Supporting development of an active Phase I/II Unit at the MCC.
4. Serving as principal investigator of a diverse portfolio of clinical trials in gynecologic oncology.

Specifically, Dr. Miller will develop a MCC Clinical Trials Feasibility Committee to review all clinical trial protocols after approval by individual CCARTs and before submission to the PRMC. She will also be responsible for the development of a Non-Interventional Regulatory Group under the MCC CRO, allowing for allocation of specific resources for non-interventional trials, which will preserve and maintain the necessary resources for active and new interventional clinical trials. Dr. Miller plans to proceed with development of a MCC Grant Writing Workshop, which will serve as an adjunct to the Protocol Development Workshop to encourage and prepare MCC junior faculty in hematologic oncology and surgical oncology to apply for funding. Dr. Miller will also work to increase the number of NCI-supported Phase I/II cooperative group trials in gynecologic oncology available at the MCC and facilitate translational research efforts with the MCC Drug Discovery, Delivery and Translational Therapeutics Research Program, providing an opportunity to investigate new or repurposed agents in the clinical setting. Dr. Miller feels that these planned activities will have a major impact on enhancing the research culture at the MCC.

**Taofeek K. Owonikoko, M.D., Ph.D.**

**Associate Professor, Department of Hematology and Medical Oncology**

**Winship Cancer Institute of Emory University**

**Focus: small cell lung cancer, aerodigestive cancer, early phase clinical trials**

Dr. Owonikoko is an associate professor in the Department of Hematology and Medical Oncology at Emory University. He is a Distinguished Cancer Scientist designated by the Georgia Research Alliance. He received his primary medical degree from the Obafemi Awolowo University, Ile-Ife, Nigeria and a doctoral degree in Anatomic Pathology from the Heinrich Heine University, Dusseldorf, Germany. He was a postdoctoral research fellow at the Johns Hopkins University in Baltimore, where he proceeded to Graduate Hospital, Drexel University in Philadelphia for Internal Medicine residency training. He was a clinical fellow in Hematology/Medical Oncology at the University of Pittsburgh and was then recruited to join the faculty at Emory University in 2008 where he is focused on translational research in aerodigestive cancer and early phase drug development. Dr. Owonikoko has received research grants from the NIH, NCI, DOD and Georgia Cancer Coalition. He is a recipient of many prestigious awards including the ASCO Leadership Development Program. He has published over 104 peer-reviewed manuscripts in high impact journals including Cell, CA Cancer Journal, Cancer Cell, Nature Communications, JCO and Oncogene.

The following integrated set of clinical, research and mentoring activities are planned during this period of funding support:

**a. Extending participation by Winship Cancer Institute of Emory University in ETCTN and NCTN activities**

*i. Experimental Therapeutics-Clinical Trials Network (ETCTN) Activities:* Dr. Owonikoko is the designated Translational PI of the Atlantic Coast Phase 2 Consortium (ACP2C) funded and supported through the NCI UM1 grant mechanism. He will also serve as the PI of the NCI Study 9950: A phase I clinical trial of VX-970 in combination with chemoradiation for locally advanced HPV negative head and neck squamous cell carcinoma to be supported through the UM1 mechanisms.

*ii. NCTN clinical trials:* Dr. Owonikoko will remain engaged in NCTN activities as a core member of the thoracic committee for ECOG/ACRIN. He will also serve as the sub study chair for the planned Arm G on the intergroup SWOG1400 (Lung-MAP) screening study, where patients with deficient homologous recombination DNA repair machinery will be assigned to receive treatment with a PARP inhibitor, talazoparib.

**b. Promoting patient access to novel therapies through expansion of investigator-initiated clinical trials:** He will serve as the sponsor-investigator for two investigator-initiated trials that bring unique access to innovative therapies to cancer patients treated at the Winship Cancer Institute of Emory University. A Phase I study of palbociclib and cisplatin in advanced solid malignancies with a translational objective looking for novel vulnerabilities conferred by tumor suppressor gene alterations for CDK4 inhibitor in solid malignancies. A phase II study of durvalumab and tremelimumab in combination with radiation therapy for relapsed small cell lung cancer (SCLC) designed to enhance the emerging promise of immune-oncology strategy in relapsed SCLC.

**c. Invigorate the cancer center molecular tumor board and strengthen its linkage with clinical research:** In collaboration with other cancer center members with complementary expertise, Dr. Owonikoko will continue to direct the Winship molecular tumor board and plans to use it as an avenue for teaching and mentoring junior faculty and trainees. This monthly meeting will also be employed as an efficient platform for identifying patients appropriate for studies within the phase I clinical trial program at the Winship Cancer Institute of Emory University.

**Geoffrey R. Oxnard, M.D.**

**Assistant Professor of Medicine**

**Dana-Farber/Harvard Cancer Center, Dana-Farber Cancer Institute**

**Focus: lung cancers, noninvasive plasma genotyping technologies**

Dr. Oxnard is a thoracic oncologist at the Dana-Farber Cancer Institute and an Assistant Professor of Medicine at Harvard Medical School. He is a clinic-based translational investigator whose research includes studies of targeted therapies for genotype-defined NSCLC populations, familial lung cancer due to germline EGFR mutations, and noninvasive plasma genotyping technologies. He was previously awarded a Young Investigator Award and Career Development Award from the Conquer Cancer Foundation of ASCO, and a Career Development Award from the US Department of Defense, and has recently been named a Damon Runyon Clinical Investigator.

He serves as Study Chair for NCTN A151216, the Adjuvant Lung Cancer Enrichment Marker Identification and Screening Trial (ALCHEMIST); coordinating this trial will be a major focus of his activities as part of this CCITLA. He additionally serves as PI of numerous clinical and correlative studies at DFCI, serves on the institutional Scientific Review Board, and runs a grant-writing seminar for fellows each summer.

**Dale R. Shepard, M.D., Ph.D.**

**Assistant Professor in Internal Medicine**

**Director, Taussig Cancer Institute Phase I and Sarcoma Programs, Cleveland Clinic**

**Case Comprehensive Cancer Center, Case Western Reserve University**

**Focus: sarcomas, early phase clinical trials**

Dr. Shepard received a PhD in pharmacology from the Ohio State University College of Medicine with an emphasis in drug metabolism and pharmacokinetics and phase I clinical trials. He then completed a multi-disciplinary NIH-sponsored Clinical Pharmacology Fellowship at the University of Chicago. Dr. Shepard returned to the Ohio State University College of Medicine for his medical degree. He completed both his Internal Medicine residency and Hematology and Medical Oncology fellowship at Cleveland Clinic where he joined the Department of Hematology and Medical Oncology and the Center for Geriatric Medicine. He is currently the Director of the Phase I and Sarcoma programs and an Assistant Professor in Internal Medicine at the Cleveland Clinic Lerner College of Medicine. Dr. Shepard is a member of the Case Comprehensive Cancer Center Developmental Therapeutics program and an active participant in the National Clinical Trials Network. He is a member of both SWOG and the Alliance. He has been a member of the Alliance Cancer in the Elderly Committee since 2013 and was the recipient of a Young Investigator award in 2010 and 2012 for a NIH/NIA-sponsored U13 grant focusing on geriatric oncology. Dr. Shepard is the Cleveland Clinic PI for an ongoing NCI Early Therapeutics Clinical Trial Network (ETCTN) UM1 consortium for early phase trials.

With the Cancer Clinical Investigator Team Leadership Award, Dr. Shepard plans to further expand the Cleveland Clinic Cancer Center's phase I clinical trials program. He will become an active member of the protocol review and monitoring committee and increase his participation in the Case Comprehensive Cancer Center Developmental Therapeutics Program which identifies and evaluates innovative new anti-cancer agents. Dr. Shepard will increase collaboration for phase I trials within the Case Comprehensive Cancer Center and will work with regional oncology practices to expand awareness of the availability of phase I trials and expand enrollment.

**Theresa L. Werner, M.D.**

**Clinical Investigator**

**Medical Director, Clinical Trials Office, Huntsman Cancer Institute**

**Assistant Professor of Medicine, Oncology Division, University of Utah**

**Focus: ovarian cancer, gynecologic cancers, early phase clinical trials**

Dr. Werner is an Assistant Professor in Medicine in the Division of Medical Oncology at the University of Utah and a Clinical Investigator at the Huntsman Cancer Institute (HCI). Dr. Werner is the Medical Director of the Clinical Trials Office and oversees over 100 staff and over 400 active clinical trials. She is a Co-Investigator for the U10 Grant as a Network Lead Academic Participating Site (NLAPS) and an Executive Team Leader for the National Clinical Trials Network (NCTN) Program.

Dr. Werner is a recognized authority in gynecologic cancers from her experience on national committees including her participation in the: National Comprehensive Cancer Network (NCCN) Ovarian Cancer Panel since 2010, the NCI Gynecologic Cancer Steering Committee Cervical Cancer Task Force since 2009, as a member of the Cervical Cancer Strategic Priorities Team in 2015, and through her participation with the NCI's Endometrial Cancer Clinical Trials Planning Meeting in 2016: "Moving Forward in Endometrial Cancer: Designing Targeted Trials for Targeted Endometrial Cancer Populations Using Targeted Agents". Dr. Werner is an active member of the Experimental Therapeutics Cancer Center Program and serves as the PI for numerous early phase trials in gynecologic and breast cancer. She writes investigator-initiated trials with a focus on genomic biomarkers aimed at predicting response to targeted therapy in cancer patients. Dr. Werner takes an active role in teaching and mentoring of trainees and junior faculty given her expertise in clinical trial concept, trial design, obtaining funding, and getting a trial through the review process. She also provides educational seminars on good clinical practice for clinical trial conduct to faculty and research staff throughout the institution.

As the Medical Director of the Huntsman Cancer Institute (HCI) Clinical Trials Office, Dr. Werner will continue to ensure physician leader engagement across the cancer center to bring the best trial concepts and NCTN trials to our patients, improve screening processes to help physicians identify trials for their patients, and identify processes to increase clinical trial enrollments from community and regional oncologists.

Dr. Werner is leading the effort to increase access to clinical trials by developing infrastructure with the University of Utah satellite clinics across the state of Utah

as well as to HCI's affiliate hospitals in neighboring states. This has involved navigating the technology to enable remote consenting, hiring an on-site coordinator and specimen processor, and training of physicians at this site. She has been visiting the cancer center's new hospital affiliations in neighboring states (Nevada, Idaho, and Colorado) to utilize expertise and existing infrastructure in clinical research to make participation in NCTN trials, via formal affiliation, a possibility for these hospitals. This has been met with much excitement from the physicians and the patients who would otherwise not likely be able to participate in a clinical trial.

Dr. Werner will continue her service on the Institutional Protocol Development Committee which facilitates the development of trial concepts, ensuring sound trial design, innovative science and correlative studies, and trial feasibility as well as prioritizing investigator-initiated trials for the cancer center. She will also continue to serve on the Data Safety Monitoring Committee to provide regular review of accumulated study data for participant safety, study conduct and progress, and efficacy when appropriate. Dr. Werner will continue her effort in enrolling high numbers of patients to clinical trials and mentoring junior faculty and trainees in good clinical trial conduct and trial design.